JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

CLINICAL PHARMACY NEWSLETTER

A Newsletter of Drug and Prescribing Information

Published by
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(A Unit of Department of Pharmacy Practice, JSS College of Pharmacy, Ooty)

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INSIDE THIS ISSUE

Stroke and Vascular Cognitive Impairment: The Role of Intestinal Microbiota Metabolite TMAO

Introduction to the Gut-Brain Axis and Trimethylamine N-oxide (TMAO)

• The gut-brain axis facilitates bidirectional communication between the gut microbiota and the brain. This communication is achieved through neural, immune, and metabolic pathways, playing a critical role in aging, cerebrovascular diseases, and neurodegenerative disorders such as Alzheimer's and Parkinson's disease. The gut microbiota can be altered by diet, probiotics, and external factors, which impacts brain health.

• TMAO, a metabolite produced from choline, betaine, and carnitine by gut microbes, can cross the blood-brain barrier (BBB). Its elevated levels have been linked to cardiovascular risks, but its role in cerebrovascular diseases like stroke remains less understood. This review focuses on the decade-long research into TMAO's effects on stroke and related cognitive impairments, particularly in vascular cognitive impairment (VCI).

Metabolism and Pathways of TMAO

TMAO is produced through microbial metabolism of choline and other nutrients found in eggs, dairy, and red meat. Intestinal microbes convert these nutrients into trimethylamine (TMA), which is further oxidized in the liver to produce TMAO. This metabolite has been implicated in several cardiovascular and metabolic diseases. While a high-fat diet increases TMAO levels, certain diets and antibiotics can inhibit its production. TMAO has also been linked to age-related increases in disease susceptibility.

TMAO's Impact on the Blood-Brain Barrier (BBB)

TMAO's ability to cross the BBB has been confirmed, but its effects on BBB integrity remain unclear. Some studies suggest it could enhance the BBB's protective functions, while others point to its potential to cause downregulation of tight junction proteins, leading to BBB disruption. The specific role TMAO plays in BBB function seems to depend on its concentration and physiological state, but it can clearly influence the central nervous system (CNS).

TMAO and Stroke

Stroke, particularly ischemic stroke, has become a major cause of disability and death globally. TMAO levels are elevated during acute phases of ischemic stroke, contributing to atherosclerosis, inflammation, and oxidative stress, all of which negatively impact stroke progression and recovery. Post-stroke cognitive impairment (PSCI) is common, with nearly 50% of patients experiencing cognitive decline within six months of the event. Research has shown that TMAO may exacerbate this impairment, especially through promoting platelet hyperresponsiveness, foam cell formation, and cholesterol metabolism disruption.

Mechanisms Through Which TMAO Influences Stroke

Cholesterol Metabolism and Atherosclerosis

TMAO affects cholesterol metabolism by inhibiting its excretion through bile acid synthesis. It also promotes foam cell formation in arteries, exacerbating atherosclerosis, a key factor in stroke development. This happens due to TMAO-induced upregulation of receptors like CD36 and SR-A1, which encourage cholesterol accumulation in macrophages.

Platelet Hyperresponsiveness and Thrombosis

TMAO promotes platelet hyperreactivity, increasing the risk of thrombosis. This effect is mediated through enhanced intracellular calcium release in response to platelet activators like ADP and thrombin. Elevated TMAO also promotes the expression of pro-thrombotic factors such as tissue factor and Vascular cell adhesion molecule 1 (VCAM-1).

Neuroinflammation and Oxidative Stress

TMAO induces neuroinflammation by activating proinflammatory pathways like MAPK/ERK and NF-κB, which can lead to increased production of reactive oxygen species (ROS). This exacerbates endothelial dysfunction and contributes to the development and progression of stroke. Conversely, some studies have suggested that TMAO may have neuroprotective effects under specific circumstances, such as reducing oxidative damage in neurons.

"TMAO originates from bad bacteria in our gut when we eat lots of choline"

TMAO and Cognitive Impairment/Dementia

Age-related cognitive decline is a natural process, but it can be exacerbated by cerebrovascular and neurodegenerative diseases. TMAO has been implicated in accelerating cognitive decline, particularly in conditions like Alzheimer's disease (AD) and vascular cognitive impairment (VCI). Elevated plasma TMAO levels correlate with increased risk of cognitive impairment, possibly due to its role in promoting neuroinflammation and oxidative stress.

TMAO's Role in Alzheimer's Disease

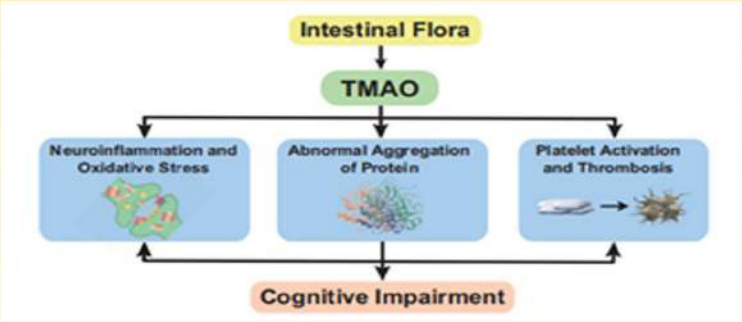
TMAO has been identified as a risk factor for AD, as it promotes the aggregation of amyloid-β (Aβ) and tau proteins, hallmark features of the disease. Studies have shown that TMAO stabilizes these proteins in their pathological forms, facilitating plaque and tangle formation in the brain. TMAO also contributes to AD by promoting inflammation and oxidative stress in neural tissues.

TMAO and Parkinson's Disease

In Parkinson's disease (PD), TMAO levels are elevated in both plasma and cerebrospinal fluid. Its role in PD may be related to its ability to stabilize misfolded proteins like α-synuclein, which are central to the disease's pathology. TMAO-induced neuroinflammation and platelet activation further exacerbate the disease's progression.

TMAO and Vascular Cognitive Impairment (VCI)

VCI is caused by cerebrovascular damage, such as strokes or small vessel disease, and is the second most common cause of cognitive decline after AD. TMAO's role in VCI has been linked to its promotion of vascular inflammation, endothelial dysfunction, and platelet hyperactivity. These effects worsen cognitive outcomes after stroke and increase the risk of dementia.



Post-Stroke Cognitive Impairment (PSCI)

PSCI affects up to 80% of stroke survivors and is often associated with persistent inflammation and vascular damage. Elevated plasma TMAO levels are an independent predictor of cognitive impairment in these patients, and regulating gut microbiota to reduce TMAO levels has been suggested as a potential therapeutic approach.

Potential Neuroprotective Effects of TMAO

Despite its detrimental effects on stroke and cognitive impairment, some studies have reported potential neuroprotective functions for TMAO. It may protect cells against damage caused by protein misfolding and oxidative stress, particularly in conditions like ALS and spinocerebellar ataxia. TMAO has also been shown to protect BBB integrity in certain contexts.

Therapeutic Approaches Targeting Intestinal Flora

• The clear role of gut microbiota in producing TMAO and influencing stroke outcomes, therapies targeting the gut-brain axis are under investigation. Probiotics, prebiotics, and dietary modifications have been shown to improve outcomes in stroke and cognitive impairment by altering the composition of gut microbiota and reducing TMAO levels.

• In conclusion, while TMAO's role in promoting cerebrovascular and neurodegenerative diseases is increasingly clear, its precise mechanisms and potential therapeutic targets remain areas of active research. The regulation of intestinal flora to manage TMAO levels holds promise as a novel approach to preventing and treating stroke and vascular cognitive impairment.

Reference:

Ruxin Tu and Jian Xia. Stroke and Vascular Cognitive Impairment: The Role of Intestinal Microbiota Metabolite TMAO. CNS & Neurological Disorders - Drug Targets, 2024, 23, 102-121.

Giant cellulitis-like sweet syndrome mimicking cellulitis: a case report

Introduction

Sweet syndrome (acute febrile neutrophilic dermatosis) is an uncommon inflammatory disorder characterized by the abrupt appearance of painful, edematous, and erythematous papules, plaques, or nodules on the skin. It is involved in a wide spectrum of diseases caused by neutrophilic dermatoses. The etiology includes the following subtypes: classical (after upper respiratory tract infections), malignancy-associated and drug-associated Sweet syndrome. However, there are lesser common variants, such as giant cellulitis-like Sweet syndrome, which refers to the development of large infiltrated inflammatory plaques. This case is unique for presenting the rare giant cellulitis-like variant of Sweet syndrome, characterized by large, infiltrated plaques in atypical areas such as the chest, neck, and arm. This clinical variant can masquerade as cellulitis because the patients present with an acute onset of large erythematous plaques, fever, and leucocytosis with neutrophil predominance. This variant is often associated with systemic inflammatory and neoplastic disorders.

Case Report

A 60-year-old Ethiopian male patient presented to the accident and emergency (A and E) department with a 5-day history of fever, chills, sweating and rigor accompanied by a reddish skin colour change around the anterolateral region of the right chest wall that was small in size. In addition, he complained of right upper extremity and right-sided chest pain.

Since the onset of his symptoms, he has been fatigued and sleepy. Four days prior, he was injured in the proximal area of his right index finger by a metallic object while fixing a car. His medical history revealed essential hypertension with good control while on Enalapril and dyslipidaemia on Atorvastatin. He had a personal history of alcohol intake of two to three beers per day, intake two times a week and cigarette smoking of eight pack years.

On presentation, he had a blood pressure of 90/60 mmHg, a pulse rate of 100, a respiratory rate of 26, an oxygen saturation of 75% with room air and a temperature of 35.8 °C. His random blood sugar was determined to be 45 mg/dL. On evaluation, there were erythematous, indurated tender plaques with ill-defined borders over the right antero- and posterolateral chest wall with extension to the lateral part of the right neck and medial aspect of the right arm.

The initial parameters were as follows: white blood cell count (WBC) 17.59× 103 /μL with neutrophilia of 88.4% and lymphopenia of 3.6%, a platelet count of 88× 103 / μL, a C-reactive protein concentration of 200 mg/L, a blood urea nitrogen concentration of 114.58 mg/dL, and a creatinine concentration of 1.59 mg/dL. On liver function tests, alanine aminotransferase was 3.8×elevated, and total and direct bilirubin were 1.75 mg/dL and 0.75 mg/dL, respectively.

His serum sodium level was 115 mmol/L, hemoglobin A1C was 6%, and his human immunodeficiency virus (HIV) antibody was negative. Soft tissue ultrasound revealed increased echogenicity and thickening/edema of the right lateral chest and abdominal wall subcutaneous tissue with a cobble stone appearance. There was slightly increased flow on color Doppler sonography with right lateral chest and abdominal wall soft tissue inflammatory changes suggestive of cellulitis. Chest X-ray was suggestive of right-sided pleural effusion.

As our initial impression was chest wall cellulitis, he was started on Ceftriaxone 1 g intravenous twice daily and Vancomycin 750 mg every 48 h (renal adjusted dose), but there was no improvement after 48 hours. Furthermore, the skin lesion extended from the chest wall to the abdominal wall and upper third of the thigh after admission (Fig. 1). The WBC count increased to 45.58× 103 / µL, with 96% neutrophilia. Therefore, Ceftriaxone was changed to Meropenem 1 g intravenous three times a day, and Vancomycin was adjusted to a full dose of 1 g intravenous twice daily after the patient's renal condition improved. This management was continued for 14 days but there was no significant improvement. During this course of management the result of the histopathological examination for the skin biopsy showed parakeratotic and moderately acanthotic epidermis overlying significant edema of the papillary dermis associated with a pattern of nodular and diffuse dermatitis. The inflammatory cells were composed of numerous neutrophils and leukocytoclastic debris of neutrophils mixed with lymphocytes and few eosinophils as well as plasma cells in the absence of signs of vasculitis. The infiltrates also extended down to the subcutaneous fat, which was suggestive of Sweet syndrome .

The atypical distribution of the plaque, lack of early response, extensive subcutaneous edema and serious oozing were indicative of inadequate response to antibiotics alone. Therefore, a diagnosis of Sweet syndrome was made after the skin biopsy, and as a result, the patient was started on 1 mg/kg/day Prednisone. One week after starting steroids, there was complete resolution of the subcutaneous edema and a significant decrease in oozing with general well-being and complete independence with activities of daily living. Moreover, there was a significant decrease in WBC count from 45.58× 103 /µL to 11.51× 103 /µL. The patient has been adherent to oral steroids and as a result he had 10 kg weight gain over a 4-month period. In addition, he had impaired glucose tolerance with hemoglobin A1C of 6.7%. Otherwise, he did not have any epigastric discomfort, bloating or any sign of infection.

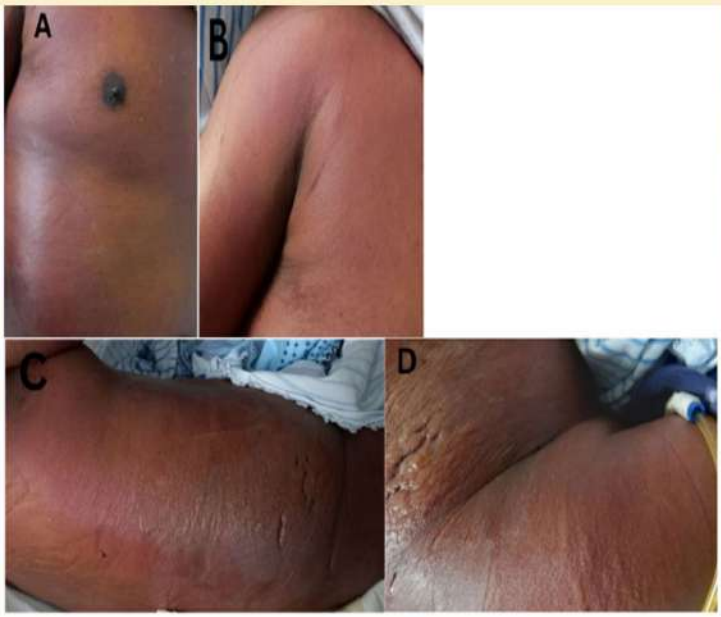


Fig. 1 Erythematous, tender plaque with ill-defned borders involving the A right side of the chest, B right medial aspect of arm, C right lateral trunk, D right fank and thigh

Discussion

Sweet syndrome is an inflammatory disorder characterized by erythematous plaques, nodules, or papules with prodromal symptoms of fever, malaise, arthralgia, and diffuse infiltration of neutrophils in the papillary dermis. Skin findings are typically asymmetrical in distribution, with the upper extremities, trunk, head, and neck being the typical sites of involvement. Although the size of the lesions ranges from millimeters to centimetres in diameter, there have been reported cases of large cellulitis-like plaques as a rare variant of Sweet syndrome, as observed in the patient. Similar case reports have indicated history of malignancy, thus malignancy-associated Sweet syndrome. While this was not observed in our patient, he may have had a preceding infection as seen in the 18 patients reported in 2013. Neutrophilic infiltration of other organs, such as the liver, spleen, heart, kidneys, central nervous system, and gastrointestinal system, may occur in Sweet syndrome. Although many extra-cutaneous manifestations of Sweet syndrome have been described in the literature, pulmonary manifestations are rare. Sweet syndrome can present with uncommon features, such as pulmonary infiltrates and pleural effusion, as observed in our patient. A case review of 34 cases on pulmonary involvement in Sweet's syndrome showed that skin involvement preceded pulmonary involvement, and bilateral or unilateral pulmonary infiltrates were the most common radiological feature. Pleural effusion accompanying lung infiltrates was uncommon and was present in only seven patients. In patients with liver involvement, such as this patient, hepatic serum enzyme elevations in aspartate aminotransferase (AST) and alanine aminotransferase (ALT) with increased lactate dehydrogenase (LDH) might be observed. However, hepatic involvement was not mentioned in other cases during our literature review. Skin biopsy is required to confirm the diagnosis, and it is demonstrated by detecting histopathological evidence of a dense neutrophilic infiltrate without leukocytoclastic vasculitis, which was similarly seen in this patient. The gold standard of treatment is systemic corticosteroids, but topical and/or intralesional corticosteroids may also be effective as either monotherapy or adjuvant therapy. Prednisone is initially recommended at 0.5–1 mg/kg per day, followed by a tapering dosage to prevent recurrence. We expect clinical improvement after a few doses and complete resolution with 1–2 weeks of treatment. This was evident in our patient as he had significant improvement of his symptoms within a week of starting prednisolone. In some cases, skin lesions may partially improve with antibiotics if there is a secondary bacterial infection.

Conclusion

We should be vigilant in diagnosing Sweet syndrome in patients who present with erythematous plaque-like skin lesions in atypical regions of the body with asymmetrical distribution. This case highlights the diagnostic challenges and efective treatment approach for a rare variant of Sweet syndrome. A 60-year-old Ethiopian male presented with skin plaques, fever, and systemic symptoms that initially mimicked cellulitis but did not respond to conventional antibiotics. The diagnosis was confirmed through a skin biopsy showing characteristic neutrophilic infltration. The condition improved signifcantly with corticosteroid therapy, demonstrating the importance of considering Sweet syndrome in cases of atypical cellulitis-like presentations that do not improve with standard treatments. This under-scores the need for a comprehensive diagnostic approach and highlights corticosteroids as an effective treatment for this rare dermatosis.

Reference

Selamawit T. Muche *et al.* Giant cellulitis-like Sweet syndrome mimicking cellulitis: a case report. Journal of Medical Case Reports (2024) 18:492. https://doi.org/10.1186/s13256-024-04848-x.

Drug Profile
COBENFY (XANOMELINE AND TROSPIUM CHLORIDE)

Pharmacological Class

Cobenfy is a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist.

Indications

Cobenfy is indicated for the treatment of schizophrenia in adults.

Dosage Forms And Strengths

- 50 mg/20 mg (xanomeline/trospium chloride): Buff capsules imprinted with Karuna 50/20 mg
- 100 mg/20 mg (xanomeline/trospium chloride): Brown capsules imprinted with Karuna 100/20 mg
- 125 mg/30 mg (xanomeline/trospium chloride): Swedish Orange capsules imprinted with Karuna 125/30 mg

Contraindications

- Urinary retention
- Moderate (child-pugh class b) or severe (child-pugh class c) hepatic impairment.
- Gastric retention.
- History of hypersensitivity to Cobenfy or trospium chloride. Angioedema has been reported with Cobenfy and trospium chloride.
- Untreated narrow-angle glaucoma.

Drug Interactions

Strong Inhibitors of CYP2D6	
Clinical Implication:	CYP2D6 contributes significantly to the metabolism of xanomeline, a component of COBENFY. Concomitant use of COBENFY with strong CYP2D6 inhibitors may increase plasma concentrations of xanomeline, which may increase the frequency and/or severity of adverse reactions from COBENFY *[see Clinical Pharmacology (12.3)]*.
Prevention or Management:	Monitor patients for increased frequency and/or severity of adverse reactions related to COBENFY in patients taking COBENFY with strong inhibitors of CYP2D6.
Drugs Eliminated by Active Tubular Secretion	
Clinical Implication:	Concomitant use of COBENFY with drugs that are eliminated by active tubular secretion may increase plasma concentrations of trospium a component of COBENFY, and/or the concomitantly used drug due to competition for this elimination pathway, which may increase the frequency and/or severity of adverse reactions from COBENFY or the drug eliminated by active tubular secretion *[see Clinical Pharmacology (12.3)]*.
Prevention or Management:	Monitor patients for increased frequency and/or severity of adverse reactions related to COBENFY and adverse reactions related to drugs eliminated by active tubular secretion in patients concomitantly receiving such drugs.
Oral Drugs That Are Sensitive Substrates of CYP3A4	
Clinical Implication:	Xanomeline, a component of COBENFY, transiently inhibits CYP3A4 locally in the gut but not systemically. Concomitant use of COBENFY with oral drugs that are sensitive substrates of CYP3A4 may result in increased plasma concentrations of the oral drugs that are sensitive substrates of CYP3A4. This may increase the frequency and/or severity of adverse reactions from such substrates *[see Clinical Pharmacology (12.3)]*.
Prevention or Management:	Monitor patients for increased frequency and/or severity of adverse reactions related to oral drugs that are sensitive substrates of CYP3A4 in patients taking COBENFY with such substrates.
Oral Drugs That Are Substrates of P-glycoprotein	
Clinical Implication:	Xanomeline, a component of COBENFY, transiently inhibits P-glycoprotein locally in the gut but not systemically. Concomitant use of COBENFY with oral drugs that are substrates of P-glycoprotein may result in increased plasma concentrations of the oral drugs that are substrates of P-glycoprotein, which may increase the frequency and/or severity of adverse reactions from such substrates *[see Clinical Pharmacology (12.3)]*.
Prevention or Management:	Monitor patients for increased frequency and/or severity of adverse reactions related to oral drugs that are narrow therapeutic index substrates of P-glycoprotein in patients taking COBENFY with such substrates.

Adverse Reactions

- *Risk of Urinary Retention*
- *Risk of Use in Patients with Hepatic Impairment*
- *Risk of Use in Patients with Biliary Disease*
- *Decreased Gastrointestinal Motility*
- *Risk of Angioedema*
- *Risk of Use in Patients with Narrow-angle Glaucoma*
- *Increases in Heart Rate*
- *Anticholinergic Adverse Reactions in Patients with Renal Impairment*
- *Central Nervous System Effects*

Mechanism of Action

The mechanism of action of xanomeline in the treatment of schizophrenia is unclear; however, its efficacy is thought to be due to its agonist activity at M1 and M4 muscarinic acetylcholine receptors in the central nervous system.

Trospium chloride is a muscarinic antagonist. Trospium chloride antagonizes the muscarinic receptors primarily in the peripheral tissues.

Pharmacodynamics

Xanomeline binds to muscarinic receptors M1 to M5 with comparable affinity (Ki=10, 12, 17, 7, and 22 nM for the M1, M2, M3, M4, and M5 receptors, respectively) and exhibits higher agonist activity at the M1 and M4 receptors. Trospium chloride antagonizes the muscarinic receptors primarily in peripheral tissues.

Cardiac Electrophysiology: At the maximum recommended dosage of 125 mg/30 mg twice daily, Cobenfy does not prolong the QT interval to any clinically relevant extent.

Pharmacokinetics

Following Cobenfy administration, xanomeline area under the plasma concentration-time curve during a 12-hour dosing interval (AUC0-12) at steady state and maximum concentration (Cmax) increases 50% when the Cobenfy dose increased from 100 mg/20 mg twice daily to 125 mg/30 mg twice daily. Trospium exposures increase dose-proportionally over the Cobenfy dosage range of 100 mg/20 mg twice daily to 125 mg/30 mg twice daily.

Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Approal Date: 9/26/2024

Reference

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216158s000lbl.pdf

Monthly Drug Safety Alert

भारतीय भेषजसंहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सैक्टर - 23, राज नगर
गाजियाबाद - 201 002 (उ.प्र.), भारत

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar
Ghaziabad - 201 002 (U.P.) INDIA

File No. P.17019/01/2024-DA **Dated: July 18, 2024**

Monthly Drug Safety Alert

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following:

Table

S. No.	Suspected Drug	Indication	Adverse Drug Reaction
1	Vancomycin	Treatment of serious infection due to Gram-positive cocci including methicillin-resistant staphylococcal infections, brain abscess, staphylococcal meningitis and septicaemia.	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Syndrome.

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADR associated with the use of above suspected drug. If, such reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (**http://www.ipc.gov.in**), through **PvPI Helpline No. 1800-180-3024.**

भारतीय भेषजसंहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सैक्टर - 23, राज नगर
गाजियाबाद - 201 002 (उ.प्र.), भारत

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar
Ghaziabad - 201 002 (U.P.) INDIA

File No. P.17019/01/2024-DA **Dated: August 28, 2024**

Monthly Drug Safety Alert

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following:

Table

S. No.	Suspected Drug	Indication	Adverse Drug Reaction
1	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	Fixed Drug Eruption (FDE)

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADR associated with the use of above suspected drug. If, such reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (**http://www.ipc.gov.in**), through **PvPI Helpline No. 1800-180-3024.**

INDIAN PHARMACOPOEIA (IP) Official Book of Drug Standards in India | IP REFERENCE SUBSTANCES (IPRS) Official Physical Standards for Assessing the Quality of Drugs | NATIONAL FORMULARY OF INDIA (NFI) Reference Book to Promote Rational Use of Generic Medicines | PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI) WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services
Tel. No.: +91-120-2783392, 2783400, 2783401; E-mail: lab.ipc@gov.in; Website: www.ipc.gov.in

भारतीय भेषजसंहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
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INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar
Ghaziabad - 201 002 (U.P.) INDIA

File No. P.17019/03/2024-DSA **Dated: September 25, 2024**

Monthly Drug Safety Alert

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following:

Table

S. No.	Suspected Drug	Indication	Adverse Drug Reaction
1	Tetracycline	Treatment of Rocky Mountain spotted fever, typhus, Q fever, rickettsial pox, tick fever caused by Rickettsiae, respiratory tract infections caused by Mycoplasma pneumonia, Chlamydia infection , nongonococcal urethritis, chancroid, plague, tularemia, cholera, brucellosis, bartonellosis, granuloma inguinale, haemophilus and kleibsella infections, psittacosis.	Fixed Drug Eruption

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADR associated with the use of above suspected drug. If, such reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (**http://www.ipc.gov.in**), through **PvPI Helpline No. 1800-180-3024.**

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Tel. No.: +91-120-2783392, 2783400, 2783401; E-mail: lab.ipc@gov.in; Website: www.ipc.gov.in

Reference

https://www.ipc.gov.in/8-category-en/1281-drugs-alerts-2024.html

EVENT CORNER

World Hepatitis Day 2024- Screening and Health Awareness Program

Coordinator: Dr Deepalakshmi M
Assistant Professor
Department of Pharmacy Practice
JSS College of Pharmacy, Ooty

Organized by: Dept. of Pharmacy Practice, JSSCPO & JSS Rotaract Club with the support extended by JSSAHER and IPA, Nilgiris local branch.
Venue: Ooty Central Bus Stand, Ooty, The Nilgiris.
Date: 28.07.2024

The program was sponsored by JSSAHER, Mysuru, and aimed to raise awareness about Hepatitis factors, and the importance of diagnosis, screening, treatment, and prevention of Hepatitis diseases among the public & employees of Tamil Nadu State Transport Corporation. A total of 7 volunteers from VI PharmD and IV Pharm D were actively involved in the health screening activities of the program, 4 faculty members delivered their counselling addressing each topic related to Hepatitis. The program began with the distribution of pamphlets by the Station Manager and the Vice Principal. The students counselled the public on the unusual symptoms of Hepatitis disease when they should go to a physician for a check-up and the importance of regular screening for the prevention of Hepatitis disease. In this health screening camp, about 70 patients benefitted. Blood pressure was monitored using an electronic sphygmomanometer, Blood samples were collected from the participants to perform Liver Function Tests and Complete Blood Counts. SPO2 levels and Body mass index were also calculated by measuring the patient's height and weight to determine whether the patient was underweight, healthy weight, overweight, or obese. Patient counselling was given to the participants according to the screening results and Patient information pamphlets were distributed to all the participants to develop awareness among the local people & employees of Tamil Nadu State Transport Corporation regarding Hepatitis disease. Faculty from Govt. Medical College and Hospital collected the blood sample to perform the Liver Function and Complete Blood Count assessments. The event was a resounding success, through informative counselling, and screening, the program encouraged valuable insights on awareness of Hepatitis. The program received positive feedback from the participants in attendance, indicating a desire for similar initiatives in the future.

World Suicide Prevention Day-2024

Coordinator: Dr Deepalakshmi M
Assistant Professor
Department of Pharmacy Practice
JSS College of Pharmacy, Ooty

Organized by: Dept. of Pharmacy Practice, JSSCPO & JSS Rotaract Club with the support extended by JSSAHER and IPA, Nilgiris local branch.
Venue: Government Arts College, Ooty
Date: 10.09.2024

The day highlighted a series of insightful talks and interactive activities aimed at raising awareness about the Signs of suicidal behaviours and how to provide help. Dr Poornajith K M, District Mental Health Psychiatrist, and Ms. Mercy, a Counselor and Psychiatric Social Worker, were invited to share their expertise on how to reduce and prevent suicide thoughts through counseling. Their talk provided valuable insights about depression, failure, guilt, expectations, self-talk, opening up, and asking for help. The session was enlightening and thought-provoking for all attendees. They also discussed the availability of a toll-free 24x7 helpline that provides counseling to prevent suicide. Dr. Deepalakshmi M, Assistant Professor, Department of Pharmacy Practice, JSS College of Pharmacy, Ooty, and Dr. Aswin, Dr. Jeyaram, Dr Jenath NSS Co-Ordinators of Govt. Arts College, Ooty gave their impact and made the event successful. Session was started by taking Oath and followed by interactive session with Dr Poornajith. Approximately 200 students participated and provided their input. Competitions such as elocution and drawing were successfully carried out on the topic of "World Suicide Prevention." Ten members participated in the drawing competition, and seven students participated in the elocution competition. Prizes were distributed to the top three winners of each competition based on their creativity, clarity, and uniqueness. Additionally, students showcased their talents through singing, dancing, acting, and dramas related to suicide prevention, making the session enjoyable and fun-loving. The event successfully raised awareness about suicide and emphasized the importance of providing help and well-being. Dr. M. Deepalakshmi coordinated the entire program.

Continuing Pharmacy Education (World Pharmacist Day 2024)

Coordinator: Dr Deepalakshmi M
Assistant Professor
Department of Pharmacy Practice
JSS College of Pharmacy, Ooty

Organized by: Dept. of Pharmacy Practice, JSSCPO & JSS Rotaract Club with the support extended by JSSAHER and IPA, Nilgiris local branch.
Venue: Ooty Central Bus Stand, Ooty, The Nilgiris.
Date: 25.19.2024.

The Department of Pharmacy Practice at JSS College of Pharmacy, Ooty, organized a one-day Continuing Pharmacy Education (CPE) program, aimed at community pharmacists. This initiative was designed to enhance both knowledge and practical skills for pharmacists across various professional settings, emphasizing the importance of continuous learning and development in the ever-evolving field of pharmacy. In a profession where advancements in medical treatments, drug therapies, and pharmaceutical technologies are frequent, it is crucial for practicing pharmacists to continuously update their knowledge. The program featured three key sessions that were highly interactive and focused on vital aspects of pharmacy practice delivered by the faculties of Department of Pharmacy Practice, JSSCPO: 1. Handling of Prescriptions - Mr. Vishwas H.N. 2. ADR Monitoring and Reporting: - Dr. Jeyaram Bharathi. 3. Drug-Related Problems - Dr. M. Deepalakshmi. A key highlight of the program was the active participation of approximately 30 community pharmacists, who engaged in discussions and shared their insights during the sessions. The interactive format encouraged peer-to-peer learning, making the program a collaborative experience. Certificates of participation were awarded to all attendees as a recognition of their commitment to professional development.
Feedback from the participants was collected, reflecting the relevance and utility of the sessions in their daily practice. The program concluded with a vote of thanks, acknowledging the contributions of the speakers and participants. The CPE program was inaugurated by Dr. S.P. Dhanabal, whose opening remarks set the tone for the day's learning activities. Dr. M. Deepalakshmi, who coordinated the event.



Current Scenario of Fibrinolytics

Guest Lecturer: Dr K Tamilarasu MD., DNB., FACC
Professor and Head
Department of Cardiology
PSG institute of Medical Sciences & Research
Coimbatore

Organized by: Dept. of Pharmacy Practice, JSSCPO & JSS Rotaract Club with the support extended by JSSAHER and IPA, Nilgiris local branch.
Venue: Government Arts College, Ooty
Date: 10.09.2024

The Department of Pharmacy Practice at JSS College of Pharmacy, Ooty, organized a guest lecture on October 2, 2024, delivered by the esteemed Dr. K. Tamilarasu on the topic "Current Scenario of Fibrinolytics." This lecture provided an insightful overview of fibrinolytic therapy, a critical area in the management of thrombotic disorders, highlighting the latest advancements and clinical applications of these life-saving treatments.
Introduction to Fibrinolytics: Dr. K. Tamilarasu began by discussing the role of fibrinolysis in the body's natural mechanism of dissolving clots, emphasizing the importance of fibrinolytic agents in medical conditions such as myocardial infarction, ischemic stroke, and pulmonary embolism.
Current Trends and Innovations: The session focused on the various types of fibrinolytics currently in clinical use, including first-generation agents like streptokinase, second-generation agents like alteplase, and third-generation agents such as tenecteplase and reteplase.
Future Prospects: The lecture also touched upon promising research in the field of fibrinolytics. Dr. Tamilarasu highlighted ongoing developments in designing next-generation fibrinolytic agents with enhanced clot selectivity, reduced bleeding risks, and more convenient dosing protocols.
Interactive Q&A Session: The lecture concluded with an engaging Q&A session, where participants from the audience, including students and faculty members, raised various questions. Dr. Tamilarasu responded with detailed explanations, discussing issues such as the comparative efficacy of newer fibrinolytics, strategies for minimizing adverse effects, and the potential for future innovations in the field.



TWO DAYS NATIONAL SEMINAR ON "EMERGING TRENDS IN CLINICAL PHARMACOLOGY RESEARCH AND PHARMACY PRACTICE"

Coordinator: Dr Deepalakshmi M
Assistant Professor
Department of Pharmacy Practice
JSS College of Pharmacy, Ooty

Organized by: Dept. of Pharmacy Practice
Sponsored by: DST-SERB & JSSAHER, Mysuru
Venue: JSS College of pharmacy, Ooty
Date: 16.03.2024

Plenary Speakers

Dr Vijay Ivaturi
Principal Scientist, Co-Founder & CEO Pumas-AI
Affiliate Professor
University of Maryland Baltimore, President ISoP

Dr Harish Kaushik
Head DMPK & Clinical (Pharmacology&Operations),
Development at Bugworks Research Inc

Dr Blessed Winston Arul Dhas
Professor
Department of Pharmacology & Clinical Pharmacology
Christian Medical College, Vellore

Dr K Gowthamarajan
Professor & Head
Department of Pharmaceutics
JSS College of Pharmacy, Ooty

Dr KP Arun
Associate Professor
Department of Pharmacy Practice
JSS College of Pharmacy, Ooty

Dr S Sriram
Professor & HoD
Department of Pharmacy Practice
College of Pharmacy
Sri Ramakrishna Institute of Paramedical Sciences
Coimbatore, Tamil Nadu

Dr Nagaprabhu VN
Consultant Rheumatology Centre
Coimbatore

Dr TK Praveen
Professor & Head
Department of Pharmacology
JSS College of Pharmacy, Ooty

Objectives

To explore and identify the current trends in clinical research and pharmacy practice, including advancements in technology, research methodologies, and patient care.
To emphasise the role and impact of personalized medicine in clinical research and pharmacy practice.
To understand the role of artificial intelligence and machine learning in clinical research and pharmacy practice.
To discuss the challenges of antibiotic resistance and the role of antibiotic stewardship programs in promoting responsible use.

About the Seminar

The seminar on "Emerging Trends in Clinical Pharmacology Research and Pharmacy Practice" was organized with the goal of addressing the rapid advancements in healthcare and ensuring that professionals in pharmacology and pharmacy practice remain well-informed and prepared to meet the challenges of the evolving medical landscape. In today's dynamic world of healthcare, the roles of pharmacists and pharmacologists are expanding, requiring them to stay updated with the latest research and trends. With this in mind, the seminar provided a platform for knowledge exchange and collaboration among professionals, researchers, and students, helping them explore how cutting-edge research can be applied to real-world patient care, thereby improving healthcare outcomes.

Scientific Sessions and Presentations

The seminar was structured into two days of scientific sessions and presentations, where experts and researchers discussed various topics related to clinical pharmacology and pharmacy practice. A total of 183 presentations were conducted, including 13 oral presentations and 170 E-poster presentations. These sessions were organized across nine venues within the JSS College of Pharmacy campus, providing ample space for participants to present their research and exchange ideas.

Conclusion

The two-day seminar was a resounding success, providing a rich platform for professionals, researchers, and students from diverse institutions to come together and share their knowledge. The seminar's seven scientific sessions covered a wide range of topics, from the application of pharmacometrics in preclinical research to the latest advancements in precision medicine. With a total of 183 presentations, the event fostered active participation and knowledge exchange, helping attendees gain a deeper understanding of how current research in clinical pharmacology can be applied to improve patient care. Overall, the seminar highlighted the importance of staying updated with emerging trends in pharmacology and pharmacy practice. By fostering collaboration and encouraging the exploration of new ideas, the event aimed to enhance healthcare outcomes and ensure that professionals are equipped to meet the challenges posed by the ever-evolving landscape of modern medicine.

Publications from the Department of Pharmacy Practice (July - September 2024)

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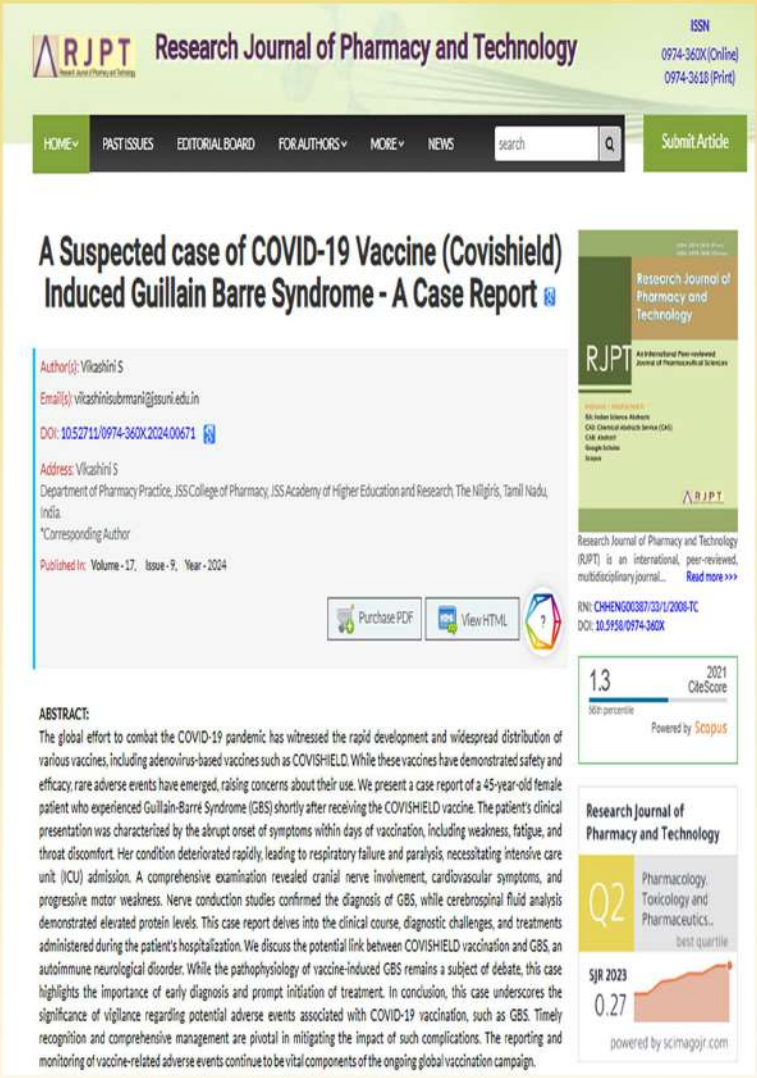
- Regin Willfred C , Suguna Kotte , Aldo Rex T , Deepak D M , Serolin S R , Raghul Kumar A , Preetha R , Taroob Runa T , Jessica Samson George , **Vikashini Subramani.** The Silent Menace: An In-depth Analysis of Nipah Virus. African journal of biological sciences. 2024;6(11):824-851.
- Mohathasim Billah A, **Rajamohamed H**, Mohamed Akram Ali S, Porkodi M, Vikashini S, Lida Sajimon. Statin-induced Rhabdomyolysis and its Management – A Case Report. Research Journal of Pharmaceutical Technology. 2024;17(7):3241-3245.
- Pramod Kumar A, Dharini Boopathi, Rahamthulla Shaik, Srikanth Naik Bhukya, Mighty goldstone Alladi, Bala Pravalika Mallavarapu, **Deepalakshmi Mani.** Identification and Reporting of Adverse Events Following Immunization – A Prospective and Observational Study. Research Journal of Pharmacy and Technology. 2024;17(7):3409-4.
- Vansh Gaur, Smritthi P, Vivek, Megha Sajith, Ranakishor Pelluri, **HN Vishwas**, Ravi Kumar Y.S. Study of Musculoskeletal Manifestations in Patients with Type II Diabetes Mellitus Visiting a Tertiary Care Hospital. African Journal of Biological Sciences. 2024;6(15):7451-7470.
- **Vikashini S**. A Suspected case of COVID-19 Vaccine (Covishield) Induced Guillain Barre Syndrome - A Case Report. Research Journal of Pharmacy and Technology. 2024; 17(9):4343-6.



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A Suspected case of COVID-19 Vaccine (Covishield) Induced Guillain Barre Syndrome - A Case Report

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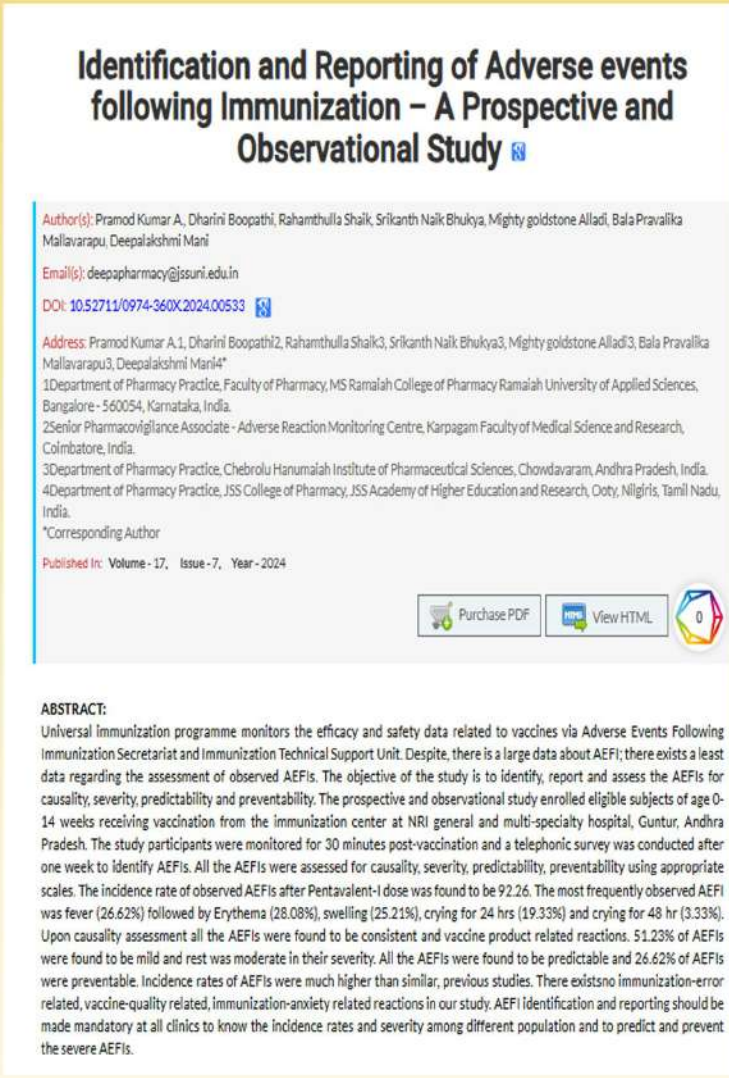
ABSTRACT:
The global effort to combat the COVID-19 pandemic has witnessed the rapid development and widespread distribution of various vaccines, including adenovirus-based vaccines such as COVISHIELD. While these vaccines have demonstrated safety and efficacy, rare adverse events have emerged, raising concerns about their use. We present a case report of a 45-year-old female patient who experienced Guillain-Barré Syndrome (GBS) shortly after receiving the COVISHIELD vaccine. The patient's clinical presentation was characterized by the abrupt onset of symptoms within days of vaccination, including weakness, fatigue, and throat discomfort. Her condition deteriorated rapidly, leading to respiratory failure and paralysis, necessitating intensive care unit (ICU) admission. A comprehensive examination revealed cranial nerve involvement, cardiovascular symptoms, and progressive motor weakness. Nerve conduction studies confirmed the diagnosis of GBS, while cerebrospinal fluid analysis demonstrated elevated protein levels. This case report delves into the clinical course, diagnostic challenges, and treatments administered during the patient's hospitalization. We discuss the potential link between COVISHIELD vaccination and GBS, an autoimmune neurological disorder. While the pathophysiology of vaccine-induced GBS remains a subject of debate, this case highlights the importance of early diagnosis and prompt initiation of treatment. In conclusion, this case underscores the significance of vigilance regarding potential adverse events associated with COVID-19 vaccination, such as GBS. Timely recognition and comprehensive management are pivotal in mitigating the impact of such complications. The reporting and monitoring of vaccine-related adverse events continue to be vital components of the ongoing global vaccination campaign.



Identification and Reporting of Adverse events following Immunization – A Prospective and Observational Study

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ABSTRACT:
Universal immunization programme monitors the efficacy and safety data related to vaccines via Adverse Events Following Immunization Secretariat and Immunization Technical Support Unit. Despite, there is a large data about AEFI; there exists a least data regarding the assessment of observed AEFIs. The objective of the study is to identify, report and assess the AEFIs for causality, severity, predictability and preventability. The prospective and observational study enrolled eligible subjects of age 0-14 weeks receiving vaccination from the immunization center at NRI general and multi-specialty hospital, Guntur, Andhra Pradesh. The study participants were monitored for 30 minutes post-vaccination and a telephonic survey was conducted after one week to identify AEFIs. All the AEFIs were assessed for causality, severity, predictability, preventability using appropriate scales. The incidence rate of observed AEFIs after Pentavalent-I dose was found to be 92.26. The most frequently observed AEFI was fever (26.62%) followed by Erythema (28.08%), swelling (25.21%), crying for 24 hrs (19.33%) and crying for 48 hr (3.33%). Upon causality assessment all the AEFIs were found to be consistent and vaccine product related reactions. 51.23% of AEFIs were found to be mild and rest was moderate in their severity. All the AEFIs were found to be predictable and 26.62% of AEFIs were preventable. Incidence rates of AEFIs were much higher than similar, previous studies. There existsno immunization-error related, vaccine-quality related, immunization-anxiety related reactions in our study. AEFI identification and reporting should be made mandatory at all clinics to know the incidence rates and severity among different population and to predict and prevent the severe AEFIs.

For clarifications/ feedback, write to:

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