SOUVENIR

International Conference on Patient Safety
&
22nd Annual Conference of
Society of Pharmacovigilance, India

SoPICON 2025

FEBRUARY 5, 2025: PRE-CONFERENCE WORKSHOPS

FEBRUARY 6-7, 2025: CONFERENCE

Organised by:
Department of Pharmacology
All India Institute of Medical Sciences Bhopal
&
Society of Pharmacovigilance, India

डॉ. सुनील मलिक
अध्यक्ष
Dr. Sunil Malik
MBBS, MD (Medicine), DM (Neurology)
President

अखिल भारतीय आयुर्विज्ञान संस्थान
साकेत नगर, भोपाल, मध्य प्रदेश - 462020
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
SAKET NAGAR, BHOPAL, MADHYA PRADESH-462020
(An Institute of National Importance under MoHFW, Government of India)
Email: president@aiimsbhopal.edu.in
Web: https://aiimsbhopal.edu.in
Phone: 0755 283 6666, 2672555

MESSAGE

It is indeed a pleasure that the Department of Pharmacology at the All India Institute of Medical Sciences (AIIMS) Bhopal is hosting the International Conference on Patient Safety and 22nd Annual Conference of Society of Pharmacovigilance, India (SoPICON 2025) from 5th to 7th February 2025.

The conference is well designed to meet the needs of young pharmacologists and researchers, focusing on advanced technologies and academic excellence in various fields of pharmacology and research. Such events are crucial for fostering new ideas and collaborative efforts in drug research and patient safety.

Wishing the conference a grand success.

(Dr. Sunil Malik)

प्रो. (डॉ.) अजय सिंह
कार्यपालक निदेशक
Prof. (Dr.) AJAI SINGH
MS, MCh, FAMS, MNAMS, FICS, FSS, FPO
Professor, Paediatric Orthopedics
Executive Director

सत्यमेव जयते

अखिल भारतीय आयुर्विज्ञान संस्थान
साकेत नगर, भोपाल - 462 020
All India Institute of Medical Sciences
Saket Nagar, Bhopal - 462 020
(An Autonomous Institute under MoHFW, Govt.of India)
Phone : 0755 - 2672317, 2672329
Fax : 0755 - 2672337
E-Mail : director@aiimsbhopal.edu.in
Web: www.aiimsbhopal.edu.in

Date: 25.01.2025

DIRECTOR'S MESSAGE

It gives me immense pleasure to know that the Department of Pharmacology, AIIMS Bhopal, is hosting the International Conference on Patient Safety and 22nd Annual Conference of Society of Pharmacovigilance, India (SoPICON 2025) from 5th to 7th February 2025.

This conference is meticulously designed to meet the needs of young pharmacologists and researchers. It will have two parallel Pre-conference workshops on Pharmacovigilance and Materi vigilance, followed by the main Conference having K.C. Singhal & John Autian Orations, Uppsala Best Oral and Poster Presentation Awards, Symposia, Pharmacovigilance Quiz & General body meeting.

The conference will serve as a dynamic platform, encouraging our pharmacologists to engage with the latest concepts in patient safety.

The goal is to foster a network and promote collaborative research to benefit the society at large.

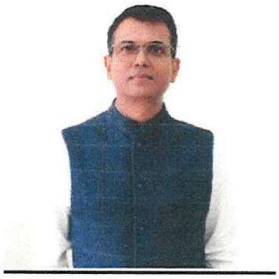
I extend my best wishes for the grand success of the conference.

Warm regards,

Prof. (Dr.) AJAI SINGH

कर्नल (डॉ.) अजीत कुमार
उप निदेशक (प्रशासन)
Col. (Dr.) Ajit Kumar
Deputy Director (Admin.)

अखिल भारतीय आयुर्विज्ञान संस्थान
साकेत नगर ,भोपाल (मध्य प्रदेश) 462020
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
Saket Nagar, Bhopal (Madhya Pra desh) 462020
(An Autonomous Institutes under MoHFW, Govt. of India)
Phone- 0755 – 2836010, 0755 2672360
Web: www.aiimsbhopal.edu.in
E-mail- dydir@aiimsbhopal.edu.in



MESSAGE

1. It is a great pleasure to know that the Department of Pharmacology, AIIMS Bhopal is organizing International Conference on Patient Safety and 22nd Annual Conference of Society of Pharmacovigilance, India (SoPICON 2025) from 5th to 7th February 2025.
2. This well-structured conference is designed to meet the needs of young pharmacologists & researchers, focusing on cutting-edge technologies and advancements in pharmacology. It is a commendable effort to bring together academicians, researchers & regulatory bodies to shed light on recent developments & future directions in the field of pharmacology.
3. The conference shall provide a dynamic platform, inspiring our pharmacologists to stay on abreast in the knowledge about side effects of drugs. It aims to foster networking & promote collaborative research that will ultimately benefit society at large.
4. I take this opportunity to extend my best wishes for the success of the conference & hope that it will serve as a valuable contribution to the field.

Col. (Dr.) Ajit Kumar
Dy. Director (Admin.)

Society of Pharmacovigilance, India

27.12.2024

MESSAGE

Dear Colleagues,

Pharmacovigilance is to improve patient care and safety with an aim to reduce substantial financial burden of adverse reactions upon the health care sector and for society as a whole. The pharmaceutical industry and physicians have equal responsibility for early detection of ADRs with an aim to prevent any tragedy like Thalidomide experienced in early 1960s.

For early detection and to coverlarge population, spontaneous reporting and its linkage with national and WHO scientific group was initiated in 1964 at the Uppsala Monitoring Centre. India has joined this WHO initiated programme like many other nations.

Society of Pharmacovigilance India (SoPI) was established with the aim of creating awareness and training Physicians, Pharmacists and other health care workers and create awareness for the participation in its programme.

SoPI since its inception in the year 2000 has earnestly pursued its activity by regularly organizing conferences, seminars, group discussions and publishing reports and articles. This year, in 2025 we are organizing the annual meeting at AIIMS, Bhopal. I am confident that this year's meeting too will be a great success and provide lead for future.

With best wishes,
Prof. K. C. Singhal
(Patron)

Society of Pharmacovigilance, India

26.12.2024

MESSAGE

It is my distinct honor to extend a warm welcome to all participants of the SoPICON. On behalf of the SoPI, I would like to express my deepest appreciation for your commitment to advancing the field of pharmacovigilance and ensuring the safe use of medicines.

The field of drug safety is evolving rapidly, with new treatments offering hope but also posing unique challenges related to safety monitoring and risk management. As professionals dedicated to pharmacovigilance, we have the shared responsibility of ensuring that these innovations are not only effective but also monitored rigorously to identify and mitigate potential risks to patients worldwide.

This conference brings together a diverse and distinguished group of experts, researchers, and healthcare professionals committed to sharing cutting-edge research, regulatory insights, and practical experiences. It is through these collaborative discussions and partnerships that we can strengthen our strategies, improve pharmacovigilance systems, and safeguard the health of patients undergoing therapeutic treatment.

I encourage all attendees to actively engage with the keynote speakers, panelists, and peers throughout this event. Let us seize this opportunity to foster collaborations, share knowledge, and contribute to the ongoing efforts to enhance drug safety.
Thank you for your participation, and I wish you an enriching, engaging, and productive conference.

With best regards,
Dr. Sandeep Agarwal
(President)

Office Adress: Department of Pharmacology, J.N. Medical College, Aligarh Muslim University, Aligarh 202002, India
Society Website: www.sopi.net.in; **Journal Website:** www.journalofsopi.com; **Email ID:** pharma.jnmc@gmail.com

Society of Pharmacovigilance, India

24.12.2024

MESSAGE

I am pleased to write this message on behalf of the secretary of the SoPI. It is once again a quite pleasing moment that the next 23rd annual conference of SoPICON, is scheduled to take place from 5th to 7th February 2025 at AIIMS Bhopal. It is with great pleasure and privilege that I extend my warmest greetings to all the participants of 23rd Annual Meeting of the SoPI. The society as collective efforts of professionals and researchers has played a significant role in advancing the drug safety and monitoring for the last 2 decades.

I congratulate the organizing committee under the guidance of Prof. Ratinder Jhaj for their dedication in bringing together many experts, stakeholders, and practitioners to exchange knowledge and share their researches. The participation and contributions of delegates will undoubtedly enrich the discussions and help shape the future of pharmacovigilance. We believe that these experts and participation of young researchers would greatly enrich the dialogue and outcomes of this event. The keynote speeches from leading experts in pharmacovigilance, panel discussions on emerging trends and regulatory updates, networking opportunities with professionals and peers and above all the workshops on practical applications and risk management, will surely be the beneficial for all the participants.

Looking forward to interact and meet all the delegates.

Warm regards,
Prof. Syed Ziaur Rahman
(Secretary)

केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद्
आयुष मंत्रालय, भारत सरकार
CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Ministry of Ayush, Govt. of India

प्रो (वैद्य) रबिनारायण आचार्य
महानिदेशक
Prof. (Vaidya) Rabinarayan Acharya
Director General

16th January 2025

MESSAGE

Patient safety is a cornerstone of healthcare, bridging traditional and modern systems with the shared objective of minimizing harm during treatment. A strong focus on patient safety not only improves health outcomes but also reduces costs associated with adverse events, enhances healthcare system efficiency, and strengthens community trust in medical services.

Pharmacovigilance is a vital component of patient safety, involving the systematic monitoring, assessment, and management of adverse drug reactions. This proactive approach identifies potential risks associated with medications and implements strategies to mitigate them, ensuring that patients receive safe and effective treatments. By continuously enhancing the quality of healthcare, pharmacovigilance contributes significantly to a safer therapeutic environment.

It is heartening to know that the **Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Bhopal**, in collaboration with the **Society of Pharmacovigilance, India (SoPI)**, is organizing the **International Conference on Patient Safety and the 22nd Annual Conference of the Society of Pharmacovigilance (SoPICON 2025)** from **5th to 7th February 2025** at AIIMS, Bhopal. This event represents a significant platform for professionals committed to advancing patient safety and the science of pharmacovigilance.

AIIMS Bhopal, a premier institution under the Ministry of Health and Family Welfare, is at the forefront of clinical and translational research, patient care, and medical education. Similarly, the Society of Pharmacovigilance, India (SoPI),one of the oldest societies on pharmacovigilance, has been a pioneer in enhancing medicine safety through education, training, and scientific initiatives, organiniging seminars and workshops making this collaboration especially meaningful.

I extend my heartfelt gratitude to the organizers, distinguished speakers, faculty, and participants whose expertise and dedication will enrich this conference. Your contributions are instrumental in advancing the shared mission of ensuring patient safety and promoting the rational use of medicines.

I am confident that the deliberations and insights shared during the conference will lead to actionable strategies, fostering significant improvements in healthcare delivery and patient safety. Wishing all participants a successful and enlightening experience.

योगादपि विषं तीक्ष्णमुत्तमं भेषजं भवेत्।

भेषजं चापि दुर्युक्तं तीक्ष्णं सम्पद्यते विषम्॥

(Charaka Samhita)
(Even the most potent poison, when used judiciously, can serve as the best medicine; however, an improperly used medicine can turn into a lethal poison.)

16/1/25

(Prof. Vaidya Rabinarayana Acharya)

जवाहर लाल नेहरू भारतीय चिकित्सा एवं होम्योपैथी अनुसंधान भवन, 61-65, सांस्थानिक क्षेत्र, सम्मुख 'डी' ब्लाक, जनकपुरी नई दिल्ली-110058
Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoepathy Anusandhan Bhawan, Institutional Area, Opp. 'D' Block, Janakpuri, New Delhi-110058
Phone : 011-28524457, 011-28520748
Website : www.ccras.nic.in **Email :** dg-ccras@nic.in, drrnacharya@gmail.com

Contents

SoPICON 2025

5th TO 7th FEBRUARY 2025

Chief Patron

Dr. Sunil Malik
President, AIIMS Bhopal

Patron & Chief Guest

Prof. (Dr.) Ajai Singh
Executive Director & CEO,
AIIMS Bhopal

Guests of Honour

Dr. Rajnish Joshi
Dean Academics,
AIIMS Bhopal

Col. Ajit Kumar
Deputy Director(Administration),
AIIMS Bhopal

Prof. Shashank Purwar
Medical Superintendent,
AIIMS Bhopal

Prof K. C. Singhal
Patron, SoPI

Dr Sandeep Agrawal
President, SoPI

Organizing Chairperson

Dr. Balakrishnan S.

Professor & HoD,
Department of Pharmacology,
AIIMS Bhopal

Organizing Secretary

Dr. Ratinder Jhaj

Professor,
Department of Pharmacology,
AIIMS Bhopal

Joint Secretary

Dr. Shilpa Kaore

Professor,
Department of Pharmacology,
AIIMS Bhopal

Registration & Publication

Dr. Ajay Kumar Shukla

Additional Professor,
Department of Pharmacology,
AIIMS Bhopal

Scientific Advisor

Dr. Shubham Atal

Additional Professor,
Department of Pharmacology,
AIIMS Bhopal

Treasurer

Dr. Ahmad Najmi

Additional Professor,
Department of Pharmacology,
AIIMS Bhopal

SoPICON 2025

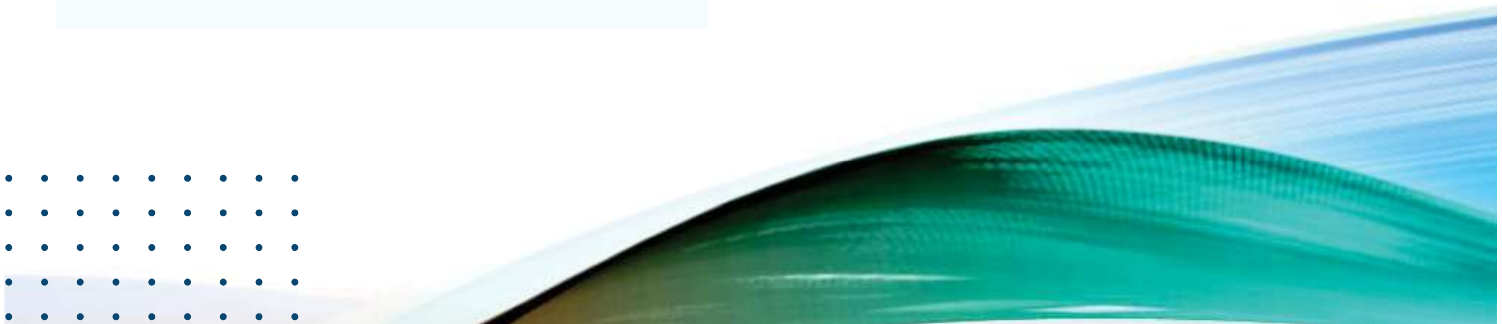
5th to 7th February 2025

Local Executive Committee

- Dr. Arun Srivastav
- Dr. Vipin Dhote
- Dr. Somya Singh
- Dr. Florance Joy
- Dr. Bhavya
- Ms. Deepa Chaudhary
- Mr. Mohd. Faizan Khan
- Mr. Sandeep Tiwari
- Ms. Bushra Siddiqui
- Mr. Sateesh Meena

SoPI Executive Committee

- Dr. K. C. Singhal
- Dr. Sandeep Agarwal
- Dr. Bharat Gajjar
- Dr. Vandana Roy
- Dr. Rabinarayan Acharya
- Dr. Anil Kumar Chaudhary
- Dr. Syed Ziaur Rahman
- Dr. Parul Agarwal
- Dr. Prithpal Singh Matreja
- Dr. S. S. Handu
- Dr. Ashok Dubey
- Dr. Nitin Kothari
- Dr. R. K. Goyal
- Dr. Hariom Kumar Singh



Local Organizing Committee

Post-graduate students

- Dr. Shamsher S. Kalra
- Dr. Rishika A.
- Dr. Harshit Vishwakarma
- Dr. Srijan G. Shetty
- Dr. Gokul Aravind
- Dr. Ashwin Babu A.
- Dr. Chirag Agrawal

PhD Scholars

- Santenna Chenchula
- Akanksha Chaturvedi

Interns

- Anjali Gupta
- Nainy Jain
- Satyam Sharma
- Shambhavi Urmaliya
- Chanchal Priyadarshani
- Kumar Sanu

Office Support Staff

- Md. Imran Alam
- Ranu Shakya
- Anand Prakash Maurya
- Deepak Kesharwani
- Santosh Sen
- Rajkumari Verma
- Dilip Parmeshwar

Department of Pharmacology

Department of Pharmacology - Faculty

SoPICON 2025

5th to 7th February 2025

Events at a glance

5th Feb.

Workshops

Two Parallel Pre-conference Workshops-

- Pharmacovigilance
- Materiovigilance

6th & 7th Feb.

Conference

- K.C. Singhal & John Autian Orations
- Uppsala Best Oral and Poster Presentation Awards
- Symposia
- Pharmacovigilance Quiz
- Oral & Poster Presentations
- General Body Meeting

Gala Dinner & Cultural Program

SCIENTIFIC PROGRAMME

Day 1: February 5, 2025: Pre-Conference Workshop 1 - Pharmacovigilance

Venue: CAL Lab, 3rd Floor, Department of Pharmacology, Sardar Vallabhbhai Patel Bhavan, AIIMS Bhopal

Time	Topic	Speaker
8.30 - 9.30 am	**WORKSHOP REGISTRATION & BREAKFAST**	
9.30 - 9.55 am	Inauguration	**Dr. Balakrishnan S.** Professor & Head, Pharmacology, AIIMS Bhopal
9.55- 10.00am	Overview of Workshop	**Dr. Ratinder Jhaj** Prof. Pharmacology, AIIMS Bhopal
10.00 - 11.00 am	Hands on Session on Causality Assessment	**Dr. S P Dhaneria** Prof. & HOD, Pharmacology, RG Gardi Medical College, Ujjain
11.00- 11.30 am	Hands-on Demonstration of Vigiflow	**Ms. Deepa Chaudhary** Pharmacovigilance Associate, AIIMS Bhopal
11.30 am- 12.30 pm	Hands-on Training on MedDRA Coding	**Dr. Anamika Dutta** Medical Officer MedDRA MSSO, Bengaluru
1.00 - 2.00 pm	**LUNCH BREAK**	
2.00 - 3.00 pm	Hands-on Processing of MAH ICSRs with Scoring	**Mr. Girjesh Vishwakarma,** Pharmacovigilance Associate, GMC Bhopal and formerly Training Division, IPC Ghaziabad
3.00 - 4.00 pm	Hands-on Demonstration of a PV Dataset/Software (PvEdge)	**Mr. Aniket Deshmukh** Assistant Mananger, Quality, Compliance, Training Fidelity Health Services, Canada, USA, India **Ms. Molisha Soni** Senior Drug Safety Executive, Fidelity Health Services
4.00 - 4.25 pm	Workshop Mini-Quiz	**Dr. Florance Joy** Senior Resident Pharmacology, AIIMS Bhopal
4.25 - 4.55 pm	Participant Feedback and Discussion	-
4.55 -5.00 pm	Vote of Thanks	**Dr. Srijan Shetty** Junior Resident Pharmacology, AIIMS Bhopal
5.00 pm: HIGH TEA		

SCIENTIFIC PROGRAMME

Day 1: February 5, 2025 : Pre-Conference Workshop 2- Materiovigilance

Venue:CMET Hall, 2nd Floor, Sardar Vallabhbhai Patel Bhavan, AIIMS Bhopal

Time	Topic	Speaker
8.30 - 9.30 am	**WORKSHOP REGISTRATION & BREAKFAST**	
9.30 -10.00 am	Inauguration	**Dr. Balakrishnan S.** Professor & Head, Pharmacology, AIIMS Bhopal
10.00 - 10.40 am	Overview of Materiovigilance Programme of India (MvPI)	**Dr. Shilpa Kaore**, Coordinator, RTC - Materiovigilance, AIIMS, Bhopal
10.40 - 11.30 am	Regulatory view on Importance of Post Marketing phase of Medical Devices & In vitro diagnostics	**Dr. Sella Senthil** Assistant Drug Controller (India), IVD Division, CDSCO, New Delhi
11.30 am - 12.00 pm	Reporting tools for MDAE & Causality Assessment	**Dr. Ahmad Najmi**, Deputy Coordinator, RTC, Materiovigilance AIIMS, Bhopal
12.00 -12.30 pm	Overall Experiences of Healthcare professionals & RTC	HCPs representatives **Mr. Faizan Khan,** MvPI, Research Associate
12.30 – 1.00 pm	Case Based Discussion	**Mr. Faizan Khan**, MvPI Research Associate & Dr. Najmi, Deputy Coordinator, MvPI
1.00 - 2.00 pm	**LUNCH BREAK**	
2.00- 2.40 pm	Hands-on ADRMS software	**Dr. Shatrunjay Shukla**, Assistant Scientist, IPC, Ghaziabad
2.40- 3.15 pm	Hands on training on MDAE reporting form	**Mr. Faizan Khan, Dr. Ahmad Najmi** **Dr. Shilpa Kaore, Dr. Ajay Shukla** **Dr. Somya**
3.15- 4.15 pm	Quiz	**Dr. Somya**, SR, Pharmacology
4.15 - 4.30 pm	Vote of Thanks & Certificate distribution	**Dr. Rishika**, JR, Pharmacology

February 6, 2025	
8.00 -9.00 am	**CONFERENCE REGISTRATION & BREAKFAST**
9.00 – 9.30 am	**Inauguration Ceremony & Release of Conference Souvenir**
9.30-10.15 am	**Keynote Address:** Dr. Shanti Pal, Team Lead, Pharmacovigilance Medicines and Health Products WHO headquarters
PROF K. C. SINGHAL ORATION **10.15 - 11.00 am**	**Orator: Dr. Yvonne Y Esseku,** Rector, Ghana College of Pharmacists, Ghana **Chairpersons:** 1. **Prof K. C. Singhal**, Patron, SOPI 2. **Dr. Peter Hjelmström**, Director/CEO, Uppsala Monitoring Centre, Sweden 3. **Dr. Shanti Pal**, Team Lead, Pharmacovigilance Medicines and Health Products WHO headquarters
11.00 - 11.30 am	**TEA BREAK**
11.30 - 12.45 pm	**PARALLEL SYMPOSIA 1 & 2**
SYMPOSIUM 1 **LT 5**	**Pharmacovigilance in the Community** **Chairpersons:** 1. **Dr. Umesh Shukla**, Principal, Pt. Khushila Sharma Govt. Ayurveda College & Institute Bhopal 2. **Dr. Abdul Latif**, Prof. & Ex-Chairman, Unani Pharmacology &Pharmaceutical Sciences, AMU, Aligarh 3.**Dr. Reeta Kh**, Prof. Pharmacology, AIIMS, New Delhi
11.30 - 11.50 am	Pharmacovigilance in the Community- An Overview: **Dr. Vandana Roy**, Prof. & HOD, Pharmacology, MAMC, New Delhi
11.50 - 12.10 pm	Pharmacovigilance of Ayurveda Medicines: **Dr. Rabinarayan Acharya**, Director General CCRAS · Central Council for Research in Ayurvedic Sciences
12.10 - 12.30 pm	Cutaneous Adverse Drug Reactions: **Dr. Ankita Srivastava**, Associate Professor, Dermatology, AIIMS Nagpur
12.30 - 12.45	Questions & Discussion
SYMPOSIUM 2 **LT 6**	**Pharmacovigilance, Therapeutics & Medical Education** **Chairpersons:** **1. Dr. Reenu Yadav,** Principal/Director, Pharmacy, Prestige Institute of Management & Research, Bhopal **2.Dr. Nitin Kothari,** Prof.& HOD, Pharmacology, GMC, Dungarpur **3. Dr. Major Vijay Yadav,** Prof.& HOD, Pharmacology, People's College of Medical Sciences & Research Centre, Bhopal
11.30 –11.50 am	Review of Indian HPE Curricula with respect to Patient Safety and Pharmacovigilance Pharmacovigilance in the Medical Curriculum: **Dr. Nirmala Rege**, Prof., Pharmacology, Era's Lucknow Medial College & Hospital, Lucknow
11.50-12.10 pm	Growth Hormone therapy beyond Growth Hormone Deficiency: Dr. **Vikas Mehrotra**, Pediatric Endocrinologist, KMCCC, Aligarh
12.10 –12.30 pm	Experiences of an ADR monitoring Centre: **Dr. S. Ziaur Rahman,** Prof. & HOD, Pharmacology, AMU, Aligarh
12.30 – 12.45 pm	Questions & Discussion

12.45-2.00pm	PARALLEL SYMPOSIA 3 & 4
SYMPOSIUM 3 LT 5	**Current Trends in Pharmacovigilance & Ecopharmacovigilance** **Chairpersons:** **1. Dr. Rekha Mehani,** Professor, People's College of Medical Sciences & Research Centre, Bhopal **2. Dr. Yogendra Narayanrao Keche**, Additional Professor, Pharmacology, AIIMS, Raipur **3. Dr. Pooja Gupta,** Addl Prof. Pharmacology, AIIMS, New Delhi
12.45 – 1.05 pm	Current Trends and Challenges in Pharmacovigilance- an Overview: **Dr. Gurpreet Singh,** Vice President & MD Integrated Safety at IQVIA, UK
1.05-1.25 pm	Ecopharmacology & Ecopharmacovigilance: Introduction and overview: **Dr. Vijay Motghare**, Prof.& HOD, Pharmacology, GMC, Nagpur
1.25 - 1.45 pm	Ecopharmacovigilance: Regulatory aspects: **Dr. Niket Rai,** Professor, Pharmacology LN Medical College, Bhopal
1.45-2.00pm	Questions & Discussion
SYMPOSIUM 4 LT 6	**Risk Assessment & Minimization in Pharmacovigilance** **Chairpersons:** **1. Dr. Tanu Garg,** Prof & Head, Mahaveer Institute of Medical Sciences & Research, Bhopal **2. Dr. Sneha Ambwani,** Prof. & HOD, Pharmacology, AIIMS, Jodhpur **3. Dr. Vipin Dhote,** Associate Director, VNS College of Pharmacy
12.45 – 1.05 pm	Drug safety regulations, clinical trials and DACH: **Dr. Joan D'Souza**, LCPPV Switzerland, Germany & Liechtenstein
1.05-1.25 pm	Risk assessment and interpretation in Medication Use: **Dr. Avijit Hazra**, Professor, Pharmacology, IGPMER, Kolkata
1.25 - 1.45 pm	Pharmacovigilance & Risk Management Measures in a Hospital: **Dr. Sanjeev Sharma,** Senior Consultant, Clinical Pharmacology, Indraprastha Apollo Hospital, New Delhi
1.45-2.00pm	Medical Devices - Regulations, Quality & Safety Practices in India - An update: **Dr V.Kalaiselvan,** Senior Principal Scientific Officer, IPC, Ghaziabad
2.00- 3.00 pm	**LUNCH & POSTER VIEWING**
3.00 -4.00 pm	**Parallel Oral Presentations**
LT 5	**Uppsala Awards Oral Paper Presentations**
LT 6	1. Integrating Pharmacogenomics into Pharmacovigilance: Enhancing Drug Safety through Genetic Insights: **Mr. Krishnendu Menon**, MS, CGC, Thermofisher Scientific 2. Drug Safety in Cardiothoracic Surgery: A surgeon's perspective: **Dr. Yogesh Niwariya,** Additional Profesor, Cardiothoracic Surgery, AIIMS Bhopal
4.00 -5.30 pm LT 5	Pharmacovigilance Quiz: **Dr. S Manikandan,** Professor, Pharmacology, JIPMER, Pondicherry and Team
5.30-6.00 pm LT 5	SOPI General Body Meeting
7.30 -10 pm	**Dinner and Cultural Programme**

DAY 3: February 7, 2025	
9.00 -10.15 am	**PARALLEL SYMPOSIA 5 & 6**
SYMPOSIUM 5 **LT 5**	**Key Issues in Pharmacovigilance** **Chairpersons:** 1. **Dr. Arun Shrivastav**, Prof. Pharmacology, GMC, Bhopal 2. **Dr. Pooja Solanki**, Prof.& HOD Pharmacology, MGMC, Indore 3. **Dr. Gurpreet Singh,** Vice President & MD Integrated Safety at IQVIA, UK
9.00–9.20am	Medication Errors: **Dr. Ashish Kakkar**, Associate Professor, Pharmacology, PGIMER, Chandigarh
9.20–9.40am	Deprescribing in Patient Safety: **Dr. Shambo Samrat Samajdar**, Clinical Pharmacologist, General Physician & Diabetologist, Kolkata
9.40–10.00am	Signal Detection in Pharmacovigilance: **Dr. Avijit Hazra**, Professor, Pharmacology, IGPMER, Kolkata
10.00 – 10.15 am	Questions & Discussion
SYMPOSIUM 6 **LT 6**	**Pharmacovigilance in Drug Development and Regulation** **Chairpersons:** **1. Dr. Bikas Medhi,** Prof. Pharmacology, PGIMER, Chandigarh **2. Dr. Surendra Boudh,** Prof. & HOD Pharmacology, GMC, Datia **3. Dr. Murali M,** Additional Prof., Translational Medicine, AIIMS Bhopal
9.00–9.20am	Pharmacovigilance in Drug Development: **Dr. Shoibal Mukherjee,** Consultant in Pharmaceutical Medicine & Drug Development Director, Medical Research, Medanta Hospitals
9.20–9.40am	Pharmacovigilance regulatory requirements for Market Authorization Holders in India: **Dr. Jai Prakash**, Senior Principal Scientific Officer, IPC, Ghaziabad
9.40–10.00am	Highlights of NDCT 2019 with focus on ADR reporting: **Dr. S P Dhaneria,** Prof. & HOD, Pharmacology, RG Gardi Medical College, Ujjain
10.00- 10.15 am	Questions & Discussion
10.15–11.00am	TEA BREAK
John Autian Oration **11.00 am–12.00pm** **LT 5**	**Orator: Dr Krishantha Janapriya Wirasinghe** Compliance Quality Assurance & Scientific Affairs Lead, Hemas Pharmaceuticals **Chairpersons:** 1. **Dr. Sandeep Agarwal,** President, SoPI 2. **Dr. Balakrishnan S.,** Prof. & Head of Pharmacology, AIIMS Bhopal 3. **Dr. Joan D'Souza,** LCPPV Switzerland, Germany & Liechtenstein

CLOSING SYMPOSIUM **12.00- 1.15 pm**	**The Future of Pharmacovigilance**
LT 5	**Chairpersons:** **1. Dr. S. Ziaur Rahman,** Prof. & HOD, Pharmacology, AMU, Aligarh **2. Dr. Avijit Hazra,** Professor, Pharmacology, IGPMER, Kolkata **3. Dr. Pooja Reddy**, Prof. & HOD, Pharmacology, SAIMS, Indore
12.00-12.30 pm	Safer use of medicines and vaccines in the AI age: Human insights in an automated PV world: **Dr. Peter Hjelmström,** Director/CEO, UMC, Sweden
12.30- 1.00 pm	Concluding Remarks: **Dr. Balakrishnan S.,** Prof. & Head of Pharmacology, AIIMS Bhopal
1.00-1.15	Discussion
1.15– 2.00pm **LT 5**	Valedictory Function followed by Prize Distribution
2.00pm	LUNCH

Poster and Paper Presentations	**Oral Paper Presentations** Day 2: 6 February 2025: 11.30am -12.30pm – Two Parallel Sessions -Skill Lab & CMET Hall 12.30 -1.30 pm - Two Parallel Sessions -Skill Lab & CMET Hall Day 3: 7 February 2025: 09.00 -10.00 am -Two Parallel Sessions -Skill Lab & CMET Hall
	Poster Presentations Day 2: 6 February 2025: 10 am -1pm, 2pm - 5 pm Day 3: 7 February 2025: 10 am -1 pm
SoPICON 2025 Pharmacovigilance Quiz Preliminary Round	Day 2: 6 February 2025: 12.00 to 1.00 pm

Our Distinguished Speakers

International Speakers

Dr. Shanthi Pal

Team Lead, Pharmacovigilance, regulation and prequalification WHO,
Geneva, Switzerland

Dr. Shanthi Pal is currently the Lead of the Pharmacovigilance Team within the Regulation and Safety division at the WHO in Geneva. A pharmacist with a PhD in Pharmacology, she has been with the WHO since 2001. Notable accomplishments include developing a risk-based "Smart" strategy to enhance Pharmacovigilance in resource-limited settings, along with creating relevant guidelines and activities. Dr. Pal represents the WHO in several international forums, such as the Council of International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonization (ICH) of pharmaceutical standards. She has also served as a member of the Governing Board of the Uppsala Monitoring Centre (UMC)

Dr. Peter Hjelmström

Director/CEO,
Uppsala Monitoring Centre,
Sweden

Dr. Peter Hjelmström, is the Director of the Uppsala Monitoring Centre (UMC), a World Health Organization (WHO) Collaborating Centre for International Drug Monitoring Programmes. He is a physician-scientist who earned both his MD and PhD from the Karolinska Institute and completed postdoctoral studies at Yale University.

Dr. Hjelmström has extensive experience in the medical field, having trained as an orthopaedic surgeon at Karolinska University Hospital and served as an associate professor. His career also includes 17 years in the pharmaceutical industry, with his most recent role before joining Uppsala Monitoring Centre in 2023 being the chief medical officer at a Swedish pharmaceutical company.

Throughout his career, Dr. Hjelmström has authored over 45 scientific papers, primarily in immunology, and has published research focusing on drug-related biology, particularly in the context of opioid dependence. His broad expertise in medicine, pharmaceuticals, and research underpins his leadership at Uppsala Monitoring Centre, where he continues to contribute to global drug safety and monitoring efforts.

Dr. Yvonne Y. Esseku

Rector, Ghana College of Pharmacists
PhD; MPhil; MGPS; PGCOSHEM; BL; LLB; B. Pharm
FGCPharm, FNSC-GH, FPSGH

Advanced Pharmacy Service and Pharmacovigilance

The practice of healthcare delivery has evolved over the years from supplying spices and herbs and applying poultices and herbal extracts to now moving towards individualized care practically all specializations of healthcare delivery. The practice of pharmacy has kept pace with this transformation. The practice has moved from supplying spices and herbs from one community to the next, through providing orders given on prescription to making direct inputs and interventions into patient and disease management at all levels.

Advanced pharmacy practice involves the application of specialized knowledge and skills to improve patient care and health outcomes (Pharmacy Council Ghana, 2025) in providing pharmaceutical service. Services provided in the advanced pharmacy practice include clinical pharmacy services, immunization services, medication therapy management, stewardship for medicines and other health products.

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other medicine or vaccine related problems (World Health Organisation, 2024). Effective PV thus requires an understanding of the pharmacological activity of vaccines and medicines, potential adverse effects and how they could be handled. In order to undertake PV effectively, particularly in specialized areas of healthcare delivery, there is a need to focus on acquiring specialized skills and providing advanced services.

Specialized skills may be obtained through many years of practice or through residency training programmes as provided by institutions that provide specialist training.

Dr Krishantha J. Wirasinghe

Senior Manager Compliance Quality Assurance
& Scientific Affairs, Hemas Pharmaceuticals &
Hemas Surgical & Diagnostics, Sri Lanka

In his presentation, he provided with an overview of the healthcare system in Sri Lanka, addressing both the private and public sectors.

The primary goal of the talk was to offer a comprehensive understanding of the pharmaceutical sector in Sri Lanka, focusing on how compliance and pharmacovigilance activities are integrated into regular business operations. I believe this will be beneficial for the potential businesses looking to expand their operations in Sri Lanka.

He gave an overview of the medicine importation process in Sri Lanka and explained the medicine regulation process.

The presentation continued by a discussion on the distribution of medicines across the island, targeting both private and public sector customers, and highlighting the role of local distributors in the logistics process.

Additionally, he outlined the functions and responsibilities of the National Medicines Regulatory Authority (NMRA), including its pharmacovigilance system. Lastly, the presentation concluded with an overview of the quality management system and how the principal manufacturer's requirements are met in compliance with pharmacovigilance standards.

Dr. Gurpreet Singh

Vice President & MD,
Integrated Safety at IQVIA, UK

Dr. Gurpreet Singh, is a distinguished professional currently serving as the Vice President and Managing Director of Integrated Safety at IQVIA, based in the United Kingdom. With a robust career spanning 20 years in the pharmaceutical industry, he has dedicated over 18 years to global drug development, contributing significantly to various high-impact projects and initiatives.

Throughout his career, Dr. Singh has collaborated with several leading global firms, including Cognizant, Tata Consultancy, Novartis, and Parexel. At Novartis, he held the pivotal role of Global Head of Pharmacovigilance Operations, where he oversaw all global pharmacovigilance activities, ensuring the highest standards of safety and compliance. His tenure at Parexel as Senior Director of Pharmacovigilance Operations involved managing crucial PV projects for top pharmaceutical and biotech companies, demonstrating his exceptional leadership and expertise in the field.

A certified Six Sigma and Project Management Professional, Dr. Singh has a keen interest in digital transformation and organizational culture. He has successfully led numerous projects that have driven innovation and efficiency within the pharmaceutical landscape. Beyond his professional pursuits, Dr. Gurpreet is an avid runner and frequently shares his insights as a speaker at various pharmaceutical conferences, inspiring others with his knowledge and experience in drug development and safety management.

Dr. Joan D'souza

Local Contact Person for
Pharmacovigilance (LCPPV),
Switzerland, Germany &
Liechtenstein

Dr. Joan D'Souza, is currently a Pharmacovigilance physician and consultant, working across the USA and Europe. In this role, she is responsible for safety narrative reviews, staying updated on local literature and regulatory changes, and serving as a local contact during audits. She has played a key role in the development of global Pharmacovigilance certification at the Institute of Pharmacovigilance in Europe and has contributed to the creation of training and certification materials for Switzerland.

Dr. D'Souza specializes in drafting critical scientific documents, including manuscripts, abstracts, and safety narratives, all in compliance with ICH guidelines, to support clinical trials and medical device documentation. Her expertise spans various therapeutic areas, including oncology, cardiovascular diseases, and autoimmune disorders, which has enriched her skills in drug and medical device safety.

Dr. D'Souza holds certifications from the PV Academy and EMWA, and has completed extensive training in project management and medical writing. She has also been an active participant in several high-profile conferences, such as the World Congress on Safe Drugs in Europe and the US, as well as the ISoP annual conferences in Italy and Indonesia.

National Speakers

Dr. Rabinarayan Acharya

Director general, Central Council for Research in Ayurvedic Sciences, Gujarat

Vaidya Rabinarayan Acharya is currently working as Director General of Central Council for Research in Ayurvedic Sciences (CCRAS) since March 2022. He was Professor of Dravyaguna (Ayurveda Pharmacology) at ITRA, Jamnagar where he has been a faculty since September 2007 to February 2022.
After his BSc (Botany Hons.) and Ayurveda Degree from Utkal University Odisha he obtained his MD and PhD from Gujarat Ayurveda University.
He is having more than 27 years of teaching and research experience in the various fields of drug research. Prof. Acharya has published more than 350 research articles in peer-reviewed indexed journals and authored five books, contributed 10 chapters to his credit.
He has served IGNOU as a course writer and WHO as a temporary advisor.
Dr. Acharya also provided his service to the Ministry of AYUSH, Govt of India, at different capacities such as Chairman, Ayurvedic Pharmacopoeia Committee, member ASUDTAB, member, SAG for drug development CCRAS, Member project screening committee of NMPB, Member Secretary National Pharmacovigilance programme for ASU drugs.
Prof Acharya has worked as principal investigator in more 10 research grant projects and under his guidance 35 Ph.D., 51 Post Graduate theses /dissertations in Dravyaguna, have been awarded.
Prof Acharya is the recipient of the Best teacher award and cash prize of Rs two lakh for Drug Research and the Best research paper award on literary research, in the field of Ayurveda from Ministry of Ayush, Govt of India.
He represented India in Nine different countries, in various capacity, including various WHO meetings such as herb-drug interaction at Beijing, Pharmacovigilance at Geneva and Research Methodology at Bhutan.

Dr. Vandana Roy

Prof. & HOD, Pharmacology, MAMC, New Delhi

Dr. Vandana Roy, is Director Professor & Head Department of Pharmacology at Maulana Azad Medical college & associated Hospitals, University of Delhi, an esteemed academic leader with over 30 years of experience in medical education, clinical pharmacology, public health, and drug policy. She has played a pivotal role in enhancing the safe and rational use of medicines, as well as advancing medical ethics. A FAIMER Fellow in Medical Education, he holds qualifications including MNAMS and FIMSA. Dr. Vandana Roy served as the former Dean of the Faculty of Medical Sciences at the University of Delhi, where she contributed significantly to the academic community.
Her professional experience extends to several key positions, including membership in the Signal Review Committee and the Core Training Panel for the Pharmacovigilance Programme of India (PVPI) under the Ministry of Health & Family Welfare. She has also led critical initiatives, serving as the Coordinator for the Adverse Drug Reaction Monitoring Centre at Maulana Azad Medical College and for the Regional Training Center of PVPI in Delhi NCR. Additionally, Dr. Roy has coordinated the National Antimicrobial Surveillance Program and contributed as an expert member of various national committees reviewing new drugs and health programs.
With more than 100 publications to his name, Dr. Vandana Roy has earned numerous accolades, including awards for Distinguished Service, Distinguished Teacher, and contributions to pharmacovigilance. She has also been recognized with the Jamshed Shroff Prize for Social Service and has led numerous research projects, further cementing her status as a respected figure in medical education and public health.

Dr. V. Kalaiselvan

Senior Principal Scientific Officer,
IPC, Ghaziabad

Dr. Vivekananda Kalaiselvan, is the Senior Principal Scientific Officer at the Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India, based in Ghaziabad. A pharmacist with a Ph.D. in Pharmaceutical Sciences, Dr. Kalaiselvan has been affiliated with IPC since 2009. His notable accomplishments include the successful implementation of the Pharmacovigilance Programme of India (PvPI) and the Materiovigilance Programme of India (MvPI), which have been rolled out nationwide. He is a representative of IPC at various national and international platforms, including the World Health Organization (WHO). Dr. Kalaiselvan has authored 11 chapters and published approximately 124 research and review articles in both national and international journals. He has also been honored with fellowships from the Department of Science and Technology (DST) and the All India Council for Technical Education (AICTE). His contributions to the field of pharmacovigilance extend globally, as he has been actively involved with the WHO in strengthening pharmacovigilance in low- and middle-income countries. In recognition of his significant contributions to pharmacovigilance, the WHO Headquarters in Geneva included him in their '50th Celebratory Album of the International Drug Monitoring Program.'

Dr. Jai Prakash

Senior Principal Scientific Officer &
Officer-in-Charge,
Indian Pharmacopoeia Commission,
Ghaziabad

Dr. Jai Prakash has done B. Pharm. and M. Pharm. (Pharmacology) from College of Pharmacy (now Delhi Institute of Pharmaceutical Sciences and Research, New Delhi, India) and Doctorate from the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi, India. At present, he is Senior Principal Scientific Officer and Officer-in-Charge, National Coordination Centre for Pharmacovigilance Programme of India at Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Govt. of India, Ghaziabad. He was also the Secretary-cum-Scientific Director, IPC. He has overall more than 20 years of experience in the area of teaching, research, pharmacovigilance, pharmacopoeia and formulary science. He was temporary advisor /expert for WHO's Expert Committees, Geneva, Switzerland. He was the member of Institutional Human Ethics Committee, National Institute of Biologicals, Noida, member of Core Group/Expert Committee for Revision of National List of Essential Medicines, 2011, 2015, 2022, member of CDSCO Expert Committee on Draize Test. member of National Expert Committee for Allergens and member of International Society of Pharmacovigilance. He is also the member of Multidisciplinary Expert Committee of National Pharmaceutical Pricing Authority, New Delhi. He has made several presentations in National and International conferences. He has many national and international publications and book chapters to his credit. Prior to joining as Senior Principal Scientific Officer, he served as Principal Scientific Officer and Senior Scientific Officer in IPC, Senior Scientific Officer Grade I (Pharmacology) in Central Indian Pharmacopoeia Laboratory (CIPL), Lecturer under the Directorate of Training and Technical Education, Govt. of Delhi etc. He has several publications to his credit in books (16 chapters), national and international journals of repute (23 national and 18 international publications). He is the recipient of Ms Geeta Mittal Medal for Basic Research in the field of Oncology for being the best postgraduate at AIIMS, Servicer Young Investigator's Award and Certificate of Merit in M. Pharm.

Dr. Shoibal Mukherjee

Consultant in Pharmaceutical Medicine & Drug Development, Director, Medical Research, Medanta Hospitals

Dr Shoibal Mukherjee has postgraduate qualifications in Medicine and Pharmacology, with over 30 years of experience in drug development and pharmaceutical medicine. He has headed medical and research departments in Pfizer India, Ranbaxy Laboratories, GVK Biosciences and Quintiles Asia. He is a founder and was first President of Indian Society for Clinical Research. He has been guest faculty for training and doctoral programs at leading medical institutions in India and is a member of research advisory boards and technical committees of various private and public sector organizations and institutions. He has been associated with the development of research regulations in India and is a recipient of the ISCR Lifetime Achievement Award, the NAPT Lifetime Achievement Award, and the Global Fellow in Medicines Development Award by the GMDP Academy, New York. He currently leads research initiatives at the Medanta group of hospitals and serves as an advisor and faculty to start-up research organizations and training institutions in India and abroad.

Dr. S.P. Dhaneria

Prof. & HOD Pharmacology, RG Gardi Medical College, Ujjain

Dr. Suryaprakash Dhaneria is a seasoned academician and medical professional with over 40 years of experience in the field of pharmacology. He holds multiple advanced degrees, including an M.D. in Pharmacology, D.M. and D.N.B. in Clinical Pharmacology & Therapeutics, an M.Sc. in Biochemistry, and an LL.B. (Hons). Dr. Dhaneria is also a Member of the National Academy of Medical Sciences (MNAMS) and is registered with the MP Medical Council under registration number 4184 since 1982.

Currently, he serves as the Professor and Head of the Department of Pharmacology, as well as the Dean (Academics) at R.D. Gardi Medical College in Ujjain, Madhya Pradesh. Prior to his current role, Dr. Dhaneria contributed significantly to the academic and clinical training at various prestigious institutions, including M.G.M. Medical College in Indore, PGIMER Chandigarh, ACPM Medical College in Dhule, and All India Institute of Medical Sciences (AIIMS) in Raipur, among others. His teaching career spans multiple medical colleges, with notable service at R.D. Gardi Medical College, where he has been a faculty member for over 12 years.

Dr. Dhaneria has published numerous papers and articles in both national and international journals and has shared his expertise on clinical pharmacology as a guest speaker at various conferences, workshops, and CMEs. He has also conducted several Clinical Pharmacology training courses. A strong advocate for rationalizing the use of medicines, Dr. Dhaneria remains committed to advancing medical science and promoting evidence-based practices in clinical settings for the betterment of society.

Dr. S. Ziaur Rahman

Prof. & HOD, Pharmacology, AMU, Aligarh

Dr. Syed Ziaur Rahman, is a Professor and Chairman of the Department of Pharmacology at Jawaharlal Nehru Medical College, Aligarh Muslim University (AMU), Aligarh. He holds an MBBS and MD from AMU and a PhD from the School of Medicine, Western Sydney University, Australia. He is the co-founder of the Ibn Sina Academy, recognized as a "Centre of Excellence" by the Ministry of AYUSH. Dr. Rahman has significantly contributed to the academy's library, adding numerous books and journals on Pharmacology and establishing the 'Centre for Advanced Study in Pharmacology.' The academy's library is the only one from India listed in the Directory of History of Medicine Collections by the US Department of Health and Human Services.
With over 200 publications in national and international journals, Dr. Rahman has also handled seven academic projects and delivered over 200 guest lectures. His work in Pharmacovigilance includes reporting multiple ADR cases and pioneering the concept of Environmental Pharmacovigilance. He coined the term "Pharmacoenvironmentology" to study the environmental impact of therapeutic drugs.

Additionally, Dr. Rahman has conducted significant research on morphine de-addiction using medicinal plants, including Delphinium denudatum and Myristica fragrans. He has received numerous awards, including fellowships from several national and international academies, in recognition of his contributions to the field of pharmacology. While working on morphine de-addiction properties of medicinal plants, proposed a modified method for moderately and severely induced morphine dependent rats, and extensively screened Delphinium denudatum and Myristica fragrans for its protective activity in morphine induced physical dependence.

Recipient of various awards including the fellowship of few national and international academies.

Dr. Avijit Hazra

Professor, Pharmacology, IGPMER, Kolkata

Dr. Avijit Hazra is a distinguished academic and medical professional with extensive experience in pharmacology and medical education. He earned his MBBS degree from the University of Calcutta in 1992 and secured 1st rank in his MD Pharmacology from the University of Bombay in 1997. Currently, Dr. Hazra serves as the Dean of Student Affairs at IPGME&R, Kolkata, overseeing administrative functions related to student admissions, activities, examinations, and class scheduling. He is also a Professor in the Department of Pharmacology, teaching undergraduate and postgraduate medical students and guiding research projects across various disciplines.

In addition to his teaching responsibilities, Dr. Hazra is deeply involved in clinical trials at IPGME & R, collaborating with multiple departments. He holds leadership roles as the Member Secretary of the Institutional Ethics Committee (IEC) at IPGME&R and SSKM Hospital and as Chairperson for several other IECs in Kolkata. His contributions extend to being a GCP trainer for the Government of West Bengal and a former member of the Curriculum Committee in Pharmacology at the National Medical Commission.

Dr. Hazra has authored over 230 peer-reviewed publications and contributed to 18 academic books. His research interests include randomized controlled trials in various medical fields and adverse drug reaction monitoring. A recipient of prestigious awards such as the Ram Nath Chopra Oration Award (2016) and the Fellowship of the Indian Pharmacological Society (2024), Dr. Hazra continues to influence the medical community both as a researcher and educator.

Prof (Dr) Tirthankar Deb

Professor, Pharmacology,
IGPMER, Kolkata

Prof (Dr) Tirthankar Deb is the Professor & Head, Pharmacology at AIIMS Kalyani
He is the Coordinator, Experts committee for guidelines on professional responsibilities of medical students, National Medical Commission (NMC)

•Has 25 publications, 1 patent, 1 copyright and 2 Grants

•Innovations:

- Deb's active surveillance & assisted reporting system of adverse drug reaction monitoring (Indian Copyright)
- Community Pharmacology

•Course initiation: Course on Patient Safety & Rational Pharmacotherapy (compulsory induction for resident doctors at AIIMS Kalyani)

•Invited talk in several universities: Integrated Medicine, One health & spirituality, Yoga & spirituality: modern medical perspective

---

Dr. Nirmala N. Rege

Professor, Pharmacology,
IGPMER, Kolkata

Dr. Nirmala N. Rege is a Professor in Pharmacology at Era's Lucknow Medical College. She completed her graduation and MD in Pharmacology from the Seth GS Medical College & KEM Hospital and secured DNB in Clinical Pharmacology. Subsequently she was awarded PhD from University of Mumbai. She served her alma mater as faculty in Pharmacology department and superannuated as Professor and Head of Department of Pharmacology and Therapeutics. She has continued her association with the same department as Professor Emeritus since December 2018.

Dr Rege was a coordinator of Medical Education Unit of KEM hospital, Convenor of MCI Regional Centre for Faculty Development and Co-Director of Regional institute of FAIMER (Foundation of Advances in Medical Education and Research, USA). She has contributed to designing of undergraduate and postgraduate pharmacology curricula, participated in research in medical education and is instrumental in organizing the national level workshop for postgraduates of pharmacology-PHARMATECH. Currently she is a faculty of Maharashtra University of Health Sciences for the Advanced Research Methodology workshops.

She is a member of Expert group instituted by National Medical Commission's UG Medical Education Board. She is a Head, Academics of National Association of Pharmacology & Therapeutics; Vice-President, AHAHPER; Past–President and Advisor, South Asian College an affiliate of the American College of Clinical Pharmacology (SAC- ACCP) and past-President and current trustee of Academy of Health Professions Educators. She was also a co-opted member of task force for the online prescribing skills course developed by ICMR to enhance Prescribing Skills of an Indian Medical Graduate.

She has been a principal investigator for projects sponsored by Dept. of AYUSH; NMITLI, CSIR; DST and ICMR and co-investigator for projects by Dept. of Biotechnology and ICMR. She is a recipient of more than 40 awards for her research in the field of pharmacology and Ayurveda. She has to her credit 125 research papers on experimental & clinical pharmacology, Ayurveda and medicinal plants and medical education in National & International journals, 22 chapters in the books and 2 textbooks viz. Satoskar-Bhandarkar's 'Pharmacology and Pharmacotherapeutics' (27th edition released in 2024) and 'Practical Pharmacology for Medical Students'. She is also a co-editor of 'The Art of Teaching Medical Students' and 'SLOs in Pharmacology' and 'Clinical and Procedural skills. A Step by Step Approach'. She is also an editorial board member of 'Medical education Research. Theory, Practice, Publication and Scholarship'.

Dr. Vijay Motghare

Prof.& HOD, Pharmacology, GMC, Nagpur

Dr. Vijay M. Motghare is a seasoned academician and researcher, who previously served as the Professor and Head of the Department of Pharmacology at Government Medical College, Nagpur. With a wealth of experience in pharmacology, he has contributed significantly to the field, including serving as a Co-Investigator for a World Health Organization (WHO) Multicenter Clinical Trial.

Dr. Motghare has held important positions such as a Member of the Drug Approval Committee at the FDA New Delhi and as a Member of the Standing National Committee on Medicine under ICMR-DHR, New Delhi. He has also been a part of the Subject Expert Committee at CDSCO, DGHS, MoHFW, New Delhi, and the Drugs Technical Advisory Board, G.O.I.

Currently, he is the President of the Indian Society for Rational Pharmacotherapeutics (ISRPT) and has previously chaired the Institutional Animal Ethics Committee for both Small and Large Animals. Dr. Motghare was also the Vice President and Executive Member of the Indian Pharmacological Society and the Founder Secretary of its Vidarbha Branch. He has served as a Member of the Institutional Animal Ethics Committees at several prestigious institutions, including GMC Nagpur, IGGMC Nagpur, AIIMS Raipur, and Government Dental College Nagpur.
An active researcher, Dr. Motghare has published over 130 papers in national and international journals, further demonstrating his commitment to advancing pharmacological science.

Dr. Vikas Mehrotra

Pediatric Endocrinologist, KMCCC, Aligarh

Dr. Vikas Mehrotra is an esteemed Medical Director and Consultant Pediatric Endocrinologist with a strong commitment to improving the lives of children suffering from endocrine disorders, particularly Type 1 Diabetes Mellitus (T1DM) and Celiac Disease. Currently serving as the Medical Director & Consultant Pediatric Intensivist at Kilkari Hospital, Aligarh, he is also the founder of the Kilkari Foundation, which provides a 24-hour helpline and support for children with T1DM.

With an impressive academic background, Dr. Mehrotra earned his M.B.B.S. as a Gold Medalist from Jawaharlal Nehru Medical College (JNMC) in 1995, followed by an M.D. in Pediatrics in 1999. His additional qualifications include a Fellowship in Pediatric Endocrinology and certifications in Pediatric and Neonatal Intensive Care, as well as Pediatric Advanced Life Support (PALS).

Dr. Mehrotra is deeply involved in medical education and community support. He organizes specialized clinics for T1DM and Celiac Disease, conducts Insulin Pump therapy classes, and leads Kilkari BUDY, a support group for children with T1DM. As a recognized leader, he holds prominent positions, including President of IAP Aligarh (2024) and Joint Secretary of IAP UP (2024). He is also the Editor of the IMA Aligarh journal.

An active contributor to medical research and education, Dr. Mehrotra has presented over 20 publications in journals and organized workshops on insulin pumps and Continuous Glucose Monitoring Systems (CGMS). His dedication to pediatric endocrinology has earned him numerous honors, underscoring his significant contributions to the field.

Dr. Shambo Samrat Samajdar

Clinical Pharmacologist, diabetologist & General Physician, Calcutta School of Tropical Medicine, Kolkata,

Dr. Shambo Samrat holds an MBBS, MD, and DM in Clinical Pharmacology, and has been awarded a Gold Medal in his DM program. He has completed a Postgraduate Diploma in Endocrinology & Diabetes (RCP, UK) and a Fellowship in Respiratory and Critical Care (WBUHS). Additionally, he holds a Diploma in Allergy, Asthma, and Immunology, also with a Gold Medal.

Dr. Samrat has authored 122 articles published in indexed medical journals and contributed extensively to the field with key publications, including Competency-Based Practical Pharmacology, Diabetes in Practice, ICP Monograph on Rational Prescribing Practices in the Elderly, Foundations of Allergy Practice, and Artificial Intelligence for Physicians. He has also written over 60 book chapters in national and international publications.

He is a Fellow of the Indian Pharmacological Society (FIPS) and Diabetes India. His achievements have been widely recognized, with accolades such as the Indian Academy of Diabetes Innovation Award (2022), Dr. JC Patel and BC Mehta Best Paper Award (JAPI 2021), the 2024 WIDF Innovator Award (Mayo Clinic), the CDRI Oration IPS 2024, RSSDI Innovation Award 2024, and the Governor's Recognition for ACP India Chapter in Research & Publication (2024). In addition, he has received the MPS Promising Young MD Pharmacologist Award (2024) and the Young Scholar Award (Indian Academy of Geriatrics, 2024).

Dr. Niket Rai

Professor and Head,
Department of Pharmacology at LNMC, Bhopal

Dr. Prof. (Dr.) Niket Rai is a distinguished academician and researcher, currently serving as the Professor and Head of the Department of Pharmacology at LNMC, Bhopal, MP, India. He completed his MBBS and MD in Pharmacology from MGM Medical College, Indore, MP, India. Dr. Rai has gained valuable experience working at renowned institutions such as All India Institute of Medical Sciences Bhopal and Maulana Azad Medical College, New Delhi, where he was mentored by leading experts in the field.

He holds certifications in rational therapeutics for managing chronic diseases, including diabetes, hypertension, thyroid disorders, pain management, palliative care, and lifestyle diseases. Dr. Rai is a strong advocate for Pharmacovigilance and Pharmaco-ecovigilance, emphasizing the importance of medication safety and environmentally responsible drug disposal. His contributions to these areas aim to improve patient care and promote sustainable healthcare practices.

Dr. Sanjeev Sharma

Senior Consultant, Clinical Pharmacology, Indraprastha Apollo Hospital, New Delhi

Dr. Sanjeev Sharma is a highly skilled and versatile professional with over 19 years of experience in medication management, research, and administration. He has made significant contributions across multiple functions at Apollo Hospitals, where he currently serves as a Clinical Pharmacologist and Coordinator for the Pharmacovigilance & Materiovigilance Center. Dr. Sharma holds a Doctor of Medicine (Pharmacology) and an MBBS degree, along with a Fellowship in Infectious Disease. He is also certified with a Six Sigma Green Belt and is an active member of the American College of Clinical Pharmacology and the Medication Safety Officer Society.

Dr. Sharma has demonstrated exceptional leadership and decision-making capabilities, efficiently managing multiple responsibilities. He was instrumental in establishing Medication Management teams at five Apollo Group hospitals and has played a key role in leading medication management efforts during 10 Joint Commission International inspections and 9 NABH inspections. Additionally, he serves as an Internal Assessor for Apollo Hospitals, evaluating Medication Management processes and overseeing Ethics Committee inspections for clinical trials.

A recognized expert in his field, Dr. Sharma has been a panelist and speaker at numerous national and international conferences and continuing medical education (CME) events. He has contributed to the academic community with 19 publications in reputed journals and six book chapters, further establishing his expertise in medication safety and management.

Dr. Ashish Kakkar

Additional Professor, Pharmacology, PGIMER, Chandigarh

Dr. Ashish Kakkar, MD, DM in Clinical Pharmacology, is an esteemed Additional Professor in the Department of Pharmacology at PGIMER, Chandigarh.
With a wealth of expertise in medical research and academia, he plays several pivotal roles in his field. Dr. Kakkar is the Member Secretary for the Institute Ethics Committee (Extramural) and the IEC Sub-committee for Serious Adverse Events at PGIMER.
He also serves as Associate Editor for notable journals such as Frontiers in Medicine and the Indian Journal of Physiology and Pharmacology.
In addition, Dr. Kakkar is the Joint Director of Research at the Society of Antimicrobial Stewardship Practices (SASPI), where he leads efforts to encourage the responsible use of antimicrobials. As a Principal Investigator, he directs multiple research projects funded by respected bodies like the Indian Council of Medical Research and the Department of Science and Technology (DST). His research primarily revolves around clinical pharmacology, with a focus on improving medical practices and ensuring research ethics are upheld.
Dr. Kakkar's contributions have significantly advanced clinical and pharmacological research, particularly in the areas of drug safety, clinical trials, infectious diseases, and neuropharmacology.

Dr. Ankita Srivastava

Associate Professor,
Department of Dermatology,
AIIMS Nagpur

Dr. Ankita Srivastava, is an Associate Professor in the Department of Dermatology, Venereology, and Leprology at AIIMS, Nagpur. She also serves as a member of the Causality Assessment Committee at the ADR Monitoring Centre at AIIMS Nagpur. Prior to this, she held the position of Deputy Coordinator for the ADR Monitoring Centre at JNUIMSRC in Jaipur. In 2024, Dr. Srivastava enhanced her expertise by attending advanced pharmacovigilance training at BJ Medical College, Ahmedabad.

An active professional, Dr. Srivastava is a clinician, educator, and researcher with a strong focus on dermatology. She has authored nearly 50 research articles published in PubMed-indexed journals. From 2020 to 2022, she was the State-level Quizmaster for the IADVL GSK National Quiz Program for Postgraduates. Additionally, she served as a National Faculty member at ACSICON 2023. Dr. Srivastava's accomplishments include winning the first prize in the award paper session at DERMAZONE WEST 2015 and the second prize at CLINICON 2017. She also achieved second place in the national IPCA Aesthetics Quiz in 2014.

She has completed the Basic Course in Biomedical Research by ICMR-NIE. Dr. Srivastava's areas of expertise include clinical dermatology, adverse drug reactions, skin involvement in systemic diseases, and emergency dermatology. Her dedication to both patient care and dermatological education is evident in her work, and she is committed to advancing the field through research and teaching.

Our Eminent Chairpersons

Prof K. C. Singhal

Patron, SoPI

Professor Krishna Chandra Singhal, Patron of the Society of Pharmacovigilance India and former Vice Chancellor of NIMS University, Jaipur, India.
Dr. Singhal's primary research interests include Pharmacovigilance, Clinical Pharmacology, and Chemotherapy. He developed a novel method for screening potential anti-filarial agents using Setaria cervi as a test organism. Dr. Singhal served as Professor and Chairman of the Department of Pharmacology at Jawahar Lal Nehru Medical College, AMU Aligarh, before becoming Vice Chancellor of NIMS University Jaipur in February 2008, where he held the position until May 31, 2015.
He has held significant leadership roles within several scientific organizations, including serving as President (1994) and Treasurer (1982-1984) of the Indian Pharmacological Society, President (1999), General Secretary (1994-1998), and Treasurer (1982-1993) of the Indian Academy of Neurosciences, and President and Chief Editor of the Indian Journal of Pharmacology (1989-1991). Dr. Singhal has also been an Editor for the Indian Journal of Physiology and Pharmacology, Vice President of the Indian Society of Hypertension, and President of the Society of Pharmacovigilance, India (2000-2005). He has contributed as a Consultant in Clinical Pharmacology for the committee on Essential Drug Categorization and continues to serve as the patron of the Society of Pharmacovigilance, India. Additionally, he is a member of the advisory committee for the National Pharmacovigilance Programme and the apex committee on Pharmacovigilance for Ayurveda, Unani, and Siddha medicines under the Indian Medical Association.
Dr. Singhal has played a pivotal role in organizing several prestigious conferences, including the National Conferences of the Indian Academy of Neurosciences, the Association of Physiologists and Pharmacologists of India, and the Association of Gerontology of India. He also served as the President of the organizing committee for the 2016 International Society of Pharmacovigilance (ISOP) and Society of Pharmacovigilance India (SOPI) conference held in Agra. Dr. Singhal coordinated a multi-centric Indian Council of Medical Research (ICMR) task force focused on the epidemiology and factors influencing adverse drug reactions (ADR) in India and led the WHO Special Centre for ADR Monitoring in India. His involvement in teaching methodology workshops, including those in Russia and the Indo-US Problem Based Learning workshop, further highlights his academic engagement. With over 200 research publications and more than 205 presentations at national and international conferences, Dr. Singhal is recognized for his contributions to medical sciences.
He is a founder fellow of multiple prominent organizations, including the Indian Medical Association Academy of Medical Specialities, the Indian Pharmacological Society, and the Indian Academy of Neurosciences. Additionally, Dr. Singhal served as a consultant for the WHO's Centre for International Drug Monitoring in Sweden for eight years. His accolades include the Lifetime Achievement Award from the Association of Physiologists and Pharmacologists of India (1994) and Aligarh Muslim University (2023), among numerous other awards. He has held prestigious roles, such as visiting professor at the University of Tennessee at Memphis and has been an invited speaker at various global conferences.

Dr. Umesh Shukla

Principal & CEO, Pt. Khushilal Sharma Govt. Ayurveda College, Bhopal

Dr. Umesh Shukla, is the Principal and CEO of Pt. Khushilal Sharma Government Ayurveda College & Institute in Bhopal. He earned his BAMS degree in 1988, ranking first in his university, followed by an MD in Kayachikitsa from Gujarat Ayurveda University in 1993, and a Ph.D. in 2006. Over his 30-year career, Dr. Shukla has contributed significantly to both education and research in Ayurveda. He has been actively involved in teaching at the undergraduate and postgraduate levels for over two decades, and his research projects include studies on conditions such as Parkinson's disease, viral hepatitis, and the management of diabetes and COVID-19. He has received several awards, including a gold medal from APS University and the prestigious "Dhanwantari Award" in 2006. His research initiatives, particularly on Ayurvedic approaches to chronic diseases, have been funded by the Indian government and state authorities. Dr. Shukla has guided numerous MD theses and Ph.D. dissertations and is currently supervising multiple Ph.D. scholars.
In addition to his academic roles, he has held various administrative positions, such as the head of departments, hospital superintendent, and chairman of several task forces, including COVID-19-related committees. Dr. Shukla has contributed to the development of educational frameworks in Ayurveda and served on various committees aimed at policy development and standardization in Ayurvedic practices. He has also authored several publications and is an active member of multiple professional boards and councils in India.

Prof. Abdul Latif

Professor, Aligarh Muslim University, Life member of SoPI

Prof. Abdul Latif, is a distinguished academician and researcher, formerly serving as the Chairman of the Department of Ilmul Advia (Unani Pharmacology & Pharmaceutical Sciences) at Ajmal Khan Tibbiya College, Aligarh Muslim University. He holds the position of honorary editor for the International Journal of Pharmacognosy & Chinese Medicine and is the Joint Secretary of the Ibn Sina Academy of Medieval Medicine & Sciences in Aligarh.

Additionally, he is a member of the Advisory Board of the Centre for Incubation and Entrepreneurship Development (CIED) at Integral University, Lucknow, and serves on the Advisory Board of the Centre for Innovation Incubation and Entrepreneurship (CIIE) at Jamia Hamdard, New Delhi. Prof. Latif is also part of the Pharmacopoeia's Subcommittee, appointed through a Gazette Notification by the Ministry of AYUSH, Government of India.

An accomplished researcher, Prof. Latif has published nearly 80 papers in national and international journals. His work spans a range of significant fields, including pharmacovigilance, pharmacology of Unani drugs, Latif-Sukul Syndrome, melanonychia, standardization, microbiology of herbal drugs, and the development of an instrument for treating skin diseases. He is also affiliated with several professional societies, including the Royal Society of Health (M.R.S.H.) in London, the Pharmacological Society of India, the Society of Pharmacovigilance India (SoPI), and the Ibn Sina Academy of Medieval Medicine and Sciences, where he is a life member.

Dr. Reeta Kh

Professor, Pharmacology, AIIMS, New Delhi

Dr. K.H. Reeta is a distinguished Professor in the Department of Pharmacology at All India Institute of Medical Sciences (AIIMS), New Delhi, with a keen interest in neuropharmacology and clinical pharmacology. She is a Fellow of the National Academy of Medical Sciences, India (FAMS), and a Fellow of the Indian Pharmacological Society (FIPS). Dr. Reeta has been honored with several prestigious awards, including the AIIMS Research Excellence Award in 2016 and 2024, the Shakuntala Amir Chand Award from ICMR in 2013, and the CL Malhotra Prize from the APPI in 2006. She was also recognized for her exceptional presentation skills with the Best Oral Paper Award at the 3rd North Zone Conference of IPS in New Delhi (2005).

A top performer during her academic career, Dr. Reeta secured the first position and honors in all professional MBBS examinations and was awarded the Kamala Devi Patni Charitable Gold Medal for being the Best Graduate of the Institute in 1994.

Dr. Reeta has significantly contributed to pharmacology research, with 68 published articles, six books or book chapters, and more than 125 published abstracts. She has managed over 25 research projects as the principal or co-investigator and has been actively involved in organizing more than 25 workshops and symposia, serving as Organizing Secretary, Joint Organizing Secretary, or a member of the organizing committee.

Since October 2023, Dr. Reeta has been serving as the Associate Editor of Frontiers in Pharmacology and was also the Associate Editor for the Indian Journal of Physiology & Pharmacology from 2009 to 2012, further underscoring her leadership in the field.

Dr Nitin Kothari

Professor & Head,
Department of Pharmacology
Government Medical College & Hospital
Dungarpur, Rajasthan.

Dr. Nitin Kothari is a highly accomplished Professor and Head of the Department at Government Medical College, Dungarpur, Rajasthan. With an MBBS, MD, DNB, and MNAMS, along with the ACME certification, Dr. Kothari has demonstrated exceptional expertise in the field of medicine and pharmacology. He is also the Medical Education Unit (MEU) Coordinator at his institute, contributing significantly to medical education and curriculum development.

Dr. Kothari has an impressive academic and research background, having published over 25 research articles in well-regarded national and international journals. He actively reviews for several prestigious journals, further emphasizing his expertise and commitment to advancing medical knowledge. In addition, he serves as an examiner for various undergraduate and postgraduate examinations across multiple universities.

He is deeply involved in pharmacovigilance at his institution, helping to ensure the safe use of medications and contributing to the overall healthcare quality. Dr. Kothari has also been invited as a speaker at numerous conferences, sharing his knowledge and insights with peers and professionals in the field. His work continues to make a significant impact on medical education, research, and patient safety.

Major Dr. V.K. Yadav

Professor & Head,
Department of Pharmacology
PCMS & RC, Bhopal

Maj.Dr. V.K. Yadav, MD, MBBS (1989), MD (Pharmacology) from GMC Bhopal, is a distinguished professional with over 24 years of experience in teaching and research. He is currently serving as the Professor and Head of the Department of Pharmacology at PCMS & RC, where he also holds the position of Vice Dean. Dr. Yadav has extensive experience in guiding MD and PhD scholars in their academic pursuits.

He has contributed significantly to the field with more than 30 national and international publications. In addition, Dr. Yadav is an active member of the Institutional Ethics Committee (IEC) at his own institute, as well as at LN Medical College and Jawaharlal Nehru Cancer Hospital in Bhopal.

His areas of interest include Medical Ethics, Psychopharmacology, and Pharmacovigilance. Dr. Yadav also has a background as an ex-RMO in the Indian Armed Forces.

Dr. Rekha Mehani

Professor
PCMS & RC
Bhopal

Dr. Rekha Mehani, is currently serving as a Professor at People's College of Medical Sciences & Research Centre in Bhopal. She completed her MBBS at RDVV Jabalpur and her MD in Pharmacology from Barkatullah University, Bhopal.

Dr Yogendra Narayanrao Keche

Professor, Pharmacology
AIIMS, Raipur

Dr. Yogendra Narayanrao Keche, is a Professor in the Department of Pharmacology at AIIMS Raipur. He holds an MBBS and an MD in Pharmacology from IGGMC Nagpur, completed in 2006. With over 18 years of experience in teaching and research following his MD, Dr. Keche has also served as the former Member Secretary of the Institutional Ethics Committee at AIIMS Raipur.

Throughout his career, he has delivered around 50 guest lectures at various training sessions and workshops. His primary areas of interest include pharmacovigilance, geriatric pharmacology, therapeutic drug monitoring, clinical trial ethics, regulatory affairs, and pharmacogenomics.

Dr. Keche has made significant contributions to the field, having published 34 research articles in both national and international journals. His research spans topics such as rational prescription practices, self-medication, clinical trials, diabetes, geriatrics, and drug interactions. Additionally, he has presented 12 research papers at national and international conferences, further establishing his expertise in pharmacology.

Dr. Pooja Gupta

Additional Professor,
Pharmacology
AIIMS, Raipur

Dr. Pooja Gupta, is an Additional Professor of Pharmacology at All India Institute of Medical Sciences, New Delhi, where she also serves as the Coordinator for the AIIMS Pharmacovigilance Programme of India / Materiovigilance Programme of India center and the Member Secretary for the Institute Ethics Subcommittee for SAE in Clinical Trials. She holds an MBBS degree from LHMC, an MD from MAMC, and a DM from AIIMS, Delhi. With over 15 years of experience in teaching and research, Dr. Pooja has contributed significantly to national health initiatives, including the National List of Essential Medicines (NLEM), the National Formulary of India (NFI), and the Pharmacovigilance Programme of India (PvPI).
Her research interests span clinical pharmacology, regulatory pharmacology, pharmacovigilance, and oncopharmacology. Dr. Pooja has published extensively in national and international journals and has been actively involved in shaping the guidelines and standards that influence healthcare practices in India.

Dr. Tanu Garg

Professor,
Head of the Department of
Pharmacology,
Mahaveer Institute of Medical Sciences
& Research, Bhopal

Dr. Tanu Garg is a Professor and Head of the Department of Pharmacology at Mahaveer Institute of Medical Sciences & Research, Bhopal. She completed her MBBS from MGM Medical College, Indore, and later earned her MD in Pharmacology from People's College of Medical Sciences & RC, Bhopal.

Dr. Murali M

Additional Professor,
Translational Medicine
AIIMS, Bhopal

Dr. Murali M is an Additional Professor in the Department of Translational Medicine, AIIMS, Bhopal. He has received his Ph.D. Degree from Neurosciences Centre, All India Institute of Medical Sciences, New Delhi, India and done his Postdoctoral Research fellowship from Centre for Pharmacogenomics and Precision Medicine, University of Florida, Gainesville, USA, Pharmacotherapeutics Unit, Department of Medicine, University of Putra, Malaysia and Translational Research , Department of Pharmacy Practice , MAHE, Manipal.

His work focussed on the Pharmacogenomics studies typically using genotyping and Genome Wide Association Screening to understand the impact of genetic variation on drug metabolism, drug efficacy, and adverse drug effects. His Research Utilizes state of the art genomic measures on inter-patient variability in drug response and translation of pharmacogenomics into clinical practice.

Dr Sneha Ambwani

Professor & HOD, Pharmacology, AIIMS Jodhpur

Dr. Sneha R. Ambwani, an experienced academician and researcher, serves as the Professor and Head of Pharmacology at AIIMS, Jodhpur. With over 30 years of experience in teaching and clinical research, she has made significant contributions to the field of pharmacology. Her work has earned her numerous prestigious awards, including the Spotlight Award from the National Association of Pharmacology & Therapeutics in 2022, the Bharat Vikas Award in 2018, and the Best Paper Award from the Indian Pharmacological Society in 2000. In recognition of her dedication and exceptional performance, she was also awarded a Certificate of Appreciation by Principal Dr. S. N. Medical College, Jodhpur, in 2013.

Dr. Ambwani is an active researcher with nearly 90 publications in both national and international journals. She also serves as a reviewer for several prominent journals in the field. Additionally, she has authored the book Review of Pharmacology (2012).

Her leadership extends to her role as the Vice President of the National Association of Pharmacology & Therapeutics (NPT) and as a member of various prestigious academic societies. Dr. Ambwani is currently the chair of the Animal Ethical Committee at AIIMS, Jodhpur, and the Institutional Ethics Committee (IEC) of IIT Jodhpur.

She has delivered numerous plenary lectures on topics such as Good Clinical Practice, Rational Use of Drugs, Research Methodology, and Medical Education. Dr. Ambwani is also deeply involved in multiple funded research projects, continuing to shape the future of pharmacology education and practice.

Dr. Pooja Reddy

Professor, Pharmacology, SAMC & PGI, Indore

Dr. Pooja Reddy is a distinguished Professor in the Department of Pharmacology at SAMC & PGI, Indore, with over 16 years of teaching experience. She currently serves as the Head of the Clinical Pharmacology Unit at the same institution. In addition to her academic roles, Dr. Reddy is a resource faculty member at the Regional Centre of the Medical Education Unit at SAMC & PGI, Indore. She also holds leadership positions as the Coordinator for both the NABH and SAIMS, as well as the MDMC at MvPI, Indore.

Dr. Reddy has further honed her expertise by completing an advanced course in Medical Education in September 2015 and is currently pursuing a PhD in Medical Education to further her academic pursuits. She has been actively involved in organizing notable conferences, including the 13th Annual Conference of ISRPT in November 2021, the 8th Workshop of the Indian Pharmacological Society on GCP, NDCT-2019, and Clinical Research in June 2022. Additionally, she served as the Organizing Secretary for the 8th National Conference of IMLEA in December 2022.

Dr. Reddy has made valuable contributions to medical literature, with multiple publications in both national and international journals. She is a life member of several prestigious professional bodies, including the Indian Pharmacological Society (IPS), Indian Medical Association (IMA), Indian Society for Rational Pharmacological Therapy (ISRPT), and the National Medical Pharmacology Teaching (NMPT) group. Her dedication to pharmacology and medical education continues to influence the field significantly.

Our Eminent Chairpersons

Dr. Arun Shrivastav

Director of Medical Education, Bhopal, Ex-Dean, GMC, Bhopal

Dr. Arun Kumar Shrivastav, MD, Ph.D., LLB, currently serves as the Director of Medical Education in Bhopal. Previously, he held the position of Dean at Gandhi Medical College, Bhopal, M.P., and served as the Superintendent of Hamidia Hospital, Bhopal.

Additionally, Dr. Shrivastav has worked as the Executive Coordinator at MPMSU and as the Joint Director of Medical Education.

He has extensive experience in academia, having served as a Professor in the Department of Pharmacology at Gandhi Medical College, Bhopal. Dr. Shrivastav also contributed to research as the Director of the Central Research Unit in Bhopal. Throughout his career, he has published over 29 research papers in national and international journals.

Dr Pooja Solanki

Prof. & head Pharmacology, MGMC Indore

Dr. Pooja Solanki is the youngest individual to have been appointed as the Head of the Department of Pharmacology at MGM Medical College, Indore (M.P.). With 23 publications to her name in both national and international journals, she has made significant contributions to the field. Dr. Solanki was honored with the Young Scientist Award 2007 by the M.P. Council of Science & Technology, Bhopal, for her research on the anti-inflammatory effects of Piper Nigrum Extract. She also received the 3rd Prize in Poster Presentation at the Indian Medical Association in Indore, showcasing her work on the analgesic activity of the same extract. In addition, Dr. Solanki was awarded the prestigious Dr. J.G. Thakur Gold Medal for 'Best Medical Writing' by MGM Medical College, Indore, recognizing her excellence in research and academic writing.

Dr. Solanki has also been actively involved in academic and professional development. She was invited as a Resource Person for a workshop on "Research Methodology & Research Techniques" at MGM Medical College, and served as Co-chairperson at the Bhartiya Vigyan Samellan, contributing to the scientific community. Furthermore, she has organized six Continuing Medical Education (CME) programs on various topics, enhancing medical education and knowledge sharing. Through her work, Dr. Solanki has demonstrated a strong commitment to advancing pharmacological research and education.

Our Eminent Chairpersons

Dr Bikash Medhi

Professor, Pharmacology, PGIMER, Chandigarh

Professor Bikash Medhi is a highly esteemed academic and researcher, currently serving as a Professor in the Department of Pharmacology at PGIMER, Chandigarh. He holds the positions of Editor-in-Chief for the Indian Journal of Pharmacology, International Journal of Pharmaceutical Sciences and Nanotechnology (IJPSN), and PGIMER Drug Bulletin. In addition, he has previously served as the Additional Medical Superintendent and is the founder of the Experimental Pharmacology and Neurobehavioral Laboratory at PGIMER. Prof. Medhi also coordinates the PGIMER Pharmacovigilance and Materiovigilance Centre, which serves as the regional centre for North India. His expertise extends to being the Regional Coordinator for NADA (North Zone), Ministry of Youth and Sports, Government of India.

Prof. Medhi is actively involved in various national initiatives, co-convening the India Initiate Programme and leading efforts in GCP, GLP, NABH, CPCSEA, and NMC assessments. He also served as the Secretary for Clinical Pharmacology of the Indian Pharmacological Society.

Throughout his career, Prof. Medhi has received numerous prestigious awards, including the Dr. D N Prasad Memorial Award (ICMR), Dr. V K Bhargava Award (NAMS), Dr. B N Ghosh Award, Col. Ram Nath Chopra Oration, and the PK Kar Oration from the Indian Pharmacological Society. He was also honored with the VAIDA Award (2023), Rudra Goswami Oration Award (2023), and the Asia-Specific Award for Forensic Science (2023), as well as the Medical Pharmacological Award (2024).

Recognized globally, Prof. Medhi is among the top 2% of scientists worldwide, as ranked by Elsevier and Stanford University. He has been nominated to the executive committee of IUPHAR for global coordination of activities in partnership with the WHO (2023-2026). He also chairs the IUPHAR Basic & Translational Science Division and serves as the GCP Chairman by the Government of India. Prof. Medhi is an active member of several prestigious bodies, including the Codex Committee, USA, and the Data Safety Monitoring Boards for various multinational trials. His prolific academic contributions include authoring 10 books, more than 300 book chapters, and over 650 research papers.

Dr. Reenu Yadav

Principal/ Director Department of Pharmacy, Prestige Institute of Management and Research Bhopal

Dr. Reenu Yadav is a trailblazing pharmaceutical expert, renowned for her groundbreaking contributions to the field. With an impressive educational background, including an M.Pharm, MBA, and PhD in Pharmaceutical Sciences, as well as a diploma in academic leadership from the USA, Dr. Yadav has established herself as a leading authority in her domain.

As the founder of Kaya Foundation in New Delhi and Principal/Director of the Department of Pharmacy at Prestige Institute of Management and Research in Bhopal, Dr. Yadav has demonstrated exceptional leadership and academic prowess. Her impressive literary portfolio boasts 8 books and 75 research papers, with 11 patents to her credit.

Dr. Yadav's research endeavors have been recognized with numerous grants and awards from government institutions. Her global lecturing engagements span 5 continents and 18 countries, solidifying her reputation as a distinguished expert in pharmaceutical sciences. Her accolades include being named among the 51 Influential Women in India, as well as receiving awards for Women in Science and Research in the Netherlands, Young Scientist and Women Achiever in France and Dubai, and Young Scientist Mentor in the USA. Dr. Yadav's women's health empowerment campaign has also earned appreciation from the Hon'ble Governor of Madhya Pradesh.

Our Eminent Chairpersons

Dr. Surendra Boudh

Prof & Head, Dept. of Pharmacology, GMC, Datia

Dr.(Prof.) Surendra Kumar Bouddh is an esteemed academician and experienced pharmacologist, currently serving as the Professor and Head of the Department of Pharmacology at Government Medical College, Datia, Madhya Pradesh. In addition to his role as department head, Dr. Bouddh holds several important positions, including Member Secretary of the Institutional Ethics Committee for Human Studies, Member Secretary of the Academic Clinical Trial Committee, and Member Secretary of the Multidisciplinary Research Unit. He is also a member of the Institutional Curriculum Support Program and serves as the AMU coordinator for ADR reporting.

Before his current position, Dr. Bouddh served as an Assistant Professor at CIMS, Bilaspur, and later as Associate Professor and Head of the Department at DSMCH, Perambalur, Tamil Nadu. Throughout his career, he has been involved in various academic committee activities, contributing to the academic and research environment of his institutions.

Dr. Bouddh completed his MBBS degree from Mahatma Gandhi Memorial Medical College, Indore, in 1999, and went on to earn his MD in Pharmacology from Pt. Jawaharlal Memorial Medical College, Raipur, in 2004. He has organized a National Two-Day Conference on Bioethics and Biostatistics at DSMCH, Perambalur. Additionally, he completed fellowships in Evidence-Based Diabetes Mellitus (2015) from the Public Health Foundation and in Critical Care and Toxicology (2017) from Vinayaka Mission Institute, Salem, Tamil Nadu.

With over 20 years of experience in teaching, Dr. Bouddh has made significant contributions to both undergraduate and postgraduate education. He has published 13 papers in reputed national and international journals and has served as an MCI Assessor. Dr. Bouddh is a Life Member of the Indian Medical Association (IMA), the Indian Pharmacological Society, and the Indian Medical Pharmacologists Association (IMPA), where he previously served as General Secretary.

Dr. Vipin Dhote

Associate Director, VNS College of Pharmacy

Dr. Vipin Dhote is an academic researcher specializing in Pharmacology, with a focus on integrating multidisciplinary research in metabolic and inflammatory diseases. His expertise lies in laboratory animal experimentation, particularly in the therapeutic areas of cardio-metabolic conditions, inflammation, and stroke, where he develops new approaches for treatment and management.

Currently, Dr. Dhote serves as a Principal and Professor of Pharmacology at the Faculty of Pharmacy, VNS Group of Institutions, Bhopal. Previously, he gained extensive experience in the R&D centers of Zydus Cadila Healthcare Ltd. in Ahmedabad and Orchid Pharmaceuticals Ltd. in Chennai, specializing in pharmacology and toxicology. Dr. Dhote completed his doctoral studies at The M.S. University of Baroda, Vadodara, focusing on cerebral ischemia and myocardial infarction. His current research interests include the role of gut microbiota in chronic disorders.

He has authored several research publications and contributed to book chapters. His work on cerebral ischemia earned him the Unvas Prize for Best Publication of the Year. Dr. Dhote has received international travel grants to present his research at notable conferences, including the American College of Clinical Pharmacology Annual Conference in Maryland, USA, in 2018, and the Drug Discovery and Therapeutic World Congress in Boston, USA, in 2014. He has also organized national conferences and seminars funded by organizations such as ICMR, AREB, and MPCST.

His long-term scientific goal is to integrate aspects of both traditional and modern medicine to enhance therapeutic and exploratory research, contributing meaningful advancements to the field.

Workshop Resource Faculty

Dr. Anamika Dutta

Medical Officer
MedDRA MSSO

Dr Anamika Dutta is a subject matter expert in clinical coding with diverse work experience with Contract Research Organizations (CROs). She has successfully lead teams on implementing new processes and client specific set ups for various line functions across data management like medical coding, SAE reconciliation and medical data review. She has held leadership positions with the medical coding and medical data review department at IQVIA and PAREXEL International in the past. In her entire tenure with IQVIA she was a faculty for medical coding and has conducted various face to face MedDRA and WHO Drug trainings for the Medical Coding, Pharmacovigilance and Medical Data review departments. Dr Anamika has been a member of the WHO Drug Advisory and the WHO Drug best practices working group in the past. Dr Anamika is actively involved as one of the organizers and session leads at the UMC WHO Drug and MedDRA User Groups in India for several years. She has been actively participating as a moderator, presenter, and expert panelist at various user group meetings for several years. Dr Anamika facilitated the Workshop on Coding at the SCDM Asia Conference in 2013.
Dr Anamika Dutta holds a BHMS degree from Calcutta University and has worked as a clinician in the past where she gained experience in general medicine, obstetrics and gynaecology, dermatology, and cosmetic dermatology practices. In her last assignment with IQVIA, she was managing a team of physicians for the Medical Data Review department and was responsible for managing the operations and delivery as well as leading the process improvement initiatives.

Mr. Girjesh Vishwakarma

Pharmacovigilance Associate,
GMC Bhopal

Mr. Girjesh Vishwakarma,
Pharmacovigilance Associate,
GMC Bhopal and formerly Training Division,
IPC Ghaziabad

Girjesh Vishwakarma, a graduate and postgraduate (pharmaceutics) from RGPV University, has 6 years of experience in the field of academics as an Associate Professor and is currently working as Pharmacovigilance Associate since the last 4 years in the Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Currently posted in Gandhi Medical College, Adverse Drug Reaction Monitoring Centre as Pharmacovigilance Associate, He has published a number of article research/review articles in National and International journals.

Mr. Aniket Deshmukh
Assistant Manager,
Quality, Compliance and Training
Fidelity Health Services

Mr. Aniket Deshmukh
Assistant Manager, Quality, Compliance and Training
Fidelity Health Services

M.S. Pharm – Professional with around 08 years of experience in Pharmacovigilance and Biopharmaceuticals mainly in Quality, Audit and Training operations.

Ms. Molisha Soni
Senior Drug Safety Executive
Fidelity Health Services

Ms. Molisha Soni
Senior Drug Safety Executive
Fidelity Health Services

M. Pharmacy - Professional with around 05 years of experience in Pharmacovigilance and Drug Safety operations including ICSR processing, aggregate reporting and PSMF.

Our Quiz Master

Dr. S. Manikandan

MBBS, MD, DNB
Professor, Pharmacology,
JIPMER, Pondicherry

Special Area of Interest:
Essential medicines, rational use of drugs, medication safety and medical education

Positions Held:
Officer-in-charge, Department of Hospital Pharmacy, JIPMER

ORAL PAPER PRESENTATIONS

Doxycycline-associated hyperpigmentation: a rare adverse drug reaction

Vikram Singh Dhapola

Department of Pharmacology, Soban Singh Jeena, Government Institute of Medical Sciences and Research, Almora, Uttarakhand

Introduction: Drug-induced hyperpigmentation is an adverse cutaneous effect; it has been associated with several systemic medications. Doxycycline is an antibiotic agent that belongs to the tetracycline class. It is commonly used for short-term therapy in the treatment of acute infection sand in the long- term management of acne vulgaris. In patients with drug-associated hyperpigmentation, skin darkening can occur as the result of the drug alone or after sun exposure. Tetracyclines, and in particular minocycline, are among the most common agents associated with drug-induced pigmentation. **Aim and objective:** The aim of presenting this case report is to support the clinical evidence that drugs like doxycycline are the potent cause of severe skin reactions like cutaneous hyperpigmentation. **Case details:** a healthy15year-old female child developed facial and palmer hand hyperpigmentation. Within two weeks of beginning doxycycline monohydrate 100 milligrams twice daily for acne. The correlation of the patient's clinical history and skin findings established a diagnosis of doxycycline-associated hyperpigmentation. Initial management included stopping the doxycycline monohydrate and it was replaced by azithromycin 250 milligrams twice daily. **Result:** causality assessment was probable as per Naranjo's algorithm. The adverse drug reaction (ADR) was reported to PvPI. **Conclusion:** doxycycline-associated hyperpigmentation frequently occurs on the face and can occur at the site of a previous scar. In most cases, doxycycline was discontinued with the resolution of hyperpigmentation. **Keywords:** Hyperpigmentation, face, doxycycline, darkening, acne, PvPI

Safety profiling of fentanyl in children using FDA adverse event reporting system (FAERS) database: a real-world analysis

Shwetha Somakumar[1], Arunangshu Ghoshal[2], Naveen S Salins[2], Vasudeva Bhat K[3], Krithika S Rao[2], Rajesh V[4]

1. Department Of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka, India.
2. Department Of Palliative Medicine and Supportive Care, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Karnataka, India.
3. Division Of Pediatric Hematology and Oncology, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Karnataka, India.
4. Centre For Pharmaceutical Care, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka, India.

Background: fentanyl, a synthetic opioid, is widely used in pediatric pain management due to its potent analgesic properties. Despite its clinical efficacy, fentanyl is associated with significant risks of adverse events (AEs). **Aim:** this study aims to identify, categorize, and assess AEs with fentanyl in pediatric patients (0-17 years) utilizing the data submitted to the FAERS database from q4 2003 to q2 2024. **Methods:** A retrospective Analysis of real-world data was conducted using the open vigil2.1platformto access and process the FAERS reports. The search criteria included all reports involving fentanyl, its acetate, and citrate forms without restrictions on the drug's role. The AEs were classified using the MedDRA27.1 platform, and disproportionality analysis was employed to detect safety signals. The entire analysis was carried out using Microsoft excel and R programming software version 4.4.0. **Results:** from the 16,955 reports, 2,771 unique entries were analysed.137 preferred terms (PT) were identified, with the most frequent in nervous system disorders. Somnolence (148reports) was the most common ae observed. Disproportionality analysis flagged 88 signals across 19 system organ classes, with the strongest for amnestic disorder (PRR:1397.741; ROR:1408.444; X^2:2373.857). Outcome analysis identified bradycardia, brain oedema, cardiac arrest, and respiratory failure, causing fatal outcomes. Hierarchy analysis comparing pts with us FDA labels showed low concordance at pt levels (6.72%). **Conclusion:** This study provides the first large-scale real-world analysis of fentanyl-associated AES in children, offering critical insights into the drug's safety profile. Further research and detailed post-marketing surveillance are recommended to enhance safer clinical practices.
Keywords: fentanyl, pediatrics, disproportionality, drug safety, signal mining.

Unveiling Materiovigilance: Insights into knowledge, attitude, and practices among Healthcare Workers

Lalita Gupta[1], Anuja Jha[1], Pooja Reddy[1]
[1]Department of Pharmacology, SAMC & PGI, Indore

Background: Materiovigilance refers to systematic identification, collection, reporting, and analysis of adverse events related to medical devices to safeguard patient health and prevent recurrences. It plays a vital role in ensuring patient safety and improving healthcare outcomes. This study aims to identify knowledge gaps and opportunities for healthcare practitioners to enhance their awareness of Materiovigilance. **Aim and objectives:** To assess the knowledge, attitude, and practices related to Materiovigilance among healthcare workers at tertiary care teaching hospital. **Materials and methods:** Following approval from the institutional ethics committee and informed consent from participants, online survey was conducted among healthcare workers at tertiary care teaching hospital using google forms. The survey consisted of 15 semi-structured, multiple-choice questions. The first section gathered demographic information, the subsequent sections assessed healthcare professionals' knowledge, attitudes, and practices regarding Materiovigilance. **Results:** A total of 291 healthcare workers responded, with 279 providing consent to participate. Among them, 59.1%were nurses, 33.3% were physicians, 6.5% were pharmacists, and 1.1% were lab technicians. While 78.9% of respondents were aware of medical devices and Materiovigilance, only 31.2% understood the classification of medical devices based on risk. Additionally, 89.2% monitored adverse events related to medical devices, and 78.4% were familiar with the tools used for reporting these events. **Conclusion:** The participants demonstrated adequate knowledge of adverse events related to medical devices and a positive attitude toward Materiovigilance. They recommended the

implementation of continuous education and training programs to ensure the safety of patients and healthcare workers.

A retrospective comparative study to assess the renal parameters among the patients on neprilysin inhibitor & angiotensin receptor blockers and valsartan

Vignesh V Nair
JIPMER, Puducherry

Background: Chronic Heart Failure (CHF) is a major public health concern, often associated with poor prognosis and renal dysfunction. Traditional therapies such as angiotensin receptor blockers (ARBs) like valsartan have been standard in heart failure management. Recently, neprilysin inhibitors combined with arbs (sacubitril/valsartan) have shown promising results in improving cardiac outcomes, but their impact on renal parameters requires further exploration. **Objective:** this retrospective comparative study aimed to assess renal parameters in patients with chronic heart failure (CHF) treated with either neprilysin inhibitor (sacubitril/valsartan) or angiotensin receptor blockers (valsartan). **Methods:** A retrospective comparative study was conducted over a six-month period at Kovai medical Centre and hospital, Coimbatore. A total of 219 patients with chronic heart failure were included, divided into two groups: 128 patients treated with valsartan and 91 patients treated with sacubitril/valsartan. Renal function was assessed by monitoring serum creatinine, eGFR, and potassium levels at baseline, first follow-up, and second follow-up. Cardiac function was assessed through left ventricular ejection fraction (LVEF), heart rate, and blood pressure measurements. Long-term studies are needed to fully understand the renal implications of sacubitril/valsartan therapy in heart failure patients. Statistical analysis was performed using paired t- tests, with p-values <0.05 considered significant. **Results:** In the sacubitril/valsartan group, 68.1% of patients had normal creatinine levels (0.7-1.2 mg/dL) at baseline, which decreased to 62.2% by the second follow-up. The valsartan group showed 66.7% with normal creatinine at baseline, improving to 70.5% by the second follow-up. A significant increase in creatinine levels was observed in the sacubitril/valsartan group ($p = 0.003$). Normal potassium levels (3.5-5.0 mg/dL) were observed in 87.7% of the sacubitril/valsartan group at baseline, increasing to 91.3% by the second follow-up. In the valsartan group, normal potassium levels were maintained in 94.4% of patients at baseline, increasing to 94.1% by the second follow-up. Elevated potassium levels (5.1-6.0 mg/dL) were observed in 7.7% of sacubitril/valsartan patients at baseline, which reduced to 2.17% by the second follow-up. The sacubitril/valsartan group showed significant improvement, with 51.1% of patients having LVEF between 30-39% at baseline, which improved to 20% by the second follow-up. In the valsartan group, 63.7% of patients had LVEF between 50-70% at baseline, remaining consistent across follow-ups. **Conclusion:** sacubitril/valsartan significantly improved LVEF and maintained better potassium control compared to valsartan, though it caused a mild, clinically acceptable increase in creatinine levels. Both treatments were effective in managing blood pressure, but sacubitril/valsartan showed superior cardiac benefits.

Keywords: Left ventricular ejection fraction, Serum creatinine, Safety, Efficacy

A comparative study of efficacy and safety of oral Sodium valproate versus divalproex in treatment of bipolar disorder

Abhishek Madhu Paserkar[1], J. L. Marko[1], Ruchi Soni[2], Muskan Khare[1]
[1]Dept. of Pharmacology, Gandhi Medical College and Hospitals, Bhopal
[2]Dept. of Psychiatry, Gandhi Medical College and Hospitals, Bhopal
Background: Bipolar disorder is a prevalent psychiatric condition that significantly impacts the quality of life, characterized by recurring episodes of mania, hypomania, and depression. Sodium valproate and divalproex are two commonly prescribed mood stabilizers for managing bipolar disorder. This study aims to evaluate the efficacy and safety of these drugs in the treatment of bipolar disorder, given the limited data from central India. **Methods**: A prospective, observational study was conducted involving 110 patients diagnosed with bipolar disorder. Participants were divided into two groups: group I received sodium valproate (500mg twice daily), and group ii received divalproex (500mg twice daily). Treatment efficacy was measured using the young mania rating scale (YMRS) and bipolar depression rating scale (BDRS) at baseline, 6 weeks, and 8 weeks. The severity and causality of adverse drug reactions were assessed using the Hartwig Severity scale and WHO UMC causality assessment scale.
Results: Both drugs showed significant improvement in YMRS and BDRS scores over the 8-week period. Sodium valproate resulted in a 53.39% reduction in YMRS and a 52.44% reduction in BDRS scores, while divalproex showed slightly better efficacy with a 54.13% reduction in YMRS and a 53.33% reduction in BDRS scores. P value was calculated using the software SPSS 30. Significant p value was found for each group. Both drugs were well tolerated, with mild adverse effects such as nausea and tremors being the most commonly reported.
Conclusion: Sodium valproate and divalproex are effective and safe options for managing bipolar disorder, with divalproex showing a marginally better efficacy profile. These findings contribute to the understanding of bipolar disorder treatment in central India and provide insights into the comparative effectiveness of these mood stabilizers
Keywords - Bipolar disorder, sodium valproate, divalproex, mood stabilizers etc

Antibiotic prescription pattern analysis in the treatment of neonatal sepsis in a tertiary care hospital –a cross sectional, observational study

Muthukumar B[1], Gokul T[1], Chandrakala K[1], Elizabeth B[1]
Department of Pharmacology, GMC, Ongole

Background: Neonatal sepsis is one of the most typical causes of neonatal morbidity and mortality in the developing countries. Neonatal infections accounts over 5,50,000 neonatal deaths every year all the world. Rational use of antibacterials is a priority to prevent the emergence of resistance and to reduce the burden of treatment failure. Hence this study is conducted to analyze the prescription pattern and rational use of antibacterials in neonatal sepsis in a tertiary care hospital. **Methods:** This is a cross sectional, observational study, all the records of patients who are admitted to special new born care unit (SNCU) between October 2024 to December 2024 with suspected neonatal Septicaemia are included. Antibacterials prescribed relating to generic/ brand name, dosage, route, frequency, duration of administration, and treatment outcome along with the approval status of the drugs and its accordance with the essential medicine list (WHO, NLEM, SLEM) were recorded. **Results:** The collected data will be entered in Microsoft excel 2021. Descriptive data is expressed in mean +/-sd. Analytical data is expressed in percentages. Collection of the data is in progress and results are awaiting conclusion and will be completed by the end of the study period. **Conclusion:** Adopting proper guide lines and rational use of drugs being the highest importance, conducting regular drug

prescribing pattern analysis are essential to study the clinical use of drugs in population and their impact on the healthcare system.

Keywords: Neonatal sepsis, Prescription pattern, Approvedstatus, Essential medicine.

A comparative study of safety and efficacy of alprazolam and clonazepam in primary insomnia

Muskan Khare[1], Neelesh Arya[1], Ruchi Soni[2]

[1]Dept. of Pharmacology, Gandhi Medical College and Hospitals, Bhopal

[2]Dept. of Psychiatry Gandhi Medical College and Hospitals, Bhopal

Background: Insomnia Disorder defines as dissatisfaction with sleep quantity or quality associated with one or more of the following symptoms: difficulty in initiating sleep, difficulty in maintaining sleep with frequent awakenings or problems returning to Sleep. alprazolam and clonazepam are two commonly prescribed hypnotics in insomnia. This study aims to evaluate the efficacy and safety of these drugs in the treatment of primary insomnia, given the limited data from Central India. **Methods**: A prospective, observational study was conducted involving 125 patients diagnosed with primary insomnia. Participants were divided into two groups: group I received alprazolam (0.5mg daily), and group ii received clonazepam (0.5mg daily). Treatment efficacy was measured using the Athens insomnia scale at baseline, and 2 weeks. The severity and causality of adverse drug reactions were assessed using the medication appropriateness index and who UMC causality assessment scale. **Results**: Both drugs showed significant improvement in ais and MAI scores over the 2-week period. Alprazolam resulted in 24.20% reduction in ais and a 13.83% reduction in MAI scores, while clonazepam showed slightly better efficacy with a 27.49% reduction in ais and a 12% reduction in MAI scores. Significant p value was found for each group. Both drugs were well tolerated, with adverse effects such as sedation and tremors being the most commonly reported. **Conclusion**: alprazolam and clonazepam are effective and safe options for managing insomnia , with clonazepam showing a better efficacy profile. These findings contribute to the understanding of insomnia treatment in central India and provide insights into the comparative effectiveness of these hypnotics.

Keywords - Primary Insomnia, Alprazolam, Clonazepam, Athens Insomnia Scale

Adverse Drug Reactions to 2nd line anti-tubercular drugs in drug-resistant tuberculosis cases

Prerna J. Karketa

Dept. of Pharmacology, Gandhi Medical College and Hospitals, Bhopal

Introduction: For the treatment of drug-resistant tuberculosis, second line anti-tubercular drugs are used, which are costly and not without adverse events. This study was conducted to find out the spectrum of adverse drug reactions to these drugs. **Methodology:** We conducted an observational, prospective study at the department of pharmacology and department of respiratory medicine (which is a nodal drug-resistant tb Center (NDR-TBC)). The patients registered at the NDR-TBC, Bhopal, during the study period between November 2022 and November 2023, were included in the study. They were enquired for any adverse events, either when they came for monthly follow-up or telephonically. The adverse drug reactions were Analyzed for severity and causality using the Hartwig's severity assessment scale and WHO-UMC causality assessment scale respectively. **Results:** 228 patients enrolled for the treatment of

DR-TB of which 199 were assessed based on inclusion and exclusion criteria. Most common adverse events were gastrointestinal in initial months and skin discoloration in later months of the follow-up period. The ADRs commonly noted were-skin discoloration (36.8%), gastritis (23.4%), peripheral neuropathy (11.0%) and ichthyosis (7.3 %). Other ADRs were found in less than 5% of the study population. None of the ADRs were severe and most had a possible causality assessment. Conclusion: second line anti-tubercular drugs cause a varied spectrum of ADRs. These need to be tackled properly for enhancing patient care. The medical staff need to be trained for early recognition of ADRs.

A study of pharmacological management of acute poisoning at a tertiary care hospital

N Ramesh Raja[1], Chetna K Desai[1], Kinjal Prajapati[1]
[1]Department of Pharmacology, B. J. Medical College, Ahmedabad

Introduction: Acute poisoning is a major global health problem affecting people of all age groups with significant morbidity and mortality. It may be due to self-consumption, accidental exposure of chemical compounds and medications. It requires immediate effective management to prevent the mortality or sequelae. **Aims & Objectives:** The study aimed to evaluate the types, clinical presentations, pharmacological management and outcome of acute poisoning cases in a tertiary care hospital in western India. **Study methods:** It was a longitudinal, prospective, observational study, with prior approval by the institutional ethics Committee. Hospitalized patients diagnosed with acute were included as per the selection criteria and followed up till discharge or death, whichever was earlier. **Results:** Among the total of 80 studied poisoning cases, with male: female 3.4:1. And mean age of 33.5 ± 10.7 years. The most common types of acute poisoning were organophosphate (op) compounds (35, 44%), drug poisoning (18, 23%), alkaline poisoning (17, 21%). The most common cause for the poisoning was suicidal (56, 70%). 29% of patients were unconscious/unresponsive/altered sensorium at time of admission. Vomiting (54, 38%) was the common complaint followed by throat pain (14, 10%).out of 80 cases, 43 cases received antidote (54%) and among them atropine and pralidoxime were the most common antidotes (72%). Drugs like pantoprazole and ondansetron were prescribed in all patients. However, all the patients were prescribed at least one antibiotic and among them ceftriaxone was the most common prescribed (67%). Majority of the patients recovered (67, 83.8%), while 11 (13.8%) patients died. Ten of these were due to ingestion of op compounds. Total 20 ADRs were observed in 80 patients. Majority of ADRs had a probable causal relationship with the suspected drug according to who (90%) and Naranjo causality assessment scale (100%). **Conclusion:** Suicidal ingestion of organophosphate compounds were the commonest causes of poisoning noted with a higher case mortality rate. The mortality rates are reduced by early management of the poisoning.

Keywords: Organophosphate compounds, acute poisoning, phenyl poisoning, antidote.

Self-Medication Risks: prevalence and awareness of adverse reactions in over-the-counter drug use

Hemlata Verma[1], Shaifali Singh[1], Saman Aatif Saulat[1]
Department of Pharmacology, Gandhi Medical College & Hamidia Hospital, Bhopal

Background: Over the counter (OTC) medications are frequently used for self-treatment of

minor ailments but carry risks of adverse drug reactions (ADRs), especially when used without professional guidance. The increasing availability of OTC medications and direct-to-consumer advertising have reduced healthcare oversight, often leading to improper use and limited awareness of the risks associated with self-medication. **Methodology:** A cross-sectional study was conducted using ethnographic interviews, focus groups, and a validated questionnaire to assess patient knowledge and awareness of ADRs related to OTC medications. Data were collected on demographics, usage patterns, and sources of drug information, with emphasis on patient-reported ADRs, their severity and management. **Results**: Participants generally had limited awareness of potential side effects. Despite this, many could identify ADRs based on their symptoms, with gastrointestinal discomfort, dizziness, and allergic reactions being most common. ADRs were typically mild to moderate, with severe cases reported infrequently. Elderly individuals and those with chronic conditions were more vulnerable. Social media and personal networks were the main information sources, while patient leaflets were rarely used due to design issues. **Conclusion**: OTC medications, despite their convenience, carry significant risks due to limited patient awareness of side effects. Improving public education, particularly for vulnerable groups, and providing clearer drug information leaflets are essential for safer self-medication practices.

Accelerating Drug Development: the impact of pharmacovigilance databases on drug repurposing

Swathi Suresh[1], Manthan Mehta[1]
Department of Pharmacology, University College of Medical Sciences, University of Delhi

Introduction: drug repurposing offers a cost-effective approach to identifying new therapeutic uses for existing medications. Pharmacovigilance (PV) databases, with their extensive big data, have emerged as valuable resources in uncovering these opportunities. This systematic review evaluates studies that leverage PV databases to identify repurposed drugs in response to evolving health needs. **Methodology:** A systematic search was conducted in PubMed from inception to October 2024, including original English articles that utilized PV databases to identify potential drug candidates for any disease. Articles without finalized repurposed drug outcomes were excluded. Data extraction focused on the databases used, signal detection methods, targeted disease areas, and identified drugs for repurposing. **Results:** Of 63 studies screened, 8 met the inclusion criteria, covering 8 disease areas, including hyperhidrosis, dysphagia in neurological patients, secondary Raynaud's phenomenon, infections, depression in diabetics, hypertension, and Alzheimer's disease. Each study proposed a top 5 list of repurposed drugs, with 1 study performing molecular docking and simulations for validation. The FDA adverse event reporting system (FAERS) was used in 5 studies, and Vigiase in 2. Signal detection predominantly involved disproportionality analysis using reporting odds ratios in 6 studies, with 1 study employing information component (IC) analysis as a statistical method and another using adverse event signature matching. **Conclusion**: PV databases play a pivotal role in identifying drug repurposing opportunities. However, challenges such as reporting bias, data inconsistencies, and validation gaps in experimental and clinical settings must be addressed to maximize their potential.

Comprehensive analysis of ADRs in first line and MDR-TB Treatment Regimens

Ruchi Baghel[1], Avani Shakalya[1], Madhav Saxena[1], Neer Arora[1], S.P. Dhaneria[1]
[1]Department of Pharmacology, RD Gardi Medical College, Ujjain, India

Introduction (background and objective): Anti-TB drugs often cause adverse drug reactions (ADRs), impacting compliance and outcomes; this study aims to improve management and treatment protocols by identifying and addressing these ADRs comprehensively. **Aim:** To identify and analyze the ADRs associated with Anti-TB treatment. To assess the causality, severity and preventability of ADRs using appropriate scales. **Methodology:** Spontaneous ADR reported in 2024 to the tertiary care teaching hospital using a standardized ADR reporting form were assessed for causality, preventability, and severity determination using appropriate scales. **Results:** Total 38 ADR were reported out of them 18 were due to first line anti TB treatment and 20 were caused by drugs used for multi drug resistant (MDR-TB). Most common ADRs from first line anti-tb drugs were hepatotoxicity and gastritis and from MDR tb drugs were peripheral neuropathy and qt prolongation. In 24 cases suspected drug was withdrawn, in 5 Dose reduced, in 1 case drug was reintroduced after recovery and in 6cases treatment was not modified. Based on who causality scale 24 cases were classified as probable and 14 as possible. Based on Naranjo scale 17 were probable and 21 were possible. According to modified Hartwig and Siegel scale 33 ADRs were moderate and 5 were mild. On applying modified Schu mock and Thornton scale07 cases were definitely preventable, 16 probably preventable and 15 were not preventable. **Conclusion:** Managing multidrug-resistant tb is particularly challenging due to the high pill burden, prolonged treatment duration, and the occurrence of ADRs adversely affecting the patient compliance and ultimate clinical outcome. This highlights the importance of pharmacovigilance in terms of continuous ADR monitoring and formulating the strategies to minimize impact of adverse effects to improve clinical outcome further.

An observational study to compare the treatment outcomes of older and newer antiretroviral regimens in HIV patients

Lily Dubey[1]**,** Lovely Lahare[1], Shashi Marko[1]
[1]Department of Pharmacology, Bundelkhand Medical College, Sagar (M.P.)

Introduction: HIV is a major public health problem with a global burden of 40 million. Recent developments in antiretroviral therapy have led to more effective and safer regimens. Dolutegravir based regimens are the preferred first line regimen as per the latest NACO guidelines. The objective of the study is to evaluate the effectiveness and adverse drug reactions with the newer dolutegravir based regimen compared to the older regimen. **Methodology:** An observational study conducted in all adult PLHIV (age ≥18 years) registered in the ART centre of Bundelkhand Medical College, Sagar (M.P). A total of 180 patients were included in the study after IEC approval. Group a comprised of 90 patients on dolutegravir based regimen and group b included patients on older TLE regimen. Data pertaining to CD4 counts, viral load, various laboratory parameters and occurrence of any adverse drug reactions were documented at the baseline and two follow up visits. **Results:** The efficacy among the two groups was comparable pertaining to CD4 counts and the two groups in terms of CD4 counts and viral load ($p>0.05$). Though it appears to cause quicker increase in CD4 counts, it was not statistically significant. The most frequent adverse effect was weight gain and diarrhea. Three patients from newer

regimen group and two from older regimen group had to substitute to abacavir from tenofovir because of adverse effects. **Conclusion:** Dolutegravir based regimen is an effective and safe regimen for the treatment of HIV with an added advantage of weight gain.

Keywords- HIV, dolutegravir based regimen, newer regimen

A comparative study of efficacy and safety of intravenous iron sucrose versus ferric carboxymaltose for iron deficiency anaemia among antenatal woman attending in MRDM hospital

Poonam Paikra[1], Usha Joshi[2], Avinashi Kujur[3], Rajesh Kumar Shivastava[4]

[1]Department of Pharmacology R.S.D.K.S. Government Medical College, Ambikapur, Chhattisgarh

[2] Department of Pharmacology, Pt. JNM Medical College, Raipur

[3] Department of Obs & Gynae, R.S.D.K.S. Government Medical College, Ambikapur, Chhattisgarh

[4] Department of Biochemistry, R.S.D.K.S. Government Medical College, Ambikapur, Chhattisgarh

Background: Anaemia is the most common manageable problem among pregnant women worldwide, which contribute to maternal and perinatal mortality. **Aims and objectives:** To study the efficacy and safety of intravenous ferric carboxymaltose (FCM) versus iron sucrose in the management of iron deficiency anemia in pregnancy. **Materials and methods:** It is a randomized prospective study conducted in department of obstetrics and gynecology at RSDKS Govt. Medical College Ambikapur Surguja Chhattisgarh, constituting of 110 pregnant women. 55 pregnant anemic patients were treated with intravenous ferric carboxymaltose and other 55 patients were treated with intravenous iron sucrose. Hemoglobin, MCV, S. Iron, S. Ferritin, TIBC, transferrin saturation level were measured before and 4 weeks after treatment. The efficacy and safety of both intravenous compounds were studied. **Results:** Anaemia in pregnancy was more prevalent among 21-29 years of age groups; it is more common in multigravida in 20-24 weeks of gestational age. The mean difference of hemoglobin 4 weeks after treatment was 2.34 g/dl for ferric carboxymaltose and 1.32g/dl for iron sucrose. The mean change in hb level and ferritin level was higher among patients of fcm compared to iron sucrose. The adverse reactions were lower among patients of fcm than iron sucrose. The other parameters also increased significantly for ferric carboxymaltose than iron sucrose. **Conclusions:** Ferric carboxymaltose is an efficient and better alternative in iron deficiency anaemia in pregnancy with fewer side effects and has the added advantage of single dose regime. This study found that FCM is safer than iron sucrose. Treatment with FCM resulted in rapid replenishment of iron stores in pregnant women with significantly high rise of Hb and ferritin levels over a 4-week period with lesser adverse effects.

A retrospective study of assessment of adverse drug reactions at ADR monitoring centre of a tertiary care hospital of northern India

Somya Singh[1], Farah Asif[2], Sanjay Khattri[3]

[1]Department of Pharmacology and Therapeutics, All India Institute of Medical Sciences, Bhopal

[2]Department of Pharmacology and Therapeutics, Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow
[3] Department of Pharmacology and Therapeutics, King George's Medical University, Lucknow, U.P

Introduction - adverse drug reactions (ADRs) is any serious, noxious and unpleasant effect occurring at a therapeutic dose which can either lead to withdrawal of treatment or use of any alternative methods. So, study of these unwanted effects by drugs can help in prevention of any future apocalyptic events. **Methodology –** this was an observational and retrospective study, which was based on the data collected from the ADR cases reported to King George Medical University ADR monitoring Centre (AMC) from December 2022 to November 2023. All the suspected ADRs which were either reported to the center or collected by department of pharmacology on regular visits in various other departments. The study subjects were assessed for demographic characteristics, causality assessment, system organ class and other parameters. **Result:** Among the reported 270 suspected ADRs, antimicrobials have recorded maximum no. Of ADRs which account for almost half of the overall ADRs reported followed by Anti cancers and NSAIDs **Conclusion:** The antimicrobial drugs showed a lot of ADRs which is a serious threat as it can lead to development of resistance which can have a very serious impact both on individual as well as community. Our study shows that majority of the ADRs reported were due to poly-pharmacy.

Preventability, predictability, severity and causality analysis of serious adverse events reported to institute ethics committee: a retrospective study

Yogendra Narayanrao Keche[1], Vikas Katiyara[2]
[1]All India Institute of Medical Sciences (AIIMS), Raipur
[2]Abhishek I Mishra Memorial Medical College and Hospital, Bhilai

Introduction: Institute ethics committee (IEC) does not use different scales for preventability, predictability and severity analysis of reported serious adverse events (SAEs). This analysis will be advantageous to the strengthening of SAE analysis carried out by IEC. There are no studies regarding analysis of SAEs reported to institute ethics committee on this aspect. **Methodology:** this was a retrospective secondary data analysis of 133 SAE reported to IEC from 1st February 2021 to 30th January 2024. The study was approved by IEC-AIIMS Raipur. Causality of SAEs was analysed as per who UMC /Naranjo scales, preventability by modified Schumock and Thornton scale and severity by modified Hartwig and Siegel scale. Predictability of SAEs was assessed as per types of SAEs and if occurrence of SAEs is very common (> 10%). **Results:** out of 133 SAEs, 117 were reported for regulatory clinical trials (CTS) and 16 were reported from academic CTS. Around 95% SAEs were not preventable as per modified Schumock and Thorton preventability scale and around 4% SAEs were definitely preventable. 42% SAEs moderate in severity as per modified Hartwig and Siegel scale were 42%. SAEs predictable were 7.52%. As per who UMC causality analysis, 91.73% SAEs were unlikely due to the drugs.as per Naranjo scale, possible SAEs were 91.73% whereas it appears to be only 4.51% possible SAEs as per who UMC scale. **Conclusion:** analysis of SAEs by different scale had provided different insight for casual relationship of SAEs with causative agents as IEC analysed SAEs as related or not related to the study medication as per table 5 of NDCT rule 2019.

Pharmacovigilance study in antimicrobial stewardship program in a tertiary care hospital in India

Peeyush Mishra[1], Vijayendra Gautam[1], Neelima Ranjan[1], D.S. Doneriya[1], Sandeep Kanojiya[1]
Gajra Raja Medical College, Gwalior (M.P.)

Introduction: By strengthening the antimicrobial stewardship program, we can effectively reduce the emergence of microbial resistance and promote a more judicious and responsible use of antibiotics, ultimately leading to better patient outcomes and a reduction in the spread of antibiotic-resistant infections. **Aim and objectives:** In antibiotic-drug-resistant hospitalized patients at the tertiary care hospital GRMC. This study was planned to monitor all adverse drug events (ADEs) for analyzing the antibiotic resistance pattern and to find the effectiveness of antibiotics. **Methods:** This observational study was carried out between 1st April and 31st July 2024. Hospitalized 150 antibiotic-resistant cases showing adverse drug events were included in the study. The study was conducted in the department of microbiology, medicine, and pharmacology at Gaja Raja Medical College, Gwalior, M.P. the antibiotic resistance was confirmed after getting a culture and sensitivity report from the microbiology department. The dose adjustment or stopping of antibiotics or replacements of antibiotic drugs were noted in the medicine department. All ADEs before and after empirical antibiotic therapy were noted. The institutional ethics committee approved the study (24/IEC-GRMC/2024). **Results:** The most common ADE found is headache (19.33%) and rashes (14%). The microorganism causing the most resistance is e. Coli. Meropenem, ceftriaxone, metronidazole, and levofloxacin are the most effective antibiotics, as they show the least resistant pattern and minimal ADEs. **Summary:** For reduction in the emergence of microbial resistance and rational use of antibiotics in hospitalized patients, studies on microbial resistance patterns and antibiotic stewardship program plays a key role in the rational use of antibiotics. **Conclusion:** through this study, we can identify and estimate the effectiveness of antimicrobial drugs. Hence, we found that the stewardship program reduced the ADRs, mortality, and morbidity and improved the patient's well-being.

Keywords: Antibiotic stewardship program, antibiotic resistance, adverse drug events

Drug utilisation and safety profile study in COVID-19 patients in Tertiary care hospital: A Retrospective Research

Vipin Kumar Jain[1], Sarfaraz Alam Khan[1]
[1]Department of Pharmacology, Chhindwara Institute of Medical Sciences (CIMS), Chhindwara

Introduction: Novel Corona Virus causing corona virus disease 2019 (COVID-19) is an infectious disease that caused 772 million confirmed cases and over 6.9 million deaths worldwide as per WHO. There is lack of data on drugs used in COVID-19 patients with very few studies evaluating the treatment patterns for first year of pandemic and as per disease severity. **Method**: This retrospective, single-centre observational drug utilization study was conducted in patients admitted in Chhindwara Institute of Medical Sciences, Chhindwara, Madhya Pradesh, a tertiary care centre of southwest India between 1st April 2021 to 31 December 2021. Data was analyzed for drug utilization pattern in term of demographic details, clinical features and severity based on SpO2 % and laboratory findings including HRCT Score along with different class of drugs prescribed like anti-inflammatory, anti-viral, antibiotics, anti-coagulants and hospital stay based on severity. **Results**: Out of 243 patients, 107(44%) were mild and 30(12%) were in severe category. The most common age group was 51-60 years (29%) and males were predominated. Overall, the common drugs prescribed for COVID-19 were Remdesivir 58%,

Low molecular weight Heparin 55%, Piperacillin-tazobactam 49% in antibiotics and Methylprednisolone in 48% cases. Duration of hospital stay was more in severe cases having comorbidities. **Conclusion:** Overprescribing of antibiotics along with off label use of drugs was encountered in most cases which may be attributed to limited research in drugs utilized in COVID-19 patients. Polypharmacy needs to be addressed for promoting rational use of drugs.

An observational study to evaluate adverse drug reactions of SSRIs in patients of depression & GAD

Shalini Shukla[1], Naveen Kumar[1], Nikhil Goel[2], Navin Budania[1], Siddharth[1]
[1]Department Of Pharmacology, SHKM GMC, Nalhar, Haryana
[2]Department Of Psychiatry, SHKM GMC, Nalhar, Haryana Ahuja, Vinod K Bhardwaj

Background: Selective serotonin reuptake inhibitors (SSRIs) are the most commonly prescribed and first-line pharmacotherapy for depression and generalised anxiety disorder (GAD) due to their safety, efficacy, and tolerability; nevertheless, this does not imply they are devoid of adverse drug reactions (ADRs). ADRs are an inevitable aspect of pharmacotherapy, presenting significant challenges for healthcare systems and patient management worldwide. **Objectives:** The objectives of this study were to identify the clinical patterns, causality, severity, preventability and factors associated with suspected adverse drug reactions to SSRIs in patients of depression and gad. **Materials & methods:** A hospital based observational and prospective study was conducted during June 2023 to May 2024 at the department of pharmacology in collaboration with department of psychiatry, SHKM GMC, Nalhar, Haryana. Drug naive adult patients with depression or gad attending the outpatient department of psychiatry were included in the study by random sampling method. **Results:** A total of 195 ADRs were recorded from 96 patients of depression (n=51) and gad(n=45). The most common ADRs observed were headache (13.34%), dizziness (8.72%) and drowsiness (8.72%). The most common system involved was central nervous system (56.92%) followed by gastrointestinal system (30.25%). The majority of ADRs were in mild category (88.50%) followed by moderate category (11.40%) as per modified Hartwig and Siegel severity assessment scale. Out of total 195 ADRs, majority were in “not preventable” category (93.70%) as per Schumock and Thornton’s preventability criteria. **Conclusion:** headache, dizziness and drowsiness are found to be most common ADRs associated with SSRIs in this study. while SSRIs are effective in alleviating depressive and anxiety symptoms, their use is not devoid of adverse drug reactions (ADRs).

Artificial intelligence driven adverse drug reaction reporting and causality assessment: Enhancing pharmacovigilance in Central India

Tasneem Hussain[1], Dr. Pooja S. Mishra[1], Dr. Ashutosh Tiwari[1]
[1]Mahatma Gandhi Memorial Medical College, Indore (M.P.)

Background: adverse drug reactions (ADRs) significantly impact patient safety and healthcare costs. In India, ADR reporting rates are notably low, with only 1% of cases reported compared to the global average of 5%. To address this issue, AI-enabled systems are being explored to enhance pharmacovigilance processes. **Objectives:** This study assesses the effectiveness of ai-enabled audio-to-text transcription and translation system for ADR data collection and automated ADR form filling. The goal is to evaluate the ai system's accuracy in transcription,

translation, form completion and causality assessment and its potential to improve ADR reporting. **Methodology:** This study was initiated after the approval from IEC (EC/MGM/AUGUST-24/193). The study involved 60 participants: 30 healthcare professionals and 30 patients who provided audio recordings of ADRs. These recordings were transcribed and translated by the ai system. The system's performance was evaluated using word error rate, character error rate, bleu score, and translation edit rate and was compared between patients and healthcare professionals recordings. The accuracy of ai-generated ADR forms and causality assessment was evaluated and compared between patient and healthcare Professionals data. **Results:** the AI system demonstrated high accuracy in transcription and translation with WER (4.58%), CER (2.81%), BLEU score (91%), TER (3.67%). AI system completed ADR forms with an accuracy >90% in patient information (100%), suspected ADR (100%), suspected medication (95%), reporter details (95%) and causality assessment (100%). **Conclusion:** AI-enabled systems show potential in improving ADR reporting by automating transcription, translation, and form filling with high accuracy. Future studies should focus on refining ai's handling of complex data and expanding its application in real-world pharmacovigilance.

Assessment of knowledge, attitude and practices (KAP) on adverse drug reactions caused by excipients in medications - among doctors across India

G. Manohar Babu[1], P. Usha Kiran[1]

[1]Department Of Pharmacology, Rangaraya Medical College, Andhra Pradesh

Background: Excipients are Inert substances added to drugs to enhance solubility, stability, and appearance, serving as diluents, binders, disintegrants, lubricants, glidants, flavours, colours and sweeteners. Despite their utility, excipients can occasionally cause adverse drug reactions. **Objectives:** To assess the knowledge, attitude and practices on adverse drug reactions caused by **excipients in medications -** Among doctors across India**. Methodology:** A cross-sectional observational study was conducted among doctors across India with the sample size of 450, in the month of November 2024. A self-administered structured questionnaire consisting of 18 questions was distributed through google forms. MS excel was used to analyse the data and the results are shown as percentages. **Results:** The study shows a **knowledge GAP** on excipients related ADRs. For knowledge - based questions, only **38.2%** of respondents on average gave accurate answers. The overall attitude of participants was positive. 70% feel all doctors should be educated about excipients. 80% feel excipients should be labelled on package insert.80% feel that there should be strict monitoring of excipients in generic drug formulations. **Conclusion:** The study concludes that drug-excipient interactions are critical considerations in drug formulation. Proper excipient selection during pre-formulation studies and adequate labelling on package inserts can significantly aid in identifying agents responsible for ADRs. These measures are essential for preventing future reactions, especially in patients with hypersensitivities, once allergies to active pharmaceutical ingredients have been excluded. Enhancing awareness and education about excipient-related ADRs among healthcare professionals is imperative to ensure safer prescribing practices.

Keywords: Excipients, active pharmaceutical ingredient (API), adverse drug reaction (ADR).

Evaluation of the impact of CME on pharmacovigilance awareness among 2nd prof MBBS students

Pinkey Kannoj[1], Anjali Kushwah[1], Pooja S. Mishra[1]
[1]Mahatma Gandhi Memorial Medical College, Indore (M.P.)

Background: Pharmacovigilance is vital for drug safety by monitoring adverse drug reactions (ADRs). However, awareness and reporting practices among healthcare professionals, particularly medical students, are inadequate. This study examines the effectiveness of a continuing medical education (CME) program in improving pharmacovigilance knowledge and ADR reporting awareness among 2nd prof MBBS students at M.G.M. Medical College, Indore. **Objectives:** To assess the impact of a CME program on the pharmacovigilance knowledge and ADR reporting practices of 2nd prof MBBS students. **Methodology:** A pre-post intervention study was conducted with 250 students. The CME program covered ADR reporting under the pharmacovigilance program of India (PvPI). A pre-test and post-test assessed students' baseline knowledge and knowledge improvement. Paired t-tests were used for statistical analysis to compare pre- and post-test scores. **Results:** the CME program led to significant improvements in pharmacovigilance knowledge. The largest gains were seen in signal detection (76.56%), the role of pharmacovigilance organizations (127.40%), and ADR reporting methods (29.17%). Minimal improvements were noted in basic concepts such as pharmacovigilance definitions (1.08%) and serious adverse events (0.54%). Paired t-test analysis revealed a statistically significant difference (p-value = 0.004) between pre- and post-test scores. **Conclusion:** The CME program effectively enhanced pharmacovigilance knowledge and ADR reporting awareness. Continuous education is essential to strengthen future healthcare professionals' ability to report ADRs accurately. Future research should explore broader student demographics and long-term knowledge retention.

Pattern of administration and outcome of reserve group of antibiotics for neonates/children admitted in ICU- a descriptive study in tertiary health care hospital in south India

Udayanilavan[1], **Mirunalini R[1]**, Maheshwari P[1], Adhisivam B[1]
[1]Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry

Introduction: Sepsis and antimicrobial resistance impose a major burden of disease on a country. The organisms associated vary with time and geographical distribution, making choosing the appropriate antibiotics difficult. We aimed to describe the usage of the reserve group of antibiotics for children admitted to the pediatric/ neonatal intensive care unit (NICU/PICU). **Methodology**: This single-center descriptive study was conducted in a tertiary care hospital, recruited neonates and children with sepsis admitted to then ICU/PICU undergoing treatment with the reserve group of antibiotics. The outcome parameter was to describe the pattern of antibiotic usage with the reserve group, clinical outcome and adverse drug reactions if any. Continuous variables were summarised as mean or median and interquartile range. Categorical variables were summarised as frequency or proportion. **Results**: Between December 2023 to January 2024,160 eligible patients were recruited, of which the median age of neonates, infants and children were 5.5 days, 4 months and 3.5 years respectively with a median duration of hospital stay of 21 days. 75.6%(n=121) of children were administered with meropenem empirically followed by colistin 18.1%(n=29) and linezolid 6.3%(n=10). Death occurred in 48.1%(n=77). Culture-positive results were seen in 57.5%(n=92), of which klebsiella pneumonia

(17.5%; n=28) was common followed by candida albicans (8.1%;n=13) and pseudomonas aeruginosa(8.1%;n=13). **Conclusion**: Our study showed that meropenem is the most commonly administered reserve group of antibiotics with high prevalence of klebsiella pneumonia and candida albicans among children with sepsis.

Keywords: Aware, antimicrobial resistance, sepsis.

A case series on fixed drug eruptions: benign, uncommon but infamous

Suman Supreeti[1], Ratikanta Tripathy[1], Elisha Paikray[1], Laxman Besra[1]

[1]Department of Pharmacology, KIMS, Bhubaneswar

Introduction: Fixed drug eruption (FDE) is an adverse drug reaction that causes recurrent lesions at same site upon re-exposure. These eruptions are sudden onset, well-defined margins, and resolves with hyperpigmentation. The ofloxacin-ornidazole combination, often prescribed for gastrointestinal and genitourinary infections, has been linked to such eruptions. This study analyzes FDE cases related to this drug combination in a tertiary care teaching hospital, focusing on self-medication practices and recurrence patterns. **Objective**: To analyze and evaluate adverse drug reactions (ADRs) related to fixed drug eruption (FDE) from ofloxacin-ornidazole combination in patients at a tertiary care teaching hospital. **Methodology**: patients diagnosed with FDE due to ofloxacin-ornidazole combination were assessed in dermatology OPD at Kalinga Institute of Medical Sciences, Bhubaneswar, Odisha. Detailed data were collected in a case record form. Each case was reported to ADR monitoring centre and assessed using who causality assessment tool. The suspected drug ofloxacin and ornidazole was stopped and patients were managed symptomatically. Patient were followed up to evaluate the resolution of eruptions. **Results**: All 9 patients (ages 18-65; m:f ratio=2:1) exhibited typical FDE lesions. Self-medication occurred in 55% of cases, and 66% had recurrent eruptions. The lips, trunk, and oral mucosa were the most frequently affected areas. Clinical improvement was noted in all patients after stopping the drug and providing symptomatic treatment. **Conclusion**: This case series underscores the potential link between FDE and the ofloxacin-ornidazole combination, necessitating further research to determine its incidence and risk factors.

Keywords: Fixed drug eruption, ofloxacin, ornidazole, adverse drug reaction, self-medication

The unseen complication: a case of dasatinib-induced pleural effusion in pediatric leukemia

Jekish E[1], Akshay Kamlay[1], Vikalp Tiwari[1], Prachi Chaudhary[1], Preeti Malpani[1]

[1]Mahatma Gandhi Memorial Medical College, Indore, M.P

Introduction: Dasatinib, a second-generation tyrosine kinase inhibitor (TKI), is a powerful tool in the treatment of philadelphia chromosome-positive acute lymphoblastic leukemia (ph+ all). However, its use is not without risks. were port the case of a 14-year-oldboywhodevelopedbilateral pleural effusions as a rare yet serious side effect, emphasizing the importance of recognizing this adverse reaction in pediatric patients. **Methodology:** Our patient, a 14-year-oldboydiagnosedwithph+b-all, was started on Dasatinib during the consolidation phase of treatment. Soon after, he developed symptoms of respiratory distress, oxygen desaturation, and radiological findings consistent with b/l pleural effusion and pulmonary edema. Further evaluation revealed bilateral pleural effusions and ascites, necessitating his admission to the

pediatric intensive care unit (PICU). Treatment included diuretics, and dasatinib was temporarily withheld to allow for clinical improvement. **Discussion:** Dasatinib-induced pleural effusion is believed to result from increased endothelial permeability and the involvement of inflammatory mediators. In this case, the close temporal relationship between the initiation of dasatinib and the onset of pleural effusion, along with the exclusion of other causes, probably suggests that the drug was the culprit. After a period of with holding the drug, dasatinib therapy was resumed at an adjusted dose without recurrence of effusion. **Conclusion:** This case under scores the need for vigilant monitoring of pleural effusion in pediatric patients receiving dasatinib. Early detection and appropriate management are critical to avoid potentially life-threatening complications while ensuring the continuation of effective therapy.

Data-driven insights into vector-borne disease vaccines: a VAERS database approach to signal detection

Pramod Kumar Adusumilli[1], Deeksha[1], Ajoshson Jhon[1]
[1]Dept. Of Pharmacy Practice, Faculty of Pharmacy, M.S. Ramaiah University of Applied Sciences, Bangalore

Background: monitoring the safety profile of vector-borne disease vaccines is crucial to ensure they remain safe, effective, and widely accepted. Due to the complexity and variability of immune responses, this monitoring is an ongoing and dynamic process that plays a key role in the success of vaccination programs. **Objective:** This study was conducted to identify potential signals and provide evidence for safety of the vaccine to support clinical decision-making. **Methodology:** A retrospective case-non-case disproportionality analysis was conducted to detect safety signals for the Japanese encephalitis, dengue, yellow fever, and chikungunya vaccines using real-world data from the vaccine adverse event reporting system (VAERS) database. Data mining algorithms, including reporting odds ratio (ROR) and chi-square ($\chi 2$) statistic, were applied. Adverse reactions were considered positive signals if the PRR was ≥ 2 and the chi-square value was ≥ 4. **Results:** A total of 1,872,495 adverse events were recorded in the database, with 4,123 cases linked to the Japanese encephalitis vaccine, 135 cases to the chikungunya vaccine, 254 cases to the dengue vaccine, and 16,634 cases associated with the yellow fever vaccine. Signal detection analysis identified the following potential safety signals: dysstasia and periarthritis for Japanese encephalitis, malaise for chikungunya, chest discomfort and loss of consciousness for dengue, and amblyopia and abasia for yellow fever. **Conclusion:** The current study identified potential adverse reactions associated with the use of these vaccines. Further pharmacogenetic and Pharmaco epidemiological research is needed to validate these findings and confirm the link between the vaccines and the reported reactions, ultimately enhancing patient safety and supporting informed clinical decision-making.

'Knowledge and attitude and practice of Materiovigilance among undergraduate medical students at a tertiary care institute in central India'

Ranjana Kale[1], Nishigandha Bangal[1]
[1]Dept. Of Pharmacology, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha

Introduction: Materiovigilance is monitoring safety of medical devices as it is equally important to monitoring drugs for patient safety. However, a significant issue globally is the underreporting of medical device adverse events (MDAES), often due to lack of awareness,

inadequate understanding and negative attitudes among healthcare professionals towards spontaneous reporting. We need a RMP to understand the threats of adverse effects caused by medical devices and the importance of reporting them in time. This study focuses on second-year medical students, who are emerging healthcare professionals expected to use various medical devices in the future, to address this concern. **Methodology:** a comparative analysis study was conducted. A questionnaire was given to 2nd MBBS students to check their existing knowledge on Materiovigilance. A workshop was conducted where concepts of pharmacovigilance and Materiovigilance were introduced. Post-test was conducted by filling the same questionnaire again. The pre and post test results were compared and impact of the workshop was measured. **Results:** Before the workshop 86% students were able to define MDAES, 64% of them knew that MDAES have to be reported and 70% knew who all can report them. Only 20% of them had seen the medical device adverse event form and 88% thought that reporting of adverse event will enhance patient safety and quality of patient care. Post workshop, 96% students were able to define MDAES, 98% of them knew that MDAES have to be reported and who all can report them. All of them have seen the medical device adverse event form and now think that reporting of adverse events will enhance patient safety and quality of patient care.

Efficacy, safety, and cost of therapy for glycolic acid vs. Azelaic acid in treatment of melasma

Purna Pandya[1], Nandini Raghva[2], Sreelakshmi Ts[2], **Rima Shah[3]**, Roshani Shetty[2], Snigdha Singh[2]

[1]Department of Dermatology, Sal Institute of Medical Sciences, Ahmedabad, Gujarat

[2]Department of Dermatology, GMERS Medical College and General Hospital, Gandhinagar, Gujarat, India

[3]Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Rajkot, Gujarat

Objective: to compare efficacy, safety, and cost of the treatment among topical glycolic acid (ga) and azelaic acid (aa) in melasma patients. **Methodology:** A total of 80 patients with melasma were randomized into two groups of 40 each and received either topical ga (12%) or aa (20%). Their demographic data, detailed clinical history, and systemic and complete local skin examination were carried out. Masi scoring and adverse events were recorded at baseline, 2, 4, 6, and 8 weeks after treatment and compared. The total cost of therapy was calculated and compared. **Results:** Most patients belong to 24-35 years with a female preponderance. No statistically significant difference was found for risk factors like exposure to sunlight, hormonal contraceptives, fitzpatrick skin type, and affected site among both groups ($p>0.05$). The mean MASI score in the aa and ga groups, respectively, was 5.13 and 4.84 at the baseline ($p=0.48$) which reduced to 4.57 and 4.86 in the aa and ga groups correspondingly ($p>0.05$) in the first week.in the 8th week, the mean MASI score was 2.82 and 2.88 in the aa and ga groups($p>0.05$). There was no statistically considerable difference in the prevalence of side effects between the two groups ($p>0.05$). all the ADRs were of "possible" category as per who- UMC criteria and only one was preventable ADR. The total cost of treatment was rs.1410 and rs.430 per patient for the AA and GA groups respectively ($p<0.05$). **Conclusion:** there is no noticeable difference between aa and ga in terms of their effectiveness and safety profiles while treating melasma but the cost of treatment was significantly higher with azelaic acid.

Note: this study has been accepted for the publication in a PubMed indexed journal but not yet published.

A prospective observational study on off-label use of medications in psychiatric and paediatric outpatient departments of a tertiary care hospital

Shubham Gadaria[1], Sapna More[1], V.S. Pal[1], Anjali Bharani[1]
[1]Mahatma Gandhi Memorial Medical College, Indore

Background: Off-label prescribing is using drugs beyond their approved indications, doses, or populations. Studies suggest 30-40% of psychiatric prescriptions and 50-90% of paediatric prescriptions in India are off-label, raising concerns about safety, efficacy, and regulatory gaps. Despite its frequency, data on off-label prescribing patterns remain limited, regarding associations with demographic variables and therapeutic appropriateness. **Objective**: This study aims to determine the prevalence, pattern, and factors associated with off-label prescribing in the psychiatry and paediatric outpatient department of a tertiary care hospital in India. Specific objectives include identifying common psychiatric and paediatric conditions associated with off-label use. **Materials and methods**: A prospective, observational cross-sectional study was conducted over three months among patients attending the psychiatric and paediatric outpatient department. Demographic data, clinical history, and prescriptions were collected using a predesigned proforma. Prescriptions were analysed against the national formulary of India (6th edition, 2021) and central drugs standard control organisation (CDSCO) records to determine off-label status. **Result:** A total of 1,000 patients, 500 from the psychiatry OPD and 500 from the paediatric OPD, were enrolled in this study. The prevalence of off-label prescriptions was 66.8% in the psychiatry opd and 28.6% in the paediatric OPD. Atypical antipsychotics were the most commonly prescribed off-label drugs in psychiatry, while antibiotics were most frequent in Paediatrics. Inappropriate indications were the primary reason for off-label use in psychiatry, whereas inappropriate dosing was the leading cause in Paediatrics. **Conclusion:** Off-label prescribing is common in psychiatric and Paediatric OPDs, highlighting the need for stricter regulations and evidence-based guidelines to ensure safety and appropriateness.

Assessment of awareness, attitude and practice of Materiovigilance among healthcare professionals and analysis of adverse events of medical devices at tertiary care hospital

Bansari Patel[1], Ishita Tannarana[1], Gadhwal Khayati[1], Akshay Shah[1], Alpa Gor[2]
[1]Anand Pharmacy College, Anand
[2]Department of Pharmacology, Pramukh Swami Medical College, Karamsad

Introduction: The growing complexity and use of medical devices have increased medical device-associated adverse events (MDAES), threatening patient safety. Materiovigilance is vital for monitoring and prevention, but healthcare professionals' (HCPS) awareness and engagement vary. This study analyzes MDAES and evaluates HCPS knowledge and practices to improve patient safety and prevent recurrence. **Methodology:** A cross-sectional study was conducted at a tertiary hospital in Gujarat (Jan–Mar 2024) involving a 30-question Materiovigilance survey. MDAES reported in 2 years were collected. Data analysis used excel and Minitab 22.1. Chi-square tests compared subgroup responses. **Result:** Participants exhibited a positive attitude (72.64%) and average knowledge (51.84%) on Materiovigilance; however, only 39.05% implemented it in practice. Time constraints and insufficient training were primary barriers. Category b devices accounted for most MDAES (76%), followed by c (16%), a (5%), and d (3%). **Conclusion:** The study reveals that while healthcare professionals possess baseline

knowledge and positive attitudes towards Materiovigilance, it's not adequately reflected in reporting practice. Targeted training and availability of offline forms can help bridge this gap. High-risk areas like the CCU, along with frequently implicated devices such as endotracheal tubes and adhesive bandages, require focused and vigilant monitoring. Consistent surveillance and safety measures for category b devices are crucial, given their widespread impact across various departments.

Gene-Drug Interaction Databases: A Need for India-Specific Pharmacogenetics resources

Harshit Prashant Desai
Department Of Pharmacy Practice, Anand Pharmacy College

Introduction (background and objective):
The integration of pharmacogenetics into clinical practice has the potential to revolutionize medicine by optimizing therapeutic effects and minimizing adverse drug reactions (ADRs). Despite India's rich genetic diversity, the absence of a population-specific gene-drug interaction database forces clinicians to rely on resources designed for western populations, which are inadequate for predicting drug responses in the Indian context. This review aims to highlight the critical need for India-specific pharmacogenetic resources to enhance precision medicine and improve therapeutic outcomes. **Methodology:** This review discusses genetic heterogeneity in the Indian population, focusing on specific genetic variants influencing drug response, such as cyp2c192 for clopidogrel metabolism, HLA-b1502 for carbamazepine-induced adverse events, and vkorc1 genotype for warfarin dosing. It also explores the necessity of integrating real-world data, genetic diversity, and drug utilization patterns to develop a comprehensive gene-drug interaction database. The review proposes frameworks involving collaborations with initiatives like the Pharmacovigilance Programme of India (PvPI), digital health tools, and big data analytics to facilitate this integration. **Results:** The analysis emphasizes the significant role of a pharmacogenetic database in revolutionizing clinical decision-making, drug development, and regulatory policies in India. Such a resource could enable clinicians to adopt precision medicine approaches, reduce ADRs, and achieve better therapeutic outcomes. **Conclusion:** The development of India-specific pharmacogenetic resources is crucial to addressing healthcare disparities, improving drug safety and efficacy, and enabling personalized medicine. Leveraging India's unique genetic diversity could position the country as a global leader in pharmacogenetics and individualized medicine. **Keywords**: Pharmacogenetics, Personalized medicine, gene-drug interactions, genetic polymorphism, adverse drug reactions.

Assessment of knowledge, attitude and practices related to antimicrobial stewardship among interns and residents of a tertiary care health institute - A questionnaire based cross-sectional study

Dr. Brijesh Kumar R Vidja[1], Dr. Amit S. Mutha[1]
[1]Department Of Pharmacology, Government Medical College, Jalgaon, Maharashtra

Introduction: Antimicrobial stewardship (AMS) programs are strategic initiatives designed to optimize antibiotic use and mitigate the growing threat of antimicrobial resistance (AMR), a critical global health challenge. The misuse of antibiotics—driven by over-prescription, self-medication, and inadequate awareness among healthcare professionals—diminishes drug

efficacy, complicates treatment outcomes, and escalates healthcare costs. This study investigates the knowledge, attitudes, and practices (KAP) of interns and residents regarding AMR and AMS to promote evidence-based prescribing and improve patient outcomes. **Methodology:** A cross-sectional survey of 200 interns and residents at a tertiary care health institute was conducted over two month. Data were collected using a structured, validated questionnaire and analyzed with Microsoft Excel 365 (version 2412) and Open Epi (version3.01) **Results:** Total Response rate from intern and residents is 177(84.29%) out of 200 participants, Including 57 Residents and 120 interns. Overall 68.36% respondents were aware of antimicrobial stewardship, 42.37 % opted for alternatives when antibiotics were unnecessary. There is significant difference in knowledge, attitude and practices regarding AMS among interns and residents. **Conclusion:** The study concluded that there is varying levels of KAP regarding rational antimicrobial use between interns and residents. Over all residents demonstrated better knowledge, attitude and practices than interns regarding AMS and AMR. **Keywords:** Antimicrobial Stewardship (AMS), Antimicrobial Resistance (AMR), Knowledge, Attitude, Practices (KAP).

Assessment of Knowledge, attitude and practices related to Adverse drug reaction (ADR) reporting among undergraduate students and healthcare providers-a cross-sectional study

Priyanka Madhukar Ahire[1], Pravin S Lohar[1], Ritesh Sonawane[1], Harshal Mahajan[1]
[1]Government Medical College, Jalgaon, Maharashtra

Introduction: Adverse Drug Reactions (ADRs) significantly contribute to morbidity and mortality, yet underreporting remains common due to limited knowledge and training. This ongoing study assesses and compares the knowledge, attitudes, and practices (KAP) of ADR reporting among healthcare professionals in a tertiary care institute. **Methodology:** This cross-sectional study targets 226 participants over period of one month, including undergraduate students, interns, residents, and faculty members. data were collected using structured questionnaires and compiled in Microsoft excel. analysis was performed using SPSS version 23. **Preliminary results:** Thus far, 145 responses have been collected (75 interns, 30 residents, 15 faculty, and 25 undergraduates). Awareness of ADRs is highest among faculty (93.3%), followed by residents (86.7%), interns (48%), and undergraduates (36%). Familiarity with causality assessment methods is limited (60% among faculty, 50% residents, 18% interns, 12% undergraduates). Major barriers include inadequate training and complex reporting processes. **Conclusion**: Preliminary findings highlight significant knowledge gaps, particularly among undergraduates and interns. Strengthening pharmacovigilance training at early stages of medical education is essential to improve ADR reporting practices and patient safety.

Keywords: adverse drug reaction reporting, pharmacovigilance

An evaluation of drug utilization pattern and safety of high-alert medications in intensive care unit at a tertiary care hospital

Pranav K. Govani[1], Jigar Kapadia[1], Chetna K. Desai[1]
[1]Department of Pharmacology, B.J. Medical College, Ahmedabad

Introduction: High-Alert Medications (HAMs) used frequently in Intensive Care Units (ICUs). A narrow therapeutic index makes these drugs vulnerable to medication errors and serious harm to patients. **Objectives:** This study was done to evaluate prescribing pattern and safety of hams

in terms of adverse drug reactions (ADRs) in patients admitted to ICUs at a tertiary care hospital. **Methodology:** this prospective, observational study included adult patients admitted in ICUs who were prescribed hams. The list of hams was drawn from the institute of safe medication practices (ISMP)–2018.thedemographic characteristics, history of presenting illness, comorbidities, prescribed hams, concomitants medicines and ADRs were noted throughout ICU stay of the patients. Data was analysed using pears on correlation & fisher's exact tests. **Results:** The mean age of 225 patient enrolled was 48.39±16.97 years with m:f of 2.17:1. Total 33 different hams were prescribed with an average of 1.48hams/day/patient(SD=1.10). Most common hams prescribed were nor ADR enaline (19.47%), insulin (9.24%), dextrose-25(8.60%), tramadol (8.60%) and3%normal saline (7.25%) respectively. A total 49 ADRs were reported of which 24(46.94%) were due to hams. Nor ADR enaline was the most casual drug (10,41.67%). Ten serious ADRs were reported. Pearson correlation shows positive correlation between use of hams and co-morbidities (r value=0.301, weak correlation).no statistically significant association was observed between ADRs and number of hams prescribed (p value=0.4– fisher's exact test). **Conclusion:** HAMs are used frequently in ICUs. Though most of the hams showed good safety profile, frequency of serious ADRs with hams is high. Hence a close monitoring of their safety and use is required.

Role of genetic testing in aids patients before initiating art therapy- a systematic literature review

Tarun Tripathi[1], Kamayani Gupta[1], Pooja Solanki[1]
[1]Department of Pharmacology, MGM Medical College, Indore

Objectives : To assess the prevalence of genetic marker HLA-b*5701 in various populations.
To evaluate the evidence linking genetic testing to reduced adverse drug reactions and improved treatment outcomes. **Methodology**: A systematic literature review was conducted, including studies from PubMed, Scopus, web of science, and Cochrane library, along with relevant guidelines and reports from organizations such as who, CDC, and UNAIDS. Grey literature, such as conference abstracts and non-peer-reviewed reports, was also considered.
Results: **Prevalence**: HLA-b*5701 prevalence is highest in individuals of European descent (5-8%) and lower in African (0.5-2%) and Asian populations (1-3%).**Impact of genetic testing**: screening for HLA-b*5701 significantly reduced abacavir-related hypersensitivity reactions by 50-90%.**Improved outcomes**: genetic testing prior to art improved adherence, reduced treatment interruptions, and enhanced overall outcomes. Routine testing was found to be cost-effective in populations with moderate-to-high HLA-b*5701 prevalence. **Quality of evidence**: strong support for genetic testing was found in randomized controlled trials and observational studies.
Conclusion: this systematic review highlights the significant role of **HLA-b*5701 genetic testing** in minimizing adverse drug reactions to abacavir, particularly hypersensitivity reactions, and in enhancing treatment adherence and outcomes in aids patients. The findings underscore the importance of **pre-treatment genetic screening** as a component of personalized medicine in antiretroviral therapy. Further efforts are needed to expand genetic testing access in low-resource settings among underrepresented populations to ensure equitable care.

Capecitabine-induced hand-foot syndrome in a 34-year-old patient with anorectal cancer: a case report

Anurag Sharma
Department Of Pharmacology & Therapeutics, King George's Medical University

Background: Capecitabine, the oral prodrug of 5-fluorouracil (5-fu), is widely used for treating solid tumors like colorectal cancer. Hand-foot syndrome (HFS), or palmar-plantar erythrodysesthesia, is a well-known side effect of capecitabine. **Case summary:** patient profile: 34-year-old patient with a known case of anorectal cancer. Clinical presentation: after 2 weeks of capecitabine-based chemotherapy, the patient presented with: bilateral painful erythema on palms and soles. Swelling, warmth, blister formation, and skin desquamation. **Diagnosis:** Symptoms correlated with hand-foot syndrome (HFS), based on:Timing of symptom onset. absence of infection or other skin disorders. **Management:** dose reduction: to reduce toxicity while maintaining capecitabine's efficacy, oncologists lowered the dose. Supportive care: use of comfortable shoes and topical application of coconut oil for symptom relief. **Discussion:** HFS occurs due to the accumulation of 5-fu in the palms and soles, leading to skin irritation and toxicity. Early detection and management of HFS are critical to avoid compromising treatment efficacy, which may occur due to dose reductions or treatment discontinuation. **Conclusion:** This case highlights successful management of capecitabine-induced HFS through early diagnosis, dose adjustment, and patient education. Clinicians should remain vigilant for HFS symptoms in patients receiving capecitabine to ensure optimal treatment outcomes.

Adverse drug reaction to apremilast in a patient with vitiligo: a case report

Zoya Khan
Department of Pharmacology & Therapeutics, King George's Medical University

Background: Apremilast, A Phosphodiesterase-4 (PDE4) inhibitor, is approved for psoriatic arthritis, plaque psoriasis, and behçet's disease but has off-label applications for autoimmune conditions like vitiligo. Despite its therapeutic benefits, gastrointestinal adverse drug reactions (ADRs) such as Diarrhoea, abdominal discomfort, and bloating can occur. Case summary: a 47-year-old male with type 2 diabetes mellitus (T2DM) and vitiligo was prescribed apremilast (30 mg every alternate day). Starting from July 21, 2024, the patient experienced gastrointestinal symptoms (abdominal discomfort, bloating, increased stool frequency) occurring 20–30 minutes post-dose. Symptoms resolved within hours but recurred with subsequent doses. The patient self-discontinued the medication on august 5, 2024. Follow-up revealed no prior ADR history and normal dietary or lifestyle changes. Mildly elevated liver enzymes and bilirubin levels were noted during laboratory evaluations. Management: Drug discontinuation: apremilast was stopped after persistent gastrointestinal symptoms. Supportive care: symptoms resolved spontaneously; no additional treatment was needed. Monitoring: lab tests showed mild liver enzyme elevations but no systemic complications. Alternative treatment: continued existing vitiligo therapies (Melasone forte, Halobetasol, tacrolimus). Discussion: This case highlights the potential for gastrointestinal adverse drug reactions (ADRs) with apremilast, especially during off-label use for conditions like vitiligo. While apremilast effectively modulates inflammatory pathways, its side effects, such as abdominal discomfort, bloating, and diarrhea, may limit tolerability. This emphasizes the need for careful risk-benefit analysis and adherence to pharmacovigilance practices to ensure patient safety. Conclusion: This case underscores the importance of ADR monitoring, particularly for off-label drug use. Although apremilast effectively reduces

inflammation, it may cause significant gastrointestinal side effects. Enhanced patient education and vigilant pharmacovigilance are essential to mitigate risks.

Assessment of knowledge, attitude and awareness towards oral hypoglycemic agents fixed-dose combination among the residents' doctors

Himanshi Yadav[1], S. P. Mahapatra[1], R.N. Tiwari[1], Pawan K. Maurya[1]
[1]Department of Pharmacology, SSMC Rewa

Introduction: The Indian Pharmaceutical market is flooded with different fixed-dose combination with intent of providing benefits primarily to patients and physician. Many patients with type 2 diabetes mellitus(T2DM) do not achieve satisfactory glycaemic control by monotherapy alone, and often require multiple oral hypoglycemic agents (OHAs). In last 5 years more than 45 OHA FDC are approved by CDSCO to be marketed with different strengths (potencies). Nevertheless, despite their multiple advantages, they have their own set of drawbacks, especially regarding irrational FDCs. **Aims and objectives:** The aim of this study is to evaluate the knowledge, attitude and awareness regarding OHA FDCs among the residents at tertiary care teaching hospital. **Methodology:** An observational cross-sectional pre-designed questionnaire via google form based analysis was undertaken to assess the knowledge, attitude and awareness regarding OHA FDCs among the residents of S.S.M.C. and S.G.M.H, Rewa (MP) **result:** Among 63 responded residents, 33, 30 and 3 were from medicine, surgery and pharmacology dept. Respectively. On an average of 60.7% residents have good knowledge (lowest 16%:1st year). The major source of information regarding FDC is from scientific medical journals and essential medicine list (36.4% both). Their attitude were 70% towards OHA FDC rationality and prescribing pattern. The residents opined the most commonly preferred OHA FDC is SGLT-2+ sulphonylureas+ biguanides (45.5%) but only 9.1% residents have knowledge about latest approved FDC. **Conclusion:** it was found that knowledge, attitude and awareness towards OHA FDC was found on same level in all participated residents and they wanted to be made aware about newer OHA FDC periodically.

Envisaging signals pertinent to citalopram induced hepatic steatosis-a disproportionality analysis in FAERS database validated through cutting-edge bioinformatics and in silico techniques

Saraswathy GR[1], Pramod Kumar[2], Gouri Nair[1], Siyad KV[1]
[1]Dept. Of Pharmacy Practice, Faculty of Pharmacy, M.S. Ramaiah University of Applied Sciences, Bangalore

Background: Citalopram, an SSRI approved for depression, is also used off-label for panic disorder, alcohol addiction, OCD, and post-menopausal flushing. Literature reveals possible links to hepatic steatosis (HS), prompting an analysis of the FAERS database and bioinformatics investigation. **Objective:** To identify the connection between hepatic steatosis (HS) and citalopram, to conduct a disproportionality analysis using FAERS database and to explore the underlying mechanism through in silico techniques. **Methods**: Data from the FAERS database was used for disproportionality analysis, employing reporting odds ratio (ROR) and proportional reporting ratio (PRR) as measures. A positive signal was indicated by ror-1.96se >1, PRR≥2, and $\chi^2 \geq 4$. Openvigil 2.1 facilitated data extraction. To confirm the mechanism of citalopram-induced hepatic steatosis, relevant DEGs from GSE151158 were analyzed via GEO2R, and binding

affinity with DEGs was assessed using AutoDock Vina. **Results**: the FAERS database contained 11,859 reports of hepatic steatosis, with 111 (0.94%) linked to citalopram. Initial disproportionality analysis revealed FOR and PRR values of 3.33 (95% ci 2.87-3.87) and 3.32 (95% ci 2.86-3.85), respectively. After filtering confounding factors, refined values were ROR 3.30 (95% ci 2.84-3.85) and PRR 3.25 (95% ci 2.78-3.78). DEGs analysis identified 6 hub genes with significant interactions, confirmed through docking studies. **Conclusion**: this study discovered a novel adverse effect of citalopram, emphasizing the importance of monitoring liver function before and during treatment. As citalopram is often prescribed long-term, hepatic steatosis may progress to irreversible liver damage. These findings should be validated through more rigorous studies in diverse clinical settings.

Left- Over medications: a community-based study among households in central districts of Telangana

Rekha Priyadarshini[1], Gerard Marshall Raj[1], Madhavi Eerike[1], Debasis Bisoi[1]
[1]Dept. of Pharmacology, AIIMS Bibinagar, Hyderabad

Introduction: Left-over medications are prescription/over-the-counter drugs that remain surplus/unused after treatment completion. Storing left-over medications for potential future use contributes to significant drug wastage (unused/expired). Additionally, inappropriatere use can result in antimicrobial resistance and ADRs. **Methods:** An observational cross-sectional study was conducted among households from Bibinagar and Kondamadugu (Yadadri-Bhuvanagiri District) and Ghatkesar (Medchal-Malkajgiri District) mandals. Households who were having allopathic medicines were included in this studyto assess the proportion of, Left-over medications out of total drugs, reused left-over medications, Households reusing left-over medicines inappropriately, expired left-over medications, Households reusing expired left-over medications. The medication details were retrieved using a comprehensive data collection form. **Results and discussion:** out of 285 households, 58.2% (166) were having left-over medications. The left-over medications were 406 (35%) out of the total 1179 drugs present in households. Most of them were NSAIDs (31%) and antihistamines (14%). The average left-over medication per household was 2.5 with 10 being the highest. 159 left-over medications (from 74 households) were reused out of which 44 were purchased over-the-counter.17left-over medications were inappropriately reused– for instance, atorvastatin-aspirin for gastric issues, ethambutol-isoniazid for fever, and cefditoren-pivoxil for cough. Indications were unknown for most of the reused medications. Overall, 31 left-over medications were expired and out of which >32% were reused. The expiry details were not found for 69 left-over medications out of which >36% were reused. In conclusion, left-over medications, which constituted >1/3rd of the total medications, were present in nearly 60% of surveyed households. Nearly 50% of the households reused the left-over medications; in 23% of these households, the left-over medications were inappropriately reused. Around 25% of left-over medications were found to be expired or the details of which are unknown and nearly 1/3rd of the expired left-over medications were reused.

Keywords: left-over medications, unused medications, households

Study of prescribing pattern of antiglaucoma drugs used in treatment of primary open angle glaucoma in ophthalmology outpatient department in a tertiary care teaching hospital

Rajendra Singh Mandloi[1], Sanjay Gedam[1]
[1]Department Of Pharmacology, N.S.C.B. Medical College & Hospital Jabalpur (M.P.)

Introduction- Glaucoma is a condition in which distinctive changes occur in the optic nerve and visual field.it is characterized by raised intraocular pressure (IOP) that compresses and damages the optic nerve.as the optic nerve is damaged, it fails to carry the visual information to the brain which cause clinically progressive loss of peripheral visual field and ultimately loss of vision. Glaucoma persists as the second-leading cause of blindness worldwide. according to the who and global glaucoma initiative, approximately 80 million people worldwide suffer with glaucoma, and this number is expected to increase to over 111 million by 2040.treatment of glaucoma depends on the type of disease. It can be treated with eye drops, oral pills, laser open surgical procedure, or a combination of methods. the whole purpose of treatment is to prevent further loss of vision. **Objective -** Study of prescribing pattern of antiglaucoma drugs used in treatment of primary open angle glaucoma in ophthalmology outpatient department in a tertiary care teaching hospital. **Methodology -** Study Design- Observational Study population-patients receiving antiglaucoma drugs Study area-department of ophthalmology at NSCB medical college and hospital, Jabalpur. Study duration -October 2024-december 2024 sample size- 150 patients enrolled in to the study **results -** the final results are pending and will be ready by December end. **Conclusion -**this study aims to study of prescribing pattern of antiglaucoma drugs used in treatment of primary open angle glaucoma in ophthalmology outpatient department in a tertiary care teaching hospital. the preliminary results are promising, and i look forward to presenting the final results soon.

Optimising Asthma Management: head-to-head comparison of Fluticasone and Montelukast

Vidushi Suneja[1], Girik Subudhi[1]
[1]Rohilkhand Medical College and Hospital, Bareilly

Introduction: Asthma, a chronic inflammatory disorder of the airways, significantly impacts the quality of life of millions of individuals worldwide. The cornerstone of asthma management involves pharmacological interventions, with first-line medications such as inhaled corticosteroids (ICS) and β2-agonists forming the primary treatment regimen.[1] These medications are highly effective in reducing airway inflammation and improving lung function but are not devoid of adverse drug reactions (ADRs). In contrast, leukotriene receptor antagonists (LTRAs), such as montelukast, have emerged as a complementary or alternative therapy for asthma management.[2] While LTRAs are generally considered safer and easier to administer due to their oral formulation, their efficacy is often perceived as secondary to first-line medications.[3] However, the profile and severity of ADRs associated with these two classes of drugs remain a subject of interest. Understanding these differences is crucial for optimizing patient outcomes, enhancing medication adherence, and minimizing treatment-associated risks.[4] This research aims to conduct a comprehensive differentiation of ADRs between LTRAs and first-line asthma medications. By analyzing clinical evidence and adverse event databases, this study will contribute to a more nuanced understanding of their safety

profiles, guiding clinicians in personalizing asthma management strategies. Aim: To compare the efficacy and ADRs of Montelukast (LTRAs) and Fluticasone (inhaled corticosteroid). Objective: To compare the efficacy of inhaled Florticosone and oral Montelukast in achievening the asthma control in adult patients. **Methodology**: • Method Database: The Electronic Medicines Compendium (EMC) and the European Molecular Biology Laboratory (ChEMBL) database were utilized to gather information on the adverse drug reactions of montelukast, zafirlukast, beclomethasone, and salbutamol. • Inclusion criteria: 1. Population: Studies encompassing all age groups irrespective of their gender and demographic characteristics were included. 2. Databases Included: A comprehensive search was conducted across major electronic databases, including PubMed, Google Scholar, Embase, RDiscovery, and CINAHL. 3. Search Terms: The following keywords were utilized: "montelukast", "zafirlukast", "first-line asthma medications", "asthma", and "asthma medication". 4. Extended Search: To ensure comprehensive coverage, reference lists of included studies were meticulously examined for additional relevant research. 5. Language: Only English-language publications were considered for inclusion. 6. Types of Papers Searched: Both full-text and half-text articles were included in the analysis. Abstracts were also used for reference. • Exclusion criteria: 1. All relevant articles which were not in english language. 2. Duplicate records. 3. Those articles which did not state the ADRs. Result: 1. Adverse Drug Reactions in LTRAs (Montelukast and Zafirlukast): - Common ADRs: - Headache - Fatigue - Gastrointestinal disturbances (e.g., nausea, diarrhea) - Neuropsychiatric effects: anxiety, agitation, depression, and in rare cases, suicidal ideation (more frequent in montelukast). - Rare but serious ADRs: - Churg-Strauss syndrome (eosinophilic vasculitis). - Liver dysfunction (more associated with zafirlukast). 2. Adverse Drug Reactions in ICS (Beclomethasone): - Common ADRs: - Oral candidiasis (thrush) - Hoarseness (dysphonia) - Throat irritation - Rare but serious ADRs (with long-term or high-dose use): - Adrenal suppression - Growth retardation in children - Osteoporosis **Conclusion**: - Leukotriene receptor antagonists (LTRAs), such as montelukast and zafirlukast, are associated with a unique ADR profile, particularly neuropsychiatric symptoms, which should be closely monitored, especially in pediatric and adolescent populations. - SABAs like salbutamol are effective but frequently cause cardiovascular ADRs (e.g., tachycardia and tremors), especially at high doses. - Inhaled corticosteroids (ICS) like beclomethasone have a localized ADR profile (e.g., oral thrush) but can cause systemic effects with prolonged use. - Overall, the choice of therapy should balance efficacy with the risk of ADRs, considering individual patient needs, comorbidities, and age.

Evaluation of Antihypertensive Agents in Alzheimer's Disease: A Preclinical Study on Telmisartan and Nifedipine

Abhinav Tiwary[1], Irfan Ahmad Khan[1], Farhan Ahmad Khan[1], Murad Ahmad[1]
[1]Department of Pharmacology, JNMC, AMU

Introduction: Alzheimer's disease is a progressive neurodegenerative disorder characterized by cognitive decline, amyloid-beta plaques, and tau tangles. The pathophysiology involves neuroinflammation, oxidative stress, and cholinergic system dysfunction. Hypertension is a significant risk factor for AD, suggesting a potential therapeutic role for antihypertensive drugs. This study evaluated the effects of telmisartan, an angiotensin ii receptor blocker, and nifedipine, a calcium channel blocker, in animal models of AD. **Methods:** In male and female wistar albino rats (150–200 g), scopolamine (2 mg/kg i.p. For 4 weeks) was used to induce alzheimer's disease. rats were treated with either telmisartan (1 mg/kg and 3 mg/kg) or nifedipine (3 mg/kg

and 10 mg/kg) as test drugs and donepezil as positive control. behavioral assessments and biochemical evaluations were done. Histopathological analysis of brain tissue was also performed. **Results:** telmisartan treatment demonstrated significant improvement in cognitive performance with reduction in MDA levels (7.5-8 nmol/ml), increase in GSH levels (4.2-4.6mg/l), decrease in AChE(10.5-11 ng/ml) activity and increase in TNF-α levels (116-122 pg/ml). In contrast, nifedipine treatment showed significant mortality in rats. Nifedipine treatment did not demonstrate significant improvement in cognitive performance in behavioural and biochemical evaluation. **Conclusion:** Telmisartan demonstrated promising therapeutic potential in preclinical models of ad, exhibiting positive effects on cognitive function, oxidative stress, ache activity, and neuroinflammation. Nifedipine, however, did not show any beneficial effects in this study.

Keywords –alzheimer's disease, telmisartan, nifedipine, scopolamine, AchE, TNF-alpha

Safety profile of triple therapy with dapagliflozin, vildagliptin, and metformin compared to dual therapy in uncontrolled type 2 diabetes

Shemeer PS[1], Farhan Ahmad Khan[1], Hamid Ashraf[2]

1. Department of Pharmacology, JNMC, AMU, Aligarh
2. RGCE, JNMC, AMU, Aligarh

Background: type 2 diabetes mellitus (T2DM) often requires combination therapy to achieve optimal glycemic control. Fixed-dose combinations (FDCs) of SGLT-2 inhibitors and DPP-4 inhibitors with metformin improve efficacy and safety compared to dual therapies. **Objective:** to evaluate the safety profile of FDC therapy (dapagliflozin, vildagliptin, and metformin) versus dual therapies (dapagliflozin + metformin or vildagliptin + metformin) in patients with poorly controlled T2DM on metformin. **Methodology:** This 24-week randomized; open-label study enrolled 240 T2DM patients inadequately controlled on metformin. Patients were randomized into four groups: group 1 (dapagliflozin + vildagliptin + metformin FDC), group 2 (dapagliflozin + metformin FDC), and group 3 (vildagliptin + metformin FDC). Adverse drug reactions (ADRs) were assessed using the Naranjo probability scale and the modified Hartwig and Siegel severity scale. **Results:** ADRs were recorded in 10 patients: group 1 (4), group 2 (2), and group 3 (1). Common ADRs included nausea, gastrointestinal distress, Hypoglycemia, and increased urination. Most ADRs were mild and resolved without intervention. No severe ADRs were observed. **Conclusion:** FDC therapy with dapagliflozin, vildagliptin, and metformin demonstrated a comparable safety profile to dual therapies. The low incidence and mild severity of ADRs suggest that FDC therapy is a safe option for managing poorly controlled t2dm. Further studies are warranted to confirm these findings.

POSTER PRESENTATIONS

Adverse drug reaction of ceftriaxone: periorbital edema as a case presentation

Anaskhwaja[1], Sanjay Khanna[1]

[1]Dept. Of Pharmacology, Career Institute of Medical Sciences & Hospital, Lucknow

Background: Ceftriaxone, a third-generation cephalosporin, is used for its broad-spectrum efficacy. It can induce adverse reactions, including rare periorbital & facial edema probably an allergic or hypersensitivity reaction, often mediated by IgE antibodies. **Objectives :** To demonstrate one of the adverse effect of ceftriaxone**. Methodology:** in this case study, a 34-year-old male patient with history of fever and pain abdomen for 5-7days was administered 1gm ceftriaxone i.v, which was non-reactive initially. Later, he developed periorbital edema. Immediate discontinuation and administration of 2ml i.v pheniramine maleate (Avil) was given to manage the allergic reaction. It was documented and follow-up care was provided to the patient. **Results:** On administration of ceftriaxone, the patient developed periorbital edema characterized by significant swelling and puffiness around the both eye. Immediate management was done and edema subsided with in a few hours of treatment. No further adverse reactions were observed. **Conclusion:** This case highlights that ceftriaxone is generally safe and effective, it can rarely cause significant adverse reactions such as periorbital edema, which may indicate a serious allergic or hypersensitivity response. This case calls for further research to better understand and prevent these rare but potentially severe reactions and help clinicians be aware of the possibility of anaphylaxis occurring because it could go unnoticed.

Disproportionality analysis of Tapentadol for cancer pain management using real-world data obtained from the FDA adverse event reporting system database

Rajesh V[1], Shwetha Somakumar[2]

1. Centre For Pharmaceutical Care, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka
2. Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka

Background: Tapentadol is a novel class of opioid analgesic that has μ-opioid receptor agonism and noradrenaline reuptake antagonism actions. The drug has been given research interest for its comparative efficacy and safety over other opioids. **Aim:** The study aims to identify safety signals for tapentadol when used for cancer pain management through the FDA adverse event reporting system (FAERS) using disproportionality analysis **methodology:** A real-world analysis was conducted for the data obtained using the open vigil 2.1 platform, accessing the adverse event reports related to tapentadol. After the duplicate and irrelevant report exclusion, 1273 unique individual safety reports were included for further analysis. The preferred terms obtained were standardized using the MedDRA 27.1 web-based browser platform. Disproportionality analysis was employed to identify safety signals based on reporting odds ratios (RORs), proportional reporting ratios (PRRs), and chi-square (χ^2) values. **Result:** tapentadol-related adverse events were initially counted in 2037 reports. After deduplication, 1273 unique reports were retrieved. A total of 222 preferred terms were identified for tapentadol-related adverse events, with the most frequent for delirium (54 reports). Disproportionality analysis flagged 59 preferred terms across various system organ classes. The strongest signal was notable for allodynia (prr:257.586; ror:270.881; χ^2:209.178), a nervous system disorder.

Conclusion This study highlighted the adverse event signals of tapentadol, used for cancer pain management, which can be important preliminary data for clinicians. The relatively lower number of reports for tapentadol is influenced by the recent FDA approval, hence warranting continued monitoring.

Keywords: Tapentadol, cancer pain management, disproportionality analysis, safety mining

Exploring the safety profile of carboplatin: an FDA label-based study using disproportionality analysis of the FDA adverse event reporting system database

Alisha Roy[1], Maria Jacob[1], Sriya Lingamagunta[1], Shwetha Somakumar[1], Rajesh V[2]

1. Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka
2. Centre For Pharmaceutical Care, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka

Background: Carboplatin-based chemotherapy is useful as a first-line agent to treat bladder cancer in patients who are unfit for cisplatin chemotherapy. **Objective:** to study the safety profile of carboplatin obtained through the most recent structured product labels (SPL) and signals mined through the FDA adverse event reporting system (FAERS) database and to estimate the importance of safety sections in the labels. **Methodology:** the adverse event (AE) data for carboplatin from the FAERS database was accessed through OpenVigil 2.1. The labels were identified from the USFDA website and the sections of boxed warnings, warnings and precautions, and adverse reactions were screened manually for the terms related to the drug's safety profile. The terms were standardized to the corresponding pt using the MedDRA 27.1 web-based platform. The pts obtained were compared to the signals mined from OpenVigil, and the importance of each section on the label was estimated using disproportionality analysis. **Results:** 1013 AE reports were obtained with carboplatin as the primary suspect. The highest frequency PT was nausea (1621 reports), and the strongest signal was for febrile neutropenia [prr:18.95, Chi-squared:20471.02, ROR:19.80]. From the label, the strongest signal was observed for neutropenia [PRR:8.77, Chi-squared:9680.27, ROR:9.19]. The safety sections in the label showed a deviation, as only anaemia representing the boxed warning was observed to be within the strongest signals. **Conclusion:** This study confirmed the existing safety signals present on the FDA label of carboplatin and helped to identify new signals not mentioned in the SPLS, thus highlighting the importance of post-marketing surveillance.

Keywords: Carboplatin, neutropenia, safety profile, signal, disproportionality analysis

Disproportionality analysis of FDA adverse event reporting system (FAERS) database for Taxanes and platinum derivatives used in ovarian cancer

Maria Jacob[1], Alisha Roy[1], Sriya Lingamagunta[1], Shwetha Somakumar[1], Rajesh V[2]

1. Department Of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka
2. Centre For Pharmaceutical Care, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka

Background: Taxanes and platinum derivatives are the gold standard in the pharmacotherapy of

ovarian cancer. **Objective:** This study aims to assess adverse drug events (ADEs) associated with Taxanes and platinum derivatives through disproportionality analysis. **Methodology:** Data mining of the FAERS database was carried out through the OpenVigil 2.1 platform from 2003Q4 to 2024Q1. Both raw data and frequentist methods options were selected for the data. Proportional reporting ratio (PRR), Chi-squared and reporting odds ratio (ROR) were employed to detect signals. **Results:** Comparing Taxanes and platinum derivatives, the frequency of preferred terms was 1209 and 1697, and the top ADEs were alopecia (19663 reports; PRR:46.458, Chi-squared:744327.1, ROR:69.855) and Nausea (4038 reports; PRR:2.003, Chi-squared:2080.717, ror:2.076), respectively. The United States was the highest reporting country in both classes (16417 reports, 60.47% in Taxanes and 3461 reports, 13% in platinum derivatives). The top reports were seen in the age group 60-70 (0.35%) for Taxanes and 50-60 (10.39%) for platinum derivatives. The disproportionality analysis flagged 459 and 950 signals for taxanes and platinum derivatives. The signals accounted for 61.37% and 64.83% of total reports in each class, respectively. **Conclusion:** ae signals were seen to be higher in platinum derivatives compared to taxanes, indicating the need for a heightened safety profile in clinical practice. However, ongoing surveillance is required for monitoring signals that were not flagged but had a significant number of reports.

Keywords: Taxanes, platinum derivatives, signals, disproportionality analysis, ovarian cancer

A disproportionality analysis of adverse events associated with the therapeutic regimen used in the induction phase treatment of acute lymphoblastic leukemia in children

Sriya Lingamagunta[1], Maria Jacob[1], Alisha Roy[1], Shwetha Somakumar[1], Rajesh V[2]

1. Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka.
2. Centre For Pharmaceutical Care, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka.

Background: Acute Lymphoblastic Leukemia (ALL) is one of the most common cancers in children. The induction phase is the first phase of the treatment for all. The chemotherapy drugs that are used in the induction phase are vincristine, l asparaginase, methotrexate, daunorubicin, prednisolone/dexamethasone. However, the safety of these drugs should be monitored in the paediatric population. **Objective:** This study aims to evaluate the safety of the drugs used in the induction phase of ALL therapy in children through a signal mining strategy on data obtained through the FAERS database. **Methodology:** The OpenVigil 2.1 was used retrieve data that were present in the FAERS database on the reported adverse events (AES) for the drugs from 2003Q4 to 2024Q2. Reporting odds ratio (ROR), proportional reporting ratio (PRR) and chi square were used to measure disproportionality. A value of ROR > 1, PRR ≥ 2, Chi square > 4 was considered as a positive signal. **Results:** a total of 839 preferred terms were found using above drugs as the primary suspect. All together 451 signals were identified for all the drugs examined. The most common AES are febrile neutropenia (n= 1316), neutropenia(n=468), neurotoxicity(n=409). Among reported AES, 50.8% were boys. The highest number of AES occurred in the 0-10 years age group (43.6%). The united states (25.3%) had the highest frequency of ae reports. **Conclusion:** this study identified ae signals due to the drugs used in the induction phase therapy of all in the paediatric population.

Keywords: Acute lymphoblastic leukemia (all), induction phase, disproportionality analysis, paediatrics, signals

Anticonvulsant potential of CoQ10: a zebrafish model of PTZ-Induced Seizures

Sahana Parween[1], Mahima Gupta[1], Manisha Kawadkar[1], Avinash Singh Mandloi[1]
[1]VNs Group of Institutions, Faculty of Pharmacy, Neelbud, Bhopal, MP, India

Introduction: Convulsions remain one of the major Central Nervous System (CNS)-related complications, contributing to morbidity. Coenzyme Q10 (CoQ10), known as a potent antioxidant, has been investigated for its neuroprotective potential. This study examines the anticonvulsant effects of CoQ10 in a zebrafish model of pentylenetetrazol (PTZ)-induced seizures. **Materials & methods:** seizures were induced by exposing zebrafish to a tank containing PTZ (5 mg/ml). The fish were divided into 7 groups (n = 6): PTZ (5 mg/ml), phenytoin (1 mg/ml), CoQ10 (0.5 mg/ml) + PTZ, CoQ10 (0.75 mg/ml) + PTZ, CoQ10 (1 mg/ml) + PTZ, CoQ10 (1.25 mg/ml) + PTZ, and CoQ10 (1.5 mg/ml) + PTZ. All treatments were directly dissolved into the tank water, and the fish were exposed to their respective treatment tanks for 1 hour before being exposed to PTZ. Following PTZ exposure, various parameters such as seizure latency, novel tank test, open field anxiety test, shoal cohesion, and light/dark test were performed. **Results:** the seizure onset latency was significantly increased in all treatment groups, with the maximum delay observed in the CoQ10 1 mg/ml group. Locomotion activity was significantly higher in all treatment groups compared to the PTZ group. Additionally, shoal cohesion significantly decreased in the PTZ group compared to the control group, whereas the treatment groups notably improved shoal behaviour. CoQ10 1 mg/ml exhibited the best outcomes across all parameters compared to other doses. **Conclusion:** the findings suggest that CoQ10 is a promising anticonvulsant agent with dose-dependent effects in zebrafish. Furthermore, the zebrafish model proves to be a valuable tool for screening antiepileptic agents.

Keywords: Convulsion; CoQ10; pentylenetetrazol; zebrafish; behavioural; locomotion

SGLT2 inhibitors inducing diabetic ketoacidosis

Praveen Kumar[1], Shajeer Ali C P[1], Deepthi Daniel, Rohith A[1], Sowmya Sagar[1]
[1]Department of Clinical Pharmacology, Aster Whitefield Hospital, Bengaluru, Karnataka

Introduction: SGLT2 inhibitors have revolutionized the management of type 2 diabetes mellitus (T2DM) and heart failure; however, recent reports indicate a concerning association with euglycemic diabetic ketoacidosis (DKA). This study investigates the incidence, risk factors, and outcomes of euglycemic DKA in patients treated with SGLT2 inhibitors. **Methodology:** a retrospective analysis was conducted using electronic health records from multiple centers, identifying patients prescribed sglt2 inhibitors between January 2015 and December 2023. Adult patients with T2DM or other approved indications were included. Data on demographics, comorbidities, and clinical outcomes were extracted. The incidence of euglycemic DKA was calculated, and risk factors were analyzed using logistic regression. **Results:** among 10,000 patients, 58 cases of euglycemic DKA were identified, yielding an incidence rate of 0.58%. Significant risk factors included renal impairment, dehydration, and concurrent insulin use. Most patients presented with typical symptoms such as nausea and abdominal pain, with elevated ketone levels despite normal blood glucose. Hospitalization was required for most cases, with a few experiencing severe complications. **Conclusion:** this study underscores the notable risk of

euglycemic DKA in patients on SGLT2 inhibitors, particularly among those with specific risk factors. Clinicians should maintain heightened awareness and provide patient education regarding this risk, while implementing appropriate monitoring strategies. Further prospective studies are needed to better understand the mechanisms involved and to develop comprehensive prescribing guidelines.

Levofloxacin Induced Hypoglycaemia: a rare but life-threatening side effect of a widely used antibiotic

Praveen Kumar[1], Shajeer Ali C P[1], Deepthi Daniel, Rohith A[1], Sowmya Sagar[1]
[1]Department of Clinical Pharmacology, Aster Whitefield Hospital, Bengaluru, Karnataka

Introduction: Fluoroquinolones are extensively used antimicrobial agents and are generally perceived to have a non-serious adverse effect profile. Levofloxacin is one of the most commonly prescribed antimicrobial agents. Although uncommon, levofloxacin-induced Hypoglycaemia can be dangerous. Delay in recognizing the etiology of the Hypoglycaemia led to serious consequences in various cases, Hypoglycaemia typically occurs within 72 hours of the initiation of the quinolone (or even quicker), and can result to be persistent and severe, often responding only to discontinuation of levofloxacin. **Methodology:** Based on the key terms used such as levofloxacin induced hypoglycaemia with the help of search engines such as elsevier, PubMed. We have selected 8 articles based on the criteria of fluroquinolones induced hypoglycaemia. **Result:** Although there is a wide use of levofloxacin around world, current data available is only 8 cases were reported of the patient who experienced Hypoglycaemia on the onset of levofloxacin treatment. In that majority of the population belong to geriatric group. After stopping the levofloxacin treatment there was a significant improvement along with the intravenous dextrose therapy. **Conclusion:** Finally, it should be noted that Hypoglycaemia is a rare side effect of levofloxacin. Elderly people with a history of type 2 diabetes seem to experience it more frequently. Hence, doctors need to be aware of this potential side effect and test blood sugar levels more regularly, particularly early in the course of medication.

Urticaria secondary to mefenamic acid- a case report

Sneha G[1], Shalini Sivadasan[1]
[1]Department of Pharmacy Practice, KMCH College of Pharmacy, Coimbatore, Tamil Nadu

Background: Urticaria is also known as hives it is characterized by abnormal redness of the skin, swollen with excessive accumulation of fluids. The factors such as infections, medicines, food, psychogenic factors and respiratory allergens are known etiology, sometimes it is idiopathic. So, here the urticaria is secondary to mefenamic acid intake. Approximately 10% of individuals exposed to mefenamic acid experience dress syndrome. So, here the case report states that the anaphylaxis reaction due to mefenamic acid intake. **Case presentation:** a 44-year-old female presented with the chief complaints of itching, skin rashes following all over the body, with giddiness and two episodes of vomiting due to the intake of mefenamic acid (NSAIDs) for the menstrual pain. She also had a history of irregular menstrual cycle (60- 70 days cycle), also a known case of adenomyosis and fibroid uterus and the Mirena inserted 8 months ago for the AUB. After the laboratory reports, it was found out her IgE level was 548.1 iu/ml and hba1c was 11.0%. She was diagnosed with urticaria and DM. She was treated with hydrocortisone, antihistamines with other supportive measures. Her symptoms got better

discharged under stable conditions. **Conclusion:** This case report describes the patient with urticaria secondary to mefenamic acid intake. This highlights the need to address the regulatory gaps and enhance the medical awareness to stringent the use of harmful medicines in the developing nations. To provide safety, efficacy to public health.

Ludwin's angina-a case report

Padma Priya R M[1], Dr. Shalini Sivadasan[1]
[1]Department of Pharmacy Practice, KMCH College Of Pharmacy, Coimbatore, Tamil Nadu, India

Introduction: Ludwig's angina is a rapidly progressing, life-threatening cellulitis of the floor of the mouth and submandibular spaces. It is typically caused by a bacterial infection that originates from dental infections, particularly of the second or third molars, but can also arise from trauma, oral surgeries, or other Infections. most commonly caused by polymicrobial infections involving organisms like: streptococcus spp, staphylococcus aureus, anaerobes (e.g., Bacteroides, fusobacterium). **Case presentation:** a 48-year-old male patient with past medical history of diabetes mellitus over 4 years, presented with a chief complaints of tooth pain after tooth extraction (right molar) a week ago. He had a history of swelling of right mandibular swelling that progressed to lift side and also pain over the swelling. Laboratory investigation revealed elevated white blood cells and pus cells. Urine culture showed presence of staphylococcus aureus which confirmed Ludwin's angina. He was conservatively treated with IV antibiotics, mouth wash and analgesics. His symptoms improved and discharged on day 8 with outpatient follow up. **Conclusion**: This case highlights the importance of early recognition, timely intervention, and aggressive management to prevent airway obstruction and other serious complications. Clinicians must maintain a high level of suspicion for Ludwig's angina in patients presenting with rapid neck swelling, difficulty breathing or swallowing, and dental infections.

Donanemab – A drug to hault the progression of Alzheimers disease

Ajink Vasudev Pawar[1], Anjleen Kaur[1]
[1]Dept. Of Pharmacology, Govt Medical College, Patiala

Background - Alzheimer's disease (AD) is the leading cause of dementia and has been recognized as a global public health priority. The global prevalence is predicted to be 152.8 million cases in 2050. Amyloid-β (Aβ) plaques and aggregated tau are two core mechanisms that contribute to the clinical deterioration of Alzheimer's disease (AD). Numerous clinical trials have failed for effective disease-modifying treatment in AD over the past 20 years. No treatments can stop or reverse its progression, though some may temporarily improve symptoms or slow the progression of the disease. **Aim**: the present work aims to review and summaries clinically useful on donanemab (KISUNLA) for prescribing physicians. **Methods:** databases such as Pubmed, scopus and google scholar were searched using the key words "Alzhiemer's disease",. "dementia" and "donanemab". Relevant publications such on donanemab were reviewed and results summarized. **Results**: donanemab, sold under the brand name Kisunla, is a humanized Immunoglobobin gamma 1 (IGG!) Monoclonal antibody used for the treatment of alzheimer's disease.it acts against the n-truncated pyroglutamate amyloid-β peptide at position 3 (pglu3-aβ, aβpe3). Pglu-3 are present in brain amyloid plaques and

contribute to the Pathphysiology of alzheimers disease. The recommended dosage for Adults patients is 700 mg every four weeks for three doses, then 1400 mg every four weeks as iv infusion over 30 minutes. Side effects may include infusion-related reactions, with symptoms such as flu-like symptoms, nausea, vomiting and changes in blood pressure and 6 % incidence of symptomatic amyloid related imaging abnormalities (ARIA), characterized as aria with edema (ARIA-E) occurs in patients receiving Kisunla. **Conclusion**: Donanemab (KISUNLA) is the first and only amyloid plaque-targeting therapy with evidence to support stopping therapy when amyloid plaques are removed, which can result in lower treatment costs and fewer infusions.

Bleomycin induced interstitial lung disease: a case report

Siva Rama Krishna[1], S.Supriya[1], K.Krishna Kanth[1], K Chandrakala[1]
[1]Department Of Pharmacology, Government Medical College, Ongole

Background: Bleomycin is a potent chemotherapeutic agent, widely used in the treatment of cancers like Hodgkin's lymphoma and germ cell tumors, but its significant adverse effect is bleomycin-induced interstitial lung disease (ILD) occurring in more than 10% of patients. ILD can be life-threatening with mortality rates of 10-20%. This case report describes a case of bleomycin induced interstitial lung disease. **Case description:** a 49 year old male chronic smoker came to casuality with complaints of shortness of breath, cough for 10 days, associated with fever and chest pain. He was diagnosed with hodgkin's lymphoma and received six cycles of chemotherapy ADR iamycin + bleomycin + vinblastine + dacarbazine (ABVD) regimen, with a two weeks gap between each cycle. the patient had no similar complaints during chemotherapy but after the completion of sixth cycle he experienced the above complaints.on clinical examination patient was diagnosed with drug induced ild which was confirmed by haematological and radiological investigations. Patient received treatment with intravenous steroids, antibiotics (cefaperazone and cotrimoxazole), nebulization (levosalbutamol, ipratropium and budesonide) and was under non invasive mechanical ventillation for 13 days. On 14th day patient had expired. The adverse event was reported to amc-prakasam at gmc/ggh ongole. Based on the who-umc scale causality for this case is assessed as possible. **Conclusion:** Bleomycin is used in treatment of hodgkin's lymphoma. Due to the occurrence of ild with bleomycin, care must be taken while prescribing the drug. Health care professionals and patients must be educated about adverse effects of bleomycin.

Key words: Bleomycin, hodgkin's lymphoma, interstitial lung disease, adverse event.

Empowering and Evaluating Ischemic Stroke Survivors: through stroke hub program for better outcomes in prevention, treatment, and rehabilitation

Hari Haran K
KMCH College of Pharmacy, Coimbatore

Background: Stroke is a major contributor to disability and mortality globally. Having an effective post-stroke management is an important factor in stroke survivors' quality of life. The purpose of this study is to identify gaps and barriers to post-stroke medications adherence that would improve the patients' outcomes. **Objective:** the main objective of the study was to initiate the stroke HUB program and to assess patients' post-stroke state with the goal of improving clinical outcomes by identifying gaps in medications adherence. **Methodology:** a prospective observational study was completed over six months in the department of neurology at KMCH.

Patients completed a post-stroke status assessment measures (barthel index, and modified rankin scale mRS). The intervention conducted an assessment to identify gaps and barriers associated with medication adherence with stroke survivors. The data were then analysed using SPSS version 22 and a p-value of <0.05 statistical significance **results:** a total of 167 stroke survivors were included in the study were observed and 78% adhered to medication regimen. In ayes were reported, the investigator found gaps in medication adherence. Additional analysis noted a higher functional independence in patients who adhered to the prescribed medications as shown by the Barthel index, mean score of 93.0 compared to non-adherents 83.4. **Conclusion:** the stroke hub deliberately identified significant gaps in post-stroke medications adherence. Further we believe this intervention will improve the patients' medications adherence outcomes, which is not only essential in medications education, but also consulting patients' medications to increase disease knowledge.

Keywords: Stroke HUB; Barthel index; medications adherence; rehabilitation; medication counselling

Adverse reaction to carbamazepine in a pediatric patient: a case report

Himanshu Saxena[1], Sanjay Gedam[1]
[1]Department of Pharmacology NSCB Medical College, Jabalpur

Introduction (background and objective): Carbamazepine is commonly used for treating seizure disorders, particularly in pediatric patients. However, it can induce severe adverse drug reactions (ADRs), including hypersensitivity reactions, which may lead to life-threatening consequences. This case report presents a pediatric patient who developed a severe adverse reaction to carbamazepine, highlighting the importance of early detection and intervention. **Methodology:** a 3-year-old male with a seizure history was prescribed carbamazepine (Zen retard 200 mg, twice daily) on 26th may 2024. On the 10th day of treatment, the patient developed red blisters starting from the face and spreading over the entire body, accompanied by high-grade fever and breathlessness. Carbamazepine was immediately discontinued, and the patient received supportive care, including IV dexamethasone (8 mg) and IV piperacillin-tazobactam (4.5 g), topical Soframycincream, Muprocin ointment, kenacort paste along with other medications. **Results:** Following the discontinuation of carbamazepine and initiation of supportive therapy, the patient's condition improved. The reaction was classified as life-threatening, and causality assessment rated it as 'probable.' no rechallenge with carbamazepine was attempted due to the severity of the reaction. **Conclusion:** This case underscores the need for vigilant monitoring of pediatric patients during carbamazepine therapy. Prompt identification and cessation of the offending drug are critical for avoiding severe outcomes. Genetic screening may help in reducing the risk of adverse reactions in high-risk individuals.

Comparative study of safety and efficacy of oral itraconazole versus fluconazole in the treatment of superficial dermatophytosis

Amruthadevi T S[1], Ritesh Churihar[1], Nitin Pandya[3]
[1]Department of Pharmacoloy, Gandhi Medical College and Hospital, Bhopal
[2]Department of Dermatology, Gandhi Medical College and Hospital, Bhopal

Background: With increasing resistance to antifungals in India, evaluating the effectiveness of

current treatments is crucial. This study compared the efficacy and safety of oral itraconazole and fluconazole in superficial dermatophytosis, a common fungal skin infection. **Methodology:** A prospective observational study was conducted with 200 newly diagnosed dermatophytosis patients. Group I (100 patients) received itraconazole 200 mg daily, and group ii (100 patients) received fluconazole 150 mg every alternate day, both for 4 weeks. Baseline parameters were measured. Follow-up evaluations were conducted at 2 and 4 weeks. Clinical improvement assessed via the dermatophytosis severity score (DSS) and percentage improvement of erythema, pruritus, scaling, and raised borders, were measured. Safety was evaluated by adverse drug reactions (ADRs). **Results:** group I showed significantly better results compared to group ii. By the 2nd follow-up, 84% of patients in group i achieved complete clinical cure, compared to 62% in group ii ($p = 0.008$). Group I also showed greater improvement in erythema (78% vs. 64%, $p = 0.012$), raised borders (72% vs. 51%, $p = 0.001$), and scaling (74% vs. 63%, $p = 0.001$). Pruritus resolved in 79% of group I versus 65% in group ii ($p = 0.032$). Both treatments were well-tolerated, with minimal ADRs. **Conclusion:** itraconazole proved to be more effective and faster than fluconazole in treating dermatophytosis. Both drugs were safe, but itraconazole is recommended for faster and more comprehensive resolution of symptoms.

Keywords: dermatophytosis severity score (DSS), itraconazole, fluconazole, efficacy, safety, antifungal therapy.

Screening of nicotine dependence in patients with coronary artery disease and to determine the role of nicotine replacement therapy (NRT) in them

Praveen Kumar[1], Shajeer Ali C P[1], Deepthi Daniel, Rohith A[1], Sowmya Sagar[1]
[1]Department of Clinical Pharmacology, Aster Whitefield Hospital, Bengaluru, Karnataka

Introduction: Cardiovascular diseases (CVDS) has been shown to be the leading cause of death worldwide. The are many risk factors among them cigarette smoking has been reported to be the most prominent factor, accounting for 140,000 premature CVD deaths annually in addition to 10% of all CVD deaths. Nicotine is the addictive ingredient in tobacco products. People who wish to quit using tobacco products are unable to do so because of the nicotine. Both behavioural therapy and FDA-approved medicines are useful treatments that assist in quitting smoking. **Methodology:** this was an 'interventional cohort study' conducted for a period of six months. Considering a confidence interval of 93%, the sample size was calculated to be 107 individuals. **Result:** out of the 102-study population, the majority of the subjects were in the age group of 31–40 years, with 36 patients (35.29%), and had moderate dependence, with 63 patients. After initiation of nicotine replacement therapy. the cessation of smoking had a huge impact on the quality of life (QOL) of patients. **Conclusion:** Along with the standard treatment and with the help of nicotine replacement therapy (NRT's), the patients were capable of quitting smoking and reducing the risk of developing in-stent restenosis. The patient's quality of life (QOL) was significantly improved by quitting smoking. Early signs of heart disease in young adults who smoke may disappear as soon as they quit smoking.

Key factors influencing effective communication practices in clinical settings

Shubha Singhal[1], Rima Shah[1], Siddhartha Dutta[1], Sumit Bansal[2]
[1]Department of Pharmacology, AIIMS, Rajkot
[2]Department of Anesthesia, AIIMS, Rajkot

Background: Effective communication is vital in a medical setting, as it directly impacts patient satisfaction, adherence to treatment, and overall health outcomes. This research was planned to find the correlation of gender, working place, year of experience, specialty and effect of communication training to current and future attitude of medical practitioners towards good communication practices. **Methods:** This cross-sectional study involving 500 randomly selected sample of medical practitioners across India. Data collection about current and future communication practices was carried out by google questionnaire form and analyzed. **Result:** There was no gender-wise significant difference in current doctor-patient communication practices($p>0.05$) and both males and female practitioners were eager to improve their future practices($p<0.01$). On analyzing the setup of practice showed that doctors working in all government, semi-government and private settings were ready to include good communication practices in their future clinical setting ($p<0.001$). Doctors who had >30 years of experience were following good communication practices ($p<0.05$), yet they were more reluctant to improve communication practices further as compared to doctors who have less year of experience ($p<0.05$). Doctors who were trained in communication practices showed higher score than those who didn't receive the training (12.1 ± 3.16 vs 9.37 ± 2.1; $p=0.06$) but the future attitude to improve in communication skills was significantly higher in those who had received the training (16.1 ± 1.5 vs 12.97 ± 2.2; $p=0.05$). **Conclusion**: The study highlights the need for awareness and teaching of good communication practices in MBBS curriculum.

The human papillomavirus (HPV) vaccination: awareness and safety data for girls aged 9-14 and 15-26 years

Dharamjeet B. Nayak[1], Dr. Sanket Harimkar[1]
[1]Pes Modern College of Pharmacy, Nigdi, Pune

Introduction (background and objective): The HPV vaccine is a critical public health tool in preventing cancers caused by HPV, such as cervical, anal, and throat cancers. Vaccination among girls aged 9-14 and young women aged 15-26 is essential to reducing HPV-related cancer incidences. This abstract aims to highlight the safety and efficacy of the HPV vaccine as a preventive healthcare measure. **Methodology:** This study reviews HPV vaccination safety data, including side effects, monitoring systems, and vaccination effectiveness in cancer prevention. It also outlines the vaccination schedules and safety guidelines for the target age groups. **Results:** Since its introduction in 2006, the HPV vaccine has been extensively monitored through the vaccine adverse event reporting system (VAERS) and vaccine safety datalink (VSD). Common side effects are mild, including pain, redness, swelling at the injection site, dizziness, and nausea. Severe allergic reactions are rare, occurring in approximately 3 cases per million doses. Large studies show no increased risk of autoimmune diseases or Guillain-barré syndrome (GBS). The vaccine has proven highly effective in preventing HPV types associated with cancer and provides long-lasting protection. **Conclusion:** the HPV vaccine is a safe, effective approach to cancer prevention, with benefits far outweighing the minimal risks. Ongoing safety monitoring and comprehensive data affirm its safety for public health.

A case report of delayed-onset cardiotoxicity following long-term use of 5-fluorouracil: underlining the importance of long-term pharmacovigilance

Aditya Vikram Singh[1], Farida Ahmad[1], Syed Shariq Naeem[1], Mohammad Akram[2]
[1]Department of Pharmacology, Jawaharlal Nehru Medical College & Hospital, AMU, Aligarh
[2] Department of Radiotherapy, Jawaharlal Nehru Medical College & Hospital, AMU, Aligarh

Introduction: Pharmacovigilance is vital for the identification, evaluation, and mitigation of adverse drug reactions, especially those with delayed onset that may manifest weeks, months or even years after initiation of drug therapy. It enhances patient care by ensuring medication safety and efficacy through the detection, monitoring, and prevention of adverse drug reactions, ultimately guiding safer and more effective treatment decisions. 5-fluorouracil is effective in treating many cancers but is associated with a risk of delayed-onset cardiotoxicity, observed in up to 18% of patients, hence necessitating vigilant monitoring to improve overall treatment outcome. **Methodology:** Patient in our case study is a 33-year-old female, diagnosed with adenocarcinoma rectum, registered in the department of radiotherapy, Jawaharlal Nehru Medical College, Aligarh Muslim University. She was started on FOLFOX regimen (5-fluorouracil, leucovorin and oxaliplatin) and was followed up at regular intervals during her treatment with routine investigations and thorough history taking with physical examination. **Result:** During regular follow-ups, the patient developed signs and clinical symptoms indicative of cardiotoxicity. Following which patient underwent comprehensive investigations, including chest X-Ray, ECG, echocardiography, cardiac biomarkers and MRI along with causality assessment, which confirmed cardiotoxicity and 5-fluorouracil as the probable causative agent. The patient was subsequently monitored with appropriate measures to manage cardiotoxicity effectively. **Conclusion:** A year after the diagnosis of 5-fluorouracil induced delayed cardiotoxicity and with consistent follow-ups and corrective measures, the patient now shows clinical improvement, with improved signs of cardiotoxicity on investigations. This case report underscores the critical role long-term pharmacovigilance plays in managing delayed-onset adverse drug reactions.

Integrating artificial intelligence in to Pharmacovigilance: a study of its potential in the Indian context

Shaifali Singh[1], Amrutha Devi TS[1], Hemlata Verma[1]
[1]Department Of Pharmacology, Gandhi Medical College, Bhopal

Background: Pharmacovigilance practices are critical for ensuring drug safety, yet challenges persist in data processing and signal detection, particularly in India. The integration of artificial intelligence (AI) holds promise for enhancing these practices by automating data analysis and improving adverse event reporting. **Methodology:** this study employs a systematic review of existing literature on ai applications in pharmacovigilance, focusing on recent advancements from 2015 to 2023. Data sources include academic articles, regulatory reports, and case studies on ai's effectiveness in processing individual case safety reports (ICSRs), identifying adverse drug events (ADES), and improving decision-making frameworks. Results
Preliminary findings indicate that ai can significantly optimize pharmacovigilance by automating the identification of safety signals and streamlining report processing. Key applications identified include machine learning algorithms for predictive analytics, natural language processing for unstructured data, and automated reporting systems. However, challenges such as data quality, resource limitations, and the need for human oversight remain. **Conclusion:** ai has

the potential to revolutionize pharmacovigilance practices in India by enhancing data handling and safety monitoring. While there is substantial promise, addressing infrastructural and regulatory Challenges is essential for successful implementation. Future research should focus on developing tailored ai solutions that accommodate the unique context of Indian healthcare and regulatory frameworks. **Key words**: pharmacovigilance, ai, systemic review.

Understanding the patterns and practices of self-medication among adults in an urban population of Bhopal city: a cross-sectional study

Raja Wasim Bakshi[1], Amrutha Devi T S[1], Shaifali Singh[1], Ritesh Churihar[1]
[1]Department of Pharmacology, Gandhi Medical College, Bhopal

Background: This study aims to investigate the self-medication practices of an educated society, with a specific focus on understanding side effects/drug-drug interactions/drug-herb interactions and the concurrent usage of other medicinal products especially herbal medicines, regulated as over-the-counter (OTC) medicinal products. **Methodology:** This descriptive, cross-sectional study was conducted in the urban population of MP Nagar, Bhopal. A total of 208 participants approaching medical shops without a prescription were provided with a structured questionnaire covering demographics, types of medications used, patterns of self-medication, and awareness and practices related to adverse drug reactions (ADRs). Descriptive statistics were used to analyse the data. **Results:** The study revealed a self-medication prevalence of 50% among participants. A positive response to self-medication was noted in 39% of participants, while among those who did not find relief, some opted to visit a hospital, increased the dose, switched medications, or turned to alternative medicines.72% of participants reported combining OTC medications with other drugs. Awareness of adverse interactions was noted in 57% of respondents, while 31% experienced side effects after combining medications. Among those who reported side effects, 46% categorized them as mild, 38% as moderate, and 15% as severe. **Conclusion:** While self-medication is prevalent in the urban population of Bhopal, there is a pressing need for education and awareness initiatives to ensure safe practices, especially regarding potential adverse drug reactions and drug interactions. Encouraging informed decision-making could help mitigate the risks associated with unsupervised self-medication.

Key words: Self-medication, drug herb/ drug-drug interactions.

Phase-II clinical trial of metformin and valproic acid combination as add-on therapy to standard treatment in patients with non-squamous non-small cell lung cancer

Vignesh A[1], Jayanthi M[1], Prasanth Ganesan[2], Biswajit Dubashi[2], Subathra A[3]
[1]Dept. Of Pharmacology, JIPMER, Puducherry
[2]Dept. of Medical Oncology, JIPMER, Puducherry
[3]Dept. Of Radiodiagnosis, JIPMER, Puducherry

Introduction: in non-small cell lung cancer (NSCLC) without targetable mutations, the standard treatment is a combination of chemotherapy (CT) with checkpoint inhibitors (CPI). However, most patients in India cannot afford cpis and receive only CT which has limited efficacy. Based, on preclinical data of synergism with CT, we studied the combination of metformin and valproic

acid in patients with NSCLC. The primary objective was to evaluate the overall response rate (ORR) of the combination of metformin, valproic acid, and pemetrexed and carboplatin in patients with newly diagnosed non-squamous NSCLC without targetable mutations. The secondary objectives were to determine the progression-free (PFS) and overall survival (OS), quality-of-life (QOL), and toxicity. **Methodology:** this prospective, single-arm, open-label phase-ii clinical trial included 30 patients with advanced non-squamous NSCLC. Participants received standard chemotherapy (carboplatin + pemetrexed) combined with metformin (1g bd) and valproic acid (500mg TDS) during their 2nd, 3rd and 4th cycles of chemotherapy. The primary endpoint was overall response rate (ORR), while secondary endpoints included progression-free survival (PFS), overall survival (OS), adverse events and quality of life (QOL). Compliance was assessed by using pill count and serum valproate levels. **Results:**30 patients were enrolled between September 2022 to June 2024. The median age was 55 years and the median follow-up period was 8.25 months. The overall response rate (ORR) was 50%, with a median PFS of 9.9 months (95% ci: 7.7 - 12.2) and a median OS of 14.5 months (95% ci: 4.7 - 24.3). Toxicities of grade 3 were seen in 17% of patients with the most common adverse events being Diarrhea (53%) followed by dizziness and sedation (40%). Dose reduction of metformin was done in two patients and valproic acid in three patients, following grade 3 toxicities. Quality of life improved significantly with respect to symptoms such as pain, dyspnea and appetite loss though diarrhea worsened. **Conclusion:** the ORR, PFS and OS were 50%, 9.9 months and 14.5 months respectively with addition of metformin and valproic acid to standard chemotherapy for advanced non-squamous NSCLC. The intervention was tolerable with manageable adverse effects. The combination showed improvement in the quality of life of patients. If the ORR of 55% is achieved after completion of sample size as per Simon's two stage design, then the study can be taken up to phase-iii clinical trials.

A study to evaluate intolerance in patients on long term statin therapy

Stephen Nan[1], Mukesh Hindoliya[1]
[1]Department of Pharmacology, Gandhi Medical College, Bhopal

Background: Statins are critical in managing dyslipidemia, a major risk factor for atherosclerotic cardiovascular diseases (ASCVDs). Despite their benefits, statin intolerance, characterized by muscle-related symptoms, elevated blood enzymes, and new-onset diabetes, remains a significant clinical issue. **Objective:** To assess the prevalence and characteristics of intolerance among patients undergoing long-term statin therapy. **Methods:** An observational study was conducted at Hamida Hospital, Bhopal, involving 110 participants selected from the medicine and cardiology outpatient departments. Data collection included detailed patient histories, physical examinations, and blood tests (creatine kinase, liver function tests, fasting and postprandial blood glucose). A scoring system was applied to evaluate the likelihood of statin-induced adverse effects. **Results:** The mean age of participants was 58 years, with 58.1% females. The majority (82.7%) were on atorvastatin, and 33.6% had been on statin therapy for over five years. Muscle-related symptoms were reported by 50.9% of patients, predominantly affecting the lower limbs. Blood tests revealed elevated creatine kinase in 24.5%, AST in 11.8%, alt in 19%, fasting blood sugar in 17.2%, and postprandial blood sugar in 24.5% of patients. The scoring system indicated that 9% of patients were highly likely to experience statin-induced adverse effects. **Conclusion**: The study demonstrates a significant prevalence of intolerance among patients on long-term statin therapy, with muscle-related symptoms and biochemical

abnormalities being the most common manifestations. These findings highlight the need for ongoing monitoring and personalized management of patients on statins to reduce the risk of adverse effects.

Keywords: Statin intolerance, dyslipidemia, long-term statin therapy, myopathy, creatine kinase, liver function tests, new-onset diabetes

Tiny livers, Big risks: uncovering drug-induced hepatic injury in pediatrics

Hiral Suresh Nichalani[1], Gayatri Tushar Kudnar[1], Shravani Sanjay Nabde[1]
[1]Mahatma Gandhi Vidyamandir's Pharmacy College, Nashik

Drug-induced hepatic injury is one of the most important reasons for drug withdrawal but very little is known about it in case of pediatric population. Pharmacovigilance studies in children are still infrequent with insufficient systemic monitoring of drug safety separately for children and adolescents. Considering the lack of comprehensive information about drug-induced hepatic injury, the objective is to assess which drugs are associated with hepatic injury in pediatrics. While drug-induced hepatic injury is rare in children, recognized hepatotoxic drugs for adults also carry risks for pediatric patient. It was understood by studying a worldwide pharmacovigilance database on suspected adverse drug reactions (ADRs) occurring in population below 18 years old. These insights underscore the need for age-specific safety monitoring and further Pharmaco epidemiological studies to enhance pediatric drug safety. In conclusion, hepatotoxicity is infrequently reported as a suspected ADR in children and adolescents and well-known hepatotoxic drugs in adults such as analgesics, anti-epileptic drugs, and antibiotics are also associated with hepatotoxicity in children.

Keywords: pharmacovigilance, children, pharmacoepidemiology, hepatotoxicity

Implementation of inter-departmental collaborative medication review to reduce inappropriate medications in the elderly in Indian healthcare settings: a mixed method study protocol

Aravinda Kumar B[1]**,** Rajesh Kumar Konduru[1], Saranya Rajaram[1], Manikandan M[1], Anusha Natarajan[2], Jerin Jose Cherian[3], Bhavani Shankara Bagepally[4], Anil J Purty[1], Nayyar Iqbal[1], Dinesh Babu S[2], Sudharsanan S[2], Manjunatha Ch[1], Isabella Topno[1]
[1]Pondicherry Institute of Medical Sciences, Puducherry, India.
[2]Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry, India
[3]Indian Council of Medical Research, New Delhi, India.
[4]ICMR-National Institute of Epidemiology, Chennai, India.

Background & Objectives: Polypharmacy poses significant challenges for India's elderly population, leading to adverse health effects and increased costs. Tools like the medication appropriateness index (MAI) and STOPP/Start criteria help identify potentially inappropriate medications (PIMs). This study aims to assess the feasibility of inter-departmental collaborative medication review (CMR) to reduce PIMs among hospitalized elderly patients amidst high healthcare expenditures. **Methods:** This study will proceed in five phases. Phase 1 involves a scoping review of collaborative medication review (CMR) practices. Phase 2 focuses on drafting standard operating procedures (SOPs) to establish and train the CMR team in India. Phase 3

assesses CMR efficacy using the MAI and STOPP/start criteria. Phase 4 explores challenges in implementing CMR in the Indian healthcare context. Finally, phase 5 evaluates the costs of CMR implementation. This multi Centered mixed-method design includes qualitative interviews to understand feasibility and a quasi-experimental study where 280 elderly patients' prescriptions will be monitored to measure inappropriate medications and hospital admissions related to medications. **Results and conclusion:** the study is in progress, and we expect that the findings of this study will provide valuable insights into the implementation and effectiveness of CMR in the Indian healthcare setting. **Trial registration:** the study was registered with the clinical trials registry–India (CTRI/2024/06/069220) registered on 19/06/2024.

Keywords: Collaborative medication review, potentially inappropriate medications, medication-related hospital admissions, elderly prescriptions, facilitators, barriers

An analysis of adverse events due to endotracheal tube at a tertiary care teaching hospital

Maldev Rana[1], Megha H. Shah[1], Sandip Jadav[1], Chetna Desai[1], Jolly G. Vaishnav[2]
[1]Department of Pharmacology, B.J Medical College Ahmedabad
[2]Department of Paediatrics, B.J Medical College Ahmedabad

Introduction: Endotracheal tubes are frequently used medical devices. Although the use of medical devices benefits the patients, they also carry significant potential risks. There are multiple instances where the device was recalled either due to defect or because of the significant morbidity and mortality in patients. The numbers of reported adverse event due to endotracheal tube in Paediatric patients are few. **Objectives**: To determine the incidence of adverse events and analyse the factors associated with adverse events due to endotracheal tube. **Methods:** This prospective observational study was conducted at department of paediatrics after taking approval from institutional ethics committee. A total 68 paediatric intensive care unit patients were enrolled as per inclusion and exclusion criteria. Duration of study was 3 months and each patient was followed up till adverse event was subsided or patient was discharged. Ae were identified, recorded and analyzed for causality, severity, recovery duration, seriousness, and outcome. Incidence of adverse event due to endotracheal tube and the factors associated with adverse event were identified and analysed. **Results**: The mean age of 68 screened patients was (4.75± 1.85) years, and male and female ratio was 1:1. Out of 68 patients 8 patients developed ae (11.7%). Most common ae was oropharyngeal injury (2.94%). All patients recovered and all MDAES were non-serious. **Conclusion:** Early identification and reporting ae due to endotracheal tubes are important to manage the MDAE due to this device.

Key words: medical device adverse events, endotracheal tube, Paediatric patients.

Clinical complications and pharmacovigilance in plasmodium falciparum malaria: an observational study from rural central India

Babita Jadhav[1], Mohan Pethe[2], Samir Yelwatkar[2]
[1]Department Of Pharmacology, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra
[2]Department of Medicine, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra

Background and Objective: the study aimed to evaluate clinical course, complications, treatment response and outcomes in patients with *plasmodium falciparum* malaria, with a focus on pharmacovigilance to monitor adverse drug reactions (ADRs) and drug resistance. **Methodology:** the study included 201 patients (aged >12 years) diagnosed with *p. Falciparum* malaria, confirmed through rapid diagnostic tests or peripheral smears. Of these, 99 cases were confirmed as *plasmodium falciparum* infections. A thorough history, physical examination, and required investigations were conducted. Patients treated with standard anti-malarial therapy and were monitored for complications, with an emphasis on pharmacovigilance to study drug efficacy and safety. **Results:** most common presenting symptom was fever (98% of cases). Thrombocytopenia was most frequent complication, followed by cerebral malaria, jaundice, acute renal failure, anemia, algid malaria, metabolic acidosis, respiratory distress, and hypoglycemia. Pharmacovigilance revealed that 91.92% of patients responded well to artemisinin-based combination therapy (ACT). However, 8.08% exhibited resistance to act and were treated successfully with arthemeter plus lumefantrine. No significant ADRs were reported, but pharmacovigilance identified emerging drug resistance, underscoring the need for continued surveillance. Cerebral malaria was most common cause of death which was observed in 100% of death. Other causes were algid malaria, severe thrombocytopenia, metabolic acidosis, jaundice, acute renal failure and respiratory distress. **Conclusion:** early diagnosis, early recognition of risk factors and complications, prompt treatment from backbone of malaria management to reducing morbidity and mortality in malaria. Pharmacovigilance is critical for monitoring drug efficacy and resistance, ensuring optimal management in severe cases.

A sporadic case of cephalexin induced cutaneous rash associated with leukopenia

Hamsini N[1], Priyanka S[1], Vasundara K[1]

[1]Department of Pharmacology, Kempegowda Institute of Medical Sciences, Bangalore

Background: Cutaneous Adverse Drug Reactions (CADR), are skin manifestations occurring due to systemic drug administration. They can range from mild erythematous skin lesions to very severe skin reactions. Cephalexin is a first-generation cephalosporin commonly indicated for infections caused by gram-positive organisms. Drug-induced leukopenia is a very rare complication of cephalosporin therapy. **Objective:** To report a probable case of cephalexin induced cutaneous rash associated with leukopenia in a 24-year-old female. **Case- report:** A 24-year-old female diagnosed with upper respiratory tract infection was prescribed oral cephalexin 500 mg twice daily for 7 days. Within 2 days of starting the treatment, she developed generalized cutaneous rash with severe itching distributed all over her upper and lower limbs. On further continuation of the treatment, her symptoms worsened with her laboratory investigations revealing leukopenia, predominantly neutropenia. The offending drug was stopped immediately, suspecting it to be a CADR along with drug induced leukopenia. Injection epinephrine 0.5mg im 0.5ml (1:1000) was given along with oral fixed dose combination of fexofenadine and montelukast 120mg/10mg. The rashes and other symptoms resolved gradually within 10 days. Laboratory parameters also improved accordingly. **Conclusion:** CADR are common with cephalosporins and other beta- lactam antibiotics. But, cutaneous rash with leukopenia is very rare. This case highlights the importance of timely identification and discontinuation of the offending drug and appropriate adverse drug reaction (ADR) management for patient safety. It also, emphasizes on the significance of pharmacovigilance, even for regularly prescribed medications. **Key words:** CADR, cephalexin, drug induced leukopenia

BEACON of Risk vs Benefit: A Case Study of Generalized Bullous Eruption from Cefotaxime, Amikacin and Diclofenac.

Sumit Prasad[1], Anant Khot[1], Ganesh Dakhale[1], Sanjiv Choudhary[1]
[1]Department of Dermatology, AIIMS Nagpur

Introduction: Fixed drug eruption (FDE) is a skin reaction that causes round, dark patches, which tend to come back in the same spots after taking certain medications. In rare cases, FDE can develop into a more severe form called GBFDE. Medications like diclofenac, cefotaxime, and amikacin are known to cause FDE, but GBFDE is uncommon. **Case summary:** A 72-year-old man came to the hospital with large, purple patches and skin peeling after taking medications for head injury caused by a fall due to giddiness. He later developed fluid-filled blisters, and was treated with steroids and antihistamines. He had a similar reaction a year ago. **Management and treatment:** Clinically diagnosis was made but there are no specific investigations performed. Patient was treated symptomatically and was prescribed Fexofenadine and Pantoprazole. **Follow up:** During a follow-up visit, skin lesions were in the stage of healing and crusting and there is no history of itching and burning sensation at the site of lesions. He was given S G Moist cream to apply twice a day for 15 days to continue his recovery. **Discussion:** GBFDE involves large blisters and can look similar to Stevens-Johnson syndrome. Although rare, drugs like diclofenac, cefotaxime, and amikacin can cause GBFDE. In this case, these medications triggered the patient's severe skin reaction. **Conclusion:** This is the first reported case of GBFDE caused by cefotaxime, amikacin, and diclofenac. It emphasizes the need for doctors to take a detailed medical history and prescribe carefully. Clinicians should be cautious with using multiple antimicrobials for prophylaxis for avoiding severe side effects like GBFDE. **Keywords**: Generalized bullous fixed drug eruption (GBFDE); Cefotaxime; Amikacin; Diclofenac; Case report;

Incidence of adverse events following Pacemakers' Implantation at a tertiary care hospital: a Materiovigilance prospective

Jahngeer Alam[1], S Z Rahman[1*], Asif Hasan[2], Mohd Sarfraz[3]
[1]Department of Pharmacology, Faculty of Medicine, Aligarh Muslim University, Aligarh
[2]Department Of Cardiology, Faculty of Medicine, Aligarh Muslim University, Aligarh
[3]Centre For Biomedical Engineering, Faculty of Engineering and Technology, AMU, Aligarh

Background: Arrhythmia is a life-threatening condition. The use of cardiac implants, namely permanent pacemaker implantation (PPI), implantable cardioverter defibrillators (ICDS), or cardiac resynchronization therapy (CRT) has been increased in the recent years due to the advancements in their technological designs; however, the safety of these devices has yet thought to be underreported in India. this study aimed to explore the incidence of adverse events (AES) linked to these devices implantation at a tertiary care hospital over the past one year. **Methods:** The data was collected from the catheterization laboratory and followed-up throughout the data collection period (i.e., 1 year) for AES of the placed implants. Data-collection encompasses the details of patients, indications, device-implantation date, device type, manufacturers, and other relevant parameters. We applied various diagnostic tests, including an ECG, ct scan, echo, and bacterial sensitivity test, to identify device-associated AES. In reporting each case, assessment methodologies: baseline study, causality assessment, and root cause

identification, were performed as per the guidelines of the Materiovigilance programme of India (MvPI). The work was statistically analyzed with IBM SPSS and approved by the IEC (*iecjnmc/1662*). **Results:** From February 2023 to January 2024, cardiac implants were placed in 183 patients, distributed to; PPI- 94.5% (173/183), CRT- 3.3% (6/183), and ICD- 2.2% (4/183). The cohort consisted of 58% males and 42% females, with an average age of 63 years (range: 10-90). Upon the follow-up of 1-year, the overall recorded ae rate was 3.8% (7/183), with 2.18% PPI infection, 1.09% PPI battery dysfunctioning, and 0.54% PPI lead fracture. No death was observed and all incidents as individual case safety reports (ICSRS) were sent to the Indian pharmacopoeia commissionusing online ADR monitoring system under the MvPI mission. **Conclusion:** Observedae rate of the implants was found to be consistent with international data; however, it was significantly lower than other reports from India. Our findings also indicate that majority of AES (71.43%) found in patients, were aged over 50 years. These outcomes have supported the vision of the MvPI and would be noteworthy for researchers interested in conducting long-term safety studies on these devices. **Keywords:** Permanent pacemaker implantation (PPI), implantable cardioverter defibrillators (ICDS), Cardiac resynchronization therapy (CRT), medical devices, adverse events

A tough pill to swallow: a case report on a medication error with methotrexate leading to oral mucositis and toxicity

Nandini N.A.[1], Anant Khot[1], Ganesh Dakhale[1]
[1]Department of Pharmacology, AIIMS Nagpur

Abstract: Medication errors, as defined by WHO, encompass preventable events that can result in inappropriate medication use or patient harm, commonly due to inaccurate dosing (34.7%) or missed doses (40%). Methotrexate remains the cornerstone therapy for rheumatoid arthritis and is generally safe when prescribed at weekly doses ranging from 5 mg to 25 mg. However, complex dosing regimens and potential patient misunderstanding create a risk for administration errors, which can lead to methotrexate toxicity. This study presents a case of a 63-year-old male with rheumatoid arthritis who developed oral bleeding and restricted mouth opening due to a medication error involving methotrexate. The literature suggests that methotrexate toxicity often presents with gastrointestinal or haematological symptoms, while isolated oral bleeding and trismus are less frequently reported as primary indicators. The patient was treated with folinic acid, antibiotics, and supportive care, resulting in a full recovery. This case highlights the critical impact of effective communication in healthcare. It aims to emphasize the heightened risk of medication errors in elderly patients with polypharmacy and limited medication awareness in the context of complex dosing regimens. The findings underscore the need for improved patient education, communication, and adherence strategies to prevent adverse drug reactions, particularly in elderly patients with chronic conditions who require long-term, multi-drug therapies. **Key Words**: Medication Error; Oral Mucositis; Methotrexate; Case Report

Building ADR reporting culture of herbal medicines for patient's safety

Ashima Shibu[1], Payal[1]
[1]Jaipur National University

Introduction: Building an evidence base that assesses the safety of medications requires the documentation and reporting of adverse responses. Many individuals support the use of herbal

medications, particularly when it comes to treating chronic illnesses. The belief that nature is safe and may be used without a doctor's prescription has led to a global trend of self-medication, sometimes with unsatisfactory outcomes, negative side effects, or unpleasant aftereffects. Using pharmacovigilance techniques to document the safety of herbal drugs presents a unique difficulty O**bjective:** To develop a robust ADR reporting culture, particularly for herbal medications, in order to enhance patient safety and public health results. **Methodology**: A comprehensive literature review was conducted using databases such as PubMed and Scopus to identify peer-reviewed case reports, clinical studies, and meta-analyses detailing adverse reactions associated with commonly used herbal products. **Results:** Gastrointestinal problems and allergic responses were the most often reported adverse drug effects. Seventy percent of healthcare patients lack knowledge on ADR reporting. **Conclusion**: Appropriate quality control methods, good regulatory oversight on herbs used in medicines, regulated distribution channels, seeking professional advice, reporting on side effects, adding community chemists and other healthcare professionals as recognized reporters, and expanding the program are all ways to report ADRs linked to herbal medicines. **Future scope**: Establishing an ADR reporting culture for herbal medicine creates the groundwork for long-term patient safety protocols, more openness, and evidence-based regulation in complementary and alternative medicine around the world.

Clinical pharmacists: key players in patient safety and quality care

Payal[1], Ashima Shibu[1]
[1]Jaipur National University, Jaipur

Introduction: Patient safety is the cornerstone of high-quality patient care. Patient safety is an important challenge and a feature in the healthcare systems that reduces the frequency and impact of unfavorable events and increases recovery from them as they can affect patient outcomes, satisfaction, and reliability. Along with other healthcare professionals, clinical pharmacists play a critical role in managing adverse reactions. Clinical pharmacists possess a unique understanding of the underlying or concurrent disorders, the potential mechanism of the putative adverse reactions, and the potential for interactions between drugs, cam, or diseases. **Objective:** To emphasize the clinical pharmacists' contributions to patient safety. **Methodology:** A survey of the literature and an examination of patient safety best practices, such as the use of evidence-based procedures, improved teamwork and communication, integration of technology (e.g., electronic health records), empowerment and involvement of patients, and constant enhancement of quality. **Results**: The data shows that medication adherence has improved by 90%, polypharmacy decreased by 30%, hospital readmissions decreased by 20%, and adverse drug events decreased by 25%. **Conclusion**: Clinical pharmacists are essential to bettering patient outcomes and drug management, as well as to increasing patient safety and service quality. It is everyone's duty to ensure patient safety. Healthcare professionals can establish a more secure and dependable care environment by cooperating.

Cefixime-induced drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome

Anusha Battina[1]**,** Snehalata Gajbhiye[1], Chaitali Chindhalore[1], Ganesh Dakhale[1], Tamil Selvi[1]
[1]Department Of Pharmacology, AIIMS Nagpur

Introduction: One of the severe cutaneous adverse reactions (SCARS) with substantial

morbidity and mortality is drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome. The a etiology of dress syndrome includes: antibiotics accounted for half of the medication used. Out of this, beta-lactams made up 87.5% of the suspected antibiotics, while macrolides made up 12.5%. **Objective:** To evaluate cefixime induced drug reaction with eosinophilia and systemic symptom (DRESS) syndrome. **Methodology:** We presented a 41yr female patient with complaints of swelling over face, redness & scaling all over the body associated with itching and fever for past 8days after intake of tab cefixime 200mg. Had similar history of illness 1year back after intake of phenytoin. Local examination shows multiple thick ill-defined crusted plaques presented over bilateral upper limbs, trunk, lower limbs and face. HPE showing features suggestive of dress syndrome. **Results:** According to WHO-UMC and Naranjo's causality assessment scale the association of cefixime was probable. As per modified Hartwig & Siegel's severity scale, severity score was moderate. **Conclusion:** The current report of cefixime induced dress syndrome brings to attention the need for practitioners to be aware that dress syndrome may develop with drug cefixime also as it is one of the cephalosporins that is regularly prescribed by practitioners and taken by patients.

Misuse of topical corticosteroids: a systematic review

Puja[1], **Mangesh Banker**[1], Sacchidanand Tewari[1]
[1]All India Institute of Medical Sciences, Raebareli, Uttar Pradesh

Introduction: Misuse of topical corticosteroids is a common worldwide with reason varying from skin lightening majority of times to dermatophytosis. The duration of misuse varying from 3days to 5 years in some cases. **Methodology:** We did a systematic review of the adverse effects resulting from topical steroid misuse by simple google search "adverse effects with misuse of topical corticosteroids". 19 study matched with our search. Data was entered in Microsoft excel. **Results**: Out of the 19 studies 4 did not mention the duration of study; in the remaining 15 the duration varied from minimum of 2 days to maximum 5 years. Females were around 65 percent of the total. Almost all the studies had female preponderance. No of patients in the study varied from 50 to 1400. The most common indication for the misuse was skin lightening followed by dermatophytosis and acne. The most common adverse effect resulting from the misuse of topical corticosteroids was tinea incognito and hypertrichosis. Beclomethasone followed by Clobetasol. In most of the cases the patients used topical corticosteroids on the advice of pharmacist followed by family and friends and quacks. **Conclusion**: Misuse of topical corticosteroids results in a number of skin problems requiring further prolonged treatment and inconvenience to the patient. In most of the cases it can be prevented by awareness among the masses specially females.

Evaluation of prescription errors and drug-drug interactions at community pharmacy

Om Suhas Kinhikar[1], Rajani Baban Mali[1]
[1]Progressive Education Society's Modern College of Pharmacy, Nigdi, Pune

Background: prescription errors and drug-drug interactions are significant concerns in healthcare, potentially leading to adverse drug reactions, medication errors, and compromised patient safety. **Aim:** This study aimed to detect and identify prescribing errors and drug interactions in outpatient prescriptions at community pharmacies. **Methods and materials:** A

cross-sectional study was conducted at community pharmacies, evaluating 150 randomly selected prescriptions over 5 months (January-May 2022). Prescriptions were analyzed for general details, medical components, and potential drug-drug interactions.All prescriptions were analyzed by following parameters: General details: name, age, sex, OPD registration number, date of consultation and legible handwriting. Medical components: history, examination diagnosis, investigations current dose and dosage, duration of treatment follow up advice, referral details, legible signature and medical council registration number and rationality and legibility of the prescriptions is also checked. **Result:** the study revealed significant deficiencies in prescription writing, including incomplete patient information (e.g., age: 4%, gender: 4.6%, OPD registration number: 2%). Although most prescriptions (98%) included the date of consultation, only 1.3% included clinical examination findings. Clear dosing instructions were provided in 99.3% of prescriptions, but drug-drug interactions were identified in 7.3% of cases. **Conclusion:** this study highlights the need for precise monitoring of prescription writing to identify causes, analyze errors, and prevent drug-drug interactions. Reducing prescription errors is crucial to improve patient safety and quality of life.

Azathioprine-induced alopecia and myelosuppression – a case report

Sabbariventhansastha[1], Ritasman Baisya[2], Sukdev Manna[2], Alapan Das[1], Deepasree Sukumaran[1], Soumitra Mandal[1]

[1]Department of Pharmacology, All India Institute of Medical Sciences, Kalyani

[2]Department Of Rheumatology, All India Institute Of Medical Sciences, Kalyani, West Bengal.

Azathioprine is an immunosuppressant used in transplant medicine and autoimmune conditions. Azathioprine is converted to 6-mercaptopurine (6-mp) and subsequently to active metabolites inhibiting purine synthesis, affecting DNA synthesis. A serious complication of this drug requiring close monitoring is myelosuppression. A clinical clue that can precede the onset of myelosuppression is alopecia. Here, we describe a case of a 42-year-old woman with systemic lupus erythematosus, taking azathioprine 50mg once a day for management of active nephritis. After 45 days of treatment, the patient complained of excessive hair loss and subsequently within a week the hemogram showed anaemia/leukocytopenia/thrombocytosis (hb-7.6/tlc-2,300/plt-496,000). Hence, azathioprine was immediately stopped. Moreover, hair fall progressed to alopecia total is within a month. The hemogram was reverted (hb-11.0/tlc-9700/plt-150,000) after 40 days of cessation of the drug. According to the WHO-UMC scale of causality assessment, the event was found to be 'probable/likely'. Hair growth began within two months after stopping the drug. Literature suggests that alopecia with myelosuppression occurs due to genetic mutations in either TPMT (or) NUDT15. The mechanism driving the toxicities of alopecia and myelosuppression could be hematopoietic precursor and root cells in the hair bulb. This could be due to the accumulation of thiopurine metabolites (mercaptopurine, 6-thioguanosine monophosphate), the metabolism of which depends on two genetically influenced enzymes – TPMT & NUDT15-encoded Nudix hydrolase. The patient is being followed up and a study is being planned for genetic confirmation of the event. Through this case, we aim to underscore the need for a genetic test before prescribing azathioprine.

Keywords: Azathioprine, mercaptopurine, thiopurine methyltransferase (TPMT), Nudix (nucleoside diphosphate linked moiety x) type motif 15 (NUDT15), alopecia totalis, myelosuppression.

Advancements in drug safety: the role of ai enhance the global drug safety monitoring

Apurv Musale[1], Shravan More[1], Karan Gend[1]
[1]Mahatma Gandhi Vidyamandir's Pharmacy College, Nashik

Pharmacovigilance (PV) is the science focused on detecting, assessing, and preventing adverse drug reactions (ADRs) to enhance drug safety. Established by the who in 1961 after the thalidomide disaster, PV has grown to include monitoring of herbals, complementary medicines, blood products, and medical devices. Central databases like Vigiflow, Vigibase, and Vigilyze, managed by the Uppsala monitoring center (UMC) plays a essential role in global drug monitoring. The artificial intelligence (AI) in PV offers significant advantages by handling large volumes of data efficiently. Machine learning (ml) are key ai tools used to analyze structured and unstructured data, respectively, improving data accuracy and case processing. PV is especially essential for assessing drug safety in sensitive groups, such as geriatric and pediatric populations, where limited trial data often require extensive post-marketing surveillance. However, PV awareness remains low in many developing countries. AI helps reduce costs and improve data processing. Since clinical trials may not fully capture drug safety profiles, PV systems address real-world risks that arise post-launch. This importance is enhanced by FDA data (2008-2017), which recorded over 10 million adverse event reports, with a significant number of serious and fatal outcomes. PV activities, combined with regulatory measures and ai-enhanced data analysis, continue to be vital for minimizing drug-related risks and ensuring patient safety globally.

Keywords-Pharmacovigilance, Uppsala Monitoring Center

Assessment of COPD symptoms and responsiveness of therapy by using clinical COPD questionnaire

Ashwani Kumar* Dr. Rahul Kumar Gupta[2]
[1] Department of Pharmacy Practice, School of Pharmaceutical Sciences, Jaipur National University, Jaipur, Rajasthan
[2] Department of Respiratory Medicine, JNU Institute of Medical Sciences and Research Center, Jaipur, Rajasthan

Background*:* COPD is a progressive disease characterized by airflow limitations that is not fully reversible. COPD is third leading cause of death globally, approximately 6% of the total death according to who in 2015, the prevalence of COPD was 174,000,000 and there were approximately 3.2 million deaths due to COPD worldwide. In 2016, there were an estimated 55.3 million cases of COPD in India, which is a prevalence of 4.2%. The prevalence of COPD increases with age, especially after age 30. **Objective:** the present study is aimed to assess the COPD symptoms and responsiveness of therapy by using clinical COPD questionnaire **Methods:** a total no of 63 patients with COPD disease has taken for study from department of respiratory medicine, JNU hospital and medical college, Jaipur with an informed consent from the patients. All the patients taken for the study has fulfilled the eligibility criteria & approved by our scientific & ethical committee for the study. **Result:** Most of the patients were from 46 to 55 age group, having occupation as farmer and from rural background. 60% of the patients have shown the symptoms like cough and breathlessness at the time of admission. There was 75% reduction in the Dyspenia before and after the treatment. **Conclusion:** However the prevalence of likely to be underestimated due to the undiagnosed of COPD. Proper management and early

detection of disease can hold the disease progression in COPD cases. 88% patients have shown complete response means there is no progression of disease.

Keywords: COPD, questionnaire

Case report of topical clobetasol propionate induced striae rubra in psoriasis patient

Somya Singh[1], Farah Asif[2], Sanjay Khattri[3]

[1]Department of Pharmacology All India Institute of Medical Sciences, Bhopal

[2] Department of Pharmacology, Dr. Ram Manohar Lohia Institute of Medical Sciences

[3]Department Of Pharmacology and Therapeutics, King George's Medical University, Lucknow

Introduction: psoriasis is a common, encounter in dermatology OPD is being treated with topical clobetasol therapy in a patient with scalp psoriasis. This case report in relation with the ADR due to topical clobetasol. **Case description:** a 20 year old male was diagnosed with scalp psoriasis in 2020, was on ketoconazole+ coal tar, clobetasol/ halobetasol +salicylic acid, isotretinoin and sertaconazole cream for 2 years, with the treatment he improved and left the treatment for one month, the lesion relapse on other body parts for which he started clobetasol on its own .after 2 month he developed multiple red striation over his upper body part which worsen and he presented for the same. Examination revealed horizontal, erythematous striation of atopic, thinned skin. A provisional diagnosis of clobetasol induced striae rubra was made, and the treatment of ketoconazole + coal tar, clobetasol + salicylic acid, stretch-rid cream, calcitriol and lotion glycerol two times a day, which lead to improvement in further condition. **Discussion:** topical corticosteroids if used inadvertently are known to produce striae rubra, present case report further strengthens this correlation. **Conclusion:** striae secondary to topical steroid use, involve large widespread areas and are related to the length, frequency and potency of steroid preparation used. **Keywords-** Scalp psoriasis, striae rubra, clobetasol propionate

Topic-Signal detection and their assessment in Pharmacovigilance

Vedika P. Lokhande[1], Priyal M. Gajbhiye[1], Bhagyashree S. Patil[1]

[1]Mahatma Gandhi Vidyamandir's Pharmacy College, Nashik

Introduction and objective- pharmacovigilance (PV) plays a critical role in ensuring drug safety post-market, identifying adverse drug reactions (ADRs) that may not have been detected during clinical trials. Since these trials often have controlled conditions and limited patient diversity, certain ADRs, particularly rare or long-term ones, may only emerge once a drug is used by a larger, more varied population. The goal of PV is to detect safety signals early, minimizing risks to public health. This article explores signal detection methods, advancements, challenges, and future directions in PV. **Methodology** - signal detection in PV primarily involves analyzing post-marketing data. Key methods include: Spontaneous reporting- healthcare professionals and patients report ADRs voluntarily, helping identify rare or unexpected reactions. Prescription event monitoring (PEM) - analyzing prescription records from the general population identifies ADRs not seen in clinical trials. Case-control surveillance - comparing individuals with and without ADRs to detect specific drug-related risks. Follow-up studies - tracking patients over time to detect long-term ADRs. These methods collectively enhance drug safety surveillance. **Results** - spontaneous reporting systems, like the uppsala monitoring centre, have been instrumental in identifying ADRs missed in clinical trials. Tools

such as the Uppsala monitoring scale and Naranjo probability scale help assess causality. These methods have uncovered ADRs in broader, real-world populations, including those with comorbidities or polypharmacy. **Conclusion** - While methods like spontaneous reporting and PEM are effective, challenges such as underreporting and detecting rare ADRs remain. Advancements in machine learning and real-world data offer promising improvements, but enhancing global networks, data quality, and proactive signal detection strategies is crucial for safeguarding public health.

Etodolac induced erythema multiforme: a case report

Sneha Sahani
Rajiv Gandhi Medical College and RGMC Thane

Introduction: Erythema multiforme major (EMM) is a severe immune-mediated hypersensitivity reaction triggered by infections or drugs like antibiotics, NSAIDs, and anticonvulsants. Etodolac, an NSAID used for arthritis, is rarely associated with EMM. Em is subdivided into minor and major forms based on mucosal involvement and severity. Drug-induced EM typically presents with atypical targetoid lesions due to hypersensitivity reactions caused by reactive drug metabolites acting as haptens. **Case description:** A 73-year-old male developed widespread skin eruptions three days after starting etodolac 200 mg bd for knee pain. Examination revealed targetoid macules on the neck, abdomen, back, and extremities, along with lip erosions, tongue ulcers, and fever (38.5°c). Laboratory tests, including hematology, biochemistry, serology, and urinalysis, were within normal limits. A diagnosis of EMM secondary to etodolac was made, and the drug was discontinued. Skin biopsy was not performed due to lack of consent, and re-challenge was avoided. Treatment included intravenous ceftriaxone (1 g BD), dexamethasone (4 mg IV), antihistamines (Avil), pantoprazole, and supportive topical therapies (silver sulfasalazine cream, hexedine mouthwash, and mucopain gel). By day five, intravenous medications were switched to oral as lesions started to heal. **Methodology**-Data were collected from pharmacovigilance ADR forms. Causality was assessed using who and Naranjo scales. Clinical data, including age, comorbidities, and medications, were recorded. Skin reactions and recovery post-intervention were documented. **Results:** By day five: noticeable reduction in erythematous macules and ulcerations. Day 12 (discharge): lesions markedly improved with no new eruptions; hyperpigmentation remained. At 2-week follow-up: complete healing of all lesions was observed, with hyperpigmentation as the only sequela. **Causality assessment:** WHO-UMC: probable; Naranjo: probable (+7).**Conclusion:** Etodolac can be a rare cause of erythema multiforme major. Early recognition and prompt withdrawal of the offending drug, combined with supportive care, result in favorable outcomes. Residual hyperpigmentation may be the only sequela.

Impact of educational interventions on adverse drug reaction reporting: a comparative study among doctor of pharmacy students, bachelor of pharmacy students and hospital pharmacist in tertiary care hospital maharashtra

Saloni Vaibhav Koli[1], Anjali R. Shinde[2], Vandana M. Thorat[2], Snehal V. Mali[1]
[1]Department Of Pharmacy Practice, Krishna Institute of Pharmacy, Krishna Vishwavidyapeeth, Karad, Maharashtra
[2]Department of Pharmacology, Krishna Institute of Medical Science, Krishna Vishwavidyapeeth,

Karad, Maharashtra

Background: Adverse Drug Reactions (ADRs) are a major concern in patient safety and form an integral part of pharmacovigilance (PV) programs worldwide. In india, underreporting of ADRs is common, primarily due to limited awareness and inadequate reporting practices. Few studies have assessed the knowledge, attitudes, and practices (KAP) related to ADR reporting in India, with none focusing on Maharashtra. Addressing this gap is essential to improve ADR reporting practices. Doctor of pharmacy (Pharm.d) students, with their clinical roles and responsibilities in patient care, are well-suited to contribute to ADR reporting. **Aim:** to assess and compare KAP related to ADR reporting among Pharm.d students, bachelor of pharmacy (b. Pharm) students, and hospital pharmacists before and after an educational workshop.

Objectives: To evaluate the KAP of ADR reporting among Pharm.d students, b. Pharm students, and hospital pharmacists. To compare pre- and post-workshop KAP levels to measure the impact of the educational intervention. **Materials and methods:** A cross-sectional study was conducted at Krishna Hospital, Karad, Maharashtra, involving 183 participants: 62 Pharm.d students, 111 b. Pharm students, and 10 hospital pharmacists. A pre-validated KAP questionnaire was used to collect data before and after an educational workshop. The workshop comprised lectures, interactive sessions on ADR types, reporting mechanisms, PV importance, and hands-on ADR form-filling training. Ethical approval was obtained, and informed consent was secured. Pre- and post-test scores were analyzed using chi-square tests and paired t-tests to assess the intervention's impact. **Results:** Pre-workshop analysis revealed higher awareness and knowledge of ADRs among Pharm.d students (85%) compared to b. Pharm students (65%) and hospital pharmacists (45%). Positive attitudes toward ADR reporting were observed, with 82% of Pharm.d students, 60% of b. Pharm students, and 50% of pharmacists identifying ADR reporting as a key responsibility. Despite this, actual ADR reporting practices were limited, particularly among b. Pharm students and pharmacists, due to gaps in training and form availability. Post-workshop analysis showed significant improvements in KAP scores across all groups. Knowledge levels increased by 12-15%, and practice-related scores improved by 20-25%, indicating the workshop's effectiveness. **Conclusion:** the educational workshop, which included ADR form-filling training, significantly enhanced KAP levels related to ADR reporting among all groups. Pharm.d students initially exhibited higher knowledge and involvement, but the workshop effectively bridged gaps, especially among b. Pharm students and pharmacists. Structured educational programs are essential to strengthen PV practices, enhance ADR reporting, and improve patient safety.

Serious adverse event induced by intravenous diclofenac: a case report

Minakshi Ghuge[1], Jyoti Bobde[1], Deepak Bhosle[1]

[1]MGM Medical College and Hospital, Aurangabad

Introduction: Diclofenac sodium is commonly used NSAID for post-operative analgesia. It can be administered by oral, intramuscular, and intravenous route. Serious adverse events with diclofenac have been reported earlier but very few cases gave been reported with intravenous diclofenac. **Case summary:** A 43-year old female patient was given iv diclofenac 75 mg for postoperative analgesia. She started complaining of burning sensation and erythema appeared all over the body. Within 5 minutes, she went into anaphylactic shock. **Management:** Infusion was stopped immediately. Injection Avil 2ml and injection hydrocort 100mg given intravenously. CPR was given with ionotropic support. **Outcome:** But response to treatment was poor and she

went into cardiac arrest. Cause of death was cardio-respiratory arrest secondary to severe anaphylactic shock due to NSAIDs (diclofenac) in post-op case of total laparoscopy hysterectomy. **Discussion:** Diclofenac is one of the commonest NSAIDs used for management of pain. Adverse events are common but SAE with iv diclofenac is an rare event. Anaphylactic reactions have been reported to trigger cardiovascular events, including myocardial infarction and acute coronary syndromes, even in patients with normal coronary vasculature. **Conclusion:** This case study is to bring awareness that although iv diclofenac sodium is a safe and widely used drug, severe and potentially fatal anaphylactic reactions may occur with its use.

Keywords: SAE, diclofenac, anaphylactic shock

Educational intervention to improve knowledge, attitude, and practices of nursing profession in a tertiary care hospital in Maharashtra

Snehal V. Mali[1], Anjali R. Shinde[2], Vandana M. Thorat[2], Saloni V. Koli[1]

[1]Department of Pharmacy Practice, Krishna Institute of Pharmacy, Krishna Vishwavidyapeeth, Karad, Maharashtra

[2]Department of Pharmacology, Krishna Institute of Medical Science, Krishna Vishwavidyapeeth, Karad, Maharashtra

Background: Adverse drug reactions (ADRs) pose significant challenges to patient safety, and nurses, as primary caregivers, are pivotal in identifying and reporting ADRs due to their constant patient interaction. However, underreporting of ADRs remains prevalent, often due to insufficient knowledge and awareness. Although we have had an ADR monitoring centre (AMC) in place, reporting continues to be low, primarily because the nursing staff is unaware of the center's existence and the importance of ADR reporting. To address this issue, an educational program was implemented to increase awareness and enhance the knowledge of nursing staff about ADRs and the reporting process, thereby encouraging greater participation in ADR reporting and improving patient safety. **Aim**: To improve ADR reporting by equipping nursing staff with the necessary knowledge and skills. **Objectives**: Assess baseline knowledge, attitudes, and practices (KAP) regarding ADR reporting. Evaluate the impact of an educational intervention on ADR reporting practices. **Materials and methods:** A cross-sectional study was conducted with 179 nursing staff at a tertiary care hospital. Pre- and post-intervention data were collected using a validated KAP questionnaire and the DSRAQ (drug safety reporting awareness questionnaire). The intervention included lectures and interactive sessions focusing on ADR types, reporting mechanisms, and pharmacovigilance. Statistical analysis, including paired t-tests, compared pre- and post-scores, expressed as percentages. **Results:** baseline assessment revealed adequate knowledge, attitudes, and practices in 42%, 35%, and 28% of participants, respectively. Post-intervention, these improved significantly to 85%, 79%, and 72%, respectively. DSRAQ scores increased from an average of 40% pre-test to 82% post-test. Nurses reported greater confidence and willingness to report ADRs. **Conclusion:** the intervention improved nursing staff's KAP regarding ADR reporting, highlighting the need for continuous education and integrating ADR reporting into clinical workflows to enhance pharmacovigilance and patient safety. Establishing ADR reporting centers and raising awareness among healthcare professionals is crucial for sustained improvement. Regular reminders and comprehensive information for new staff help maintain engagement, while future group discussions among nursing staff will support ongoing learning and experience sharing.

Drug-induced Stevens-Johnson Syndrome (SJS) / SJS-toxic epidermal necrolysis (Ten) overlap: a case series and review of culprit medications

Chirag Agrawal[1], Ratinder Jhaj[1], Deepa Choudhary[1]
[1]Department of Pharmacology, AIIMS Bhopal

Background: Stevens-Johnson Syndrome (SJS) and SJS-ten (toxic epidermal necrolysis) overlap are rare but life-threatening hypersensitivity reactions often triggered by medications. They can lead to significant morbidity and mortality, making early diagnosis and intervention crucial. This case series aims to explore the clinical presentations, underlying drugs, and outcomes in patients with drug-induced SJS and SJS-Ten overlap. **Methodology:** It includes 20 patients diagnosed with drug-induced SJS and 6 patients with drug induced SJS-Ten overlap at a tertiary care hospital. Medical records were reviewed to assess drug exposure, clinical presentation, treatment interventions, and outcomes. A total of 26 patients (16 males, 10 females) aged 4 to 76 years were diagnosed. The drugs implicated can be classified into antimicrobials, anticonvulsants, NSAIDs, diuretic and antitussive. The mean time from drug exposure to onset of symptoms was 9.5 days (5 minutes - 35 days) for SJS and 14.5 days (1 day – 29 days) for SJS-Ten overlap. **Results:** all patients presented with the typical mucocutaneous lesions and required hospitalization. Treatment with corticosteroids and supportive care was initiated in all cases. All the patients showed recovery. This case series underscores the importance of early recognition and intervention in drug-induced SJS and SJS-Ten overlap. While most patients recovered with timely treatment, the severity of SJS emphasizes the need for vigilant monitoring of drug reactions. Further research is needed to establish more effective preventive strategies and treatment protocols. **Keywords:** Steven Johnson Syndrome (SJS), SJS-Ten (Toxic epidermal necrolysis) overlap, antimicrobials, anticonvulsants, NSAIDs, Diuretic, Antitussive, case series

Amoxicillin-Clavulanic acid induced toxic epidermal necrolysis

Shuchita Gaur[1], Tushar Bagle[1], Rohan Hire[1]
[1]Rajiv Gandhi Medical College, Thane

Background- Stevens Johnson Syndrome (SJS) and its severe form, toxic epidermal necrolysis (Ten) are idiosyncratic, life threatening, mucocutaneous reaction, characterized by necrosis and detachment of the epidermis. The incidence is 5 cases/million yearly, adverse drug reactions (ADRs) such as SJS lead to significant morbidity and mortality [1,2,3] this case documents drug-induced ten with Naranjo's calculation and who UMC scales which are the most widely accepted methods for causality evaluation. [5,6] **Objective**- To increase awareness of drug induced SJS and use of causality tools for prompt diagnosis. **Methodology** This case has been reported to our ADR monitoring center under the Pharmacovigilance Programme of India (PvPI). **Results** Case- A 42-year male patient was given cefixime 400 mg on 30-9-24 for injury, followed by generalized itching. Next, he took (Augmentin) 625 mg. Upon switching to azithromycin and paracetamol, he developed signs of ten including mucocutaneous lesions and widespread rash. Drugs were withdrawn, IVIG administered and patient improved. He had a past history of SJS induced by Augmentin and NSAIDs. Naranjo scale: Augmentin- possible. Cefixime possible. Who scale: Augmentin- possible. Cefixime possible. **Conclusion**: This case underscores importance of early identification, drug withdrawal, use of causality tools in confirming diagnosis of SJS and helping clinicians make informed treatment decisions.

Enhanced awareness and vigilance when prescribing drugs, especially those with known SJS risk, can help reduce its incidence.

Thalidomide induced neurological symptoms: a case report

Bhardwaj R[1], Joshi K[1], Srivastava B[1], Ashish R.S, Singh A[1]
[1]Department of Pharmacology, Government Medical College, Haldwani

Introduction: Thalidomide was initially used as sedative and antiemetic for morning sickness in pregnant women, but withdrawn owing to phocomelia as teratogenic effect. Since then, it has been used for dermatological, oncological effects and in 1994 it was found to have angiogenic effect and so it led to its use in bleeding associated with g.i.t diseases. **Case summary:** a 55 – year old male who was being treated for gave therapy for Esophageal varices was prescribed thalidomide capsule- USP 500 mg oral od, experienced dysarthria, confusion, disorientation and movement incoordination, dizziness, sedation & fatigue, drooping of right shoulder and loss of recent memory after 15 days of initiation of therapy. The patient had history of portal hypertension and chronic liver disease since 2014 **Management and treatment:** the drug therapy was discontinued. **Outcome:** the patient recovered after 1-3 days. **Disscussion:** gave (gastric antral vascular ectasia) is rare cause of upper gastrointestinal bleeding (UGIB). Multiple drugs, such as oestrogen-progesterone, octreotide, steroids, tranexamic acid and even bevacizumab have been tried to control gave-related bleeding. In 2006, the first patient with refractory Anaemia secondary to Gave was successfully treated with thalidomide, since then thalidomide has sometimes been administered to cirrhotic patients with gastrointestinal bleeding related to vascular malformations. **Conclusion:** thalidomide induces dose dependent neurological problems, hence the patient receiving thalidomide therapy should be closely monitored.

A case of anti-tubercular therapy-induced lichenoid eruptions: a rare adverse reaction in a patient with extrapulmonary tuberculosis

V. Nandhakumar[1], P. Ushakiranmd[1], R. Srinivasa Rao Md[1]
[1]Department of Pharmacology, Rangaraya Medical College, Kakinada

Introduction: Antitubercular therapy (ATT), including rifampicin, isoniazid, and ethambutol, is crucial for managing tuberculosis, including extrapulmonary forms like elbow joint tuberculosis. However, rare adverse drug reactions, such as lichenoid eruptions, can complicate therapy. These reactions manifest as pruritic, violaceous lesions, often requiring careful management to ensure treatment adherence. This report highlights a case of ATT-induced lichenoid eruptions in a 60-year-old female with extrapulmonary tuberculosis and elevated eosinophil count (1000/mm^3). **Methodology:** after initiating ATT, the patient presented with itchy, violaceous papules localized to the forehead and cheeks, drug-induced lichenoid eruptions were diagnosed based on clinical features and laboratory findings. The treatment involved oral prednisolone (10 mg daily), topical betamethasone cream, and oral cetirizine (10 mg daily). ATT was continued cautiously, with close monitoring of symptoms and lesion progression. **Results:** One week after starting therapy, pruritus significantly reduced, and lesions showed partial resolution. By the fourth week, the lesions had flattened completely, leaving post-inflammatory hyperpigmentation. The patient tolerated ATT well without

recurrence of lichenoid eruptions during follow-up, ensuring uninterrupted tuberculosis management. This case, recorded under in IPC unique number 301020573, contributes to the 16 previously reported cases of similar reactions visible in vigiaccess. **Conclusion:** This case emphasizes the importance of recognizing AT-induced lichenoid eruptions to prevent premature treatment discontinuation. The combined use of corticosteroids and antihistamines effectively resolved symptoms while maintaining att. Clinicians should remain vigilant for such rare adverse reactions to optimize patient outcomes.

Causality assessment of adverse drug reactions: a retrospective analysis

Anuj Satarkar[1], Deepak Bhosle[1], Jyoti Bobde[1]
[1]MGM medical college & hospital, Aurangabad

Introduction: Pharmacovigilance is the science of ensuring medication safety by identifying, evaluating, assessing and preventing adverse drug reactions (ADRs), with causality assessment playing a crucial role in determining drug relevance and guiding appropriate regulatory actions. The objectives of this study were to establish the causality between the drugs and the ADRs, and to assess the severities of the reported ADRs. **Methodology**: ADR reports from the past one year (November 2023 to November 2024) were analysed using the WHO UMC causality assessment scale for establishing the causality between drugs and their ADRs. ADRs were categorised depending upon their severity. Analysis was done in MS-excel. **Results**: a total of 72 ADRs were reported at our adverse drug monitoring centre (AMC). Maximum number of ADRs were reported from nephrology department (26; 36.11%). After causality assessment, maximum number of ADRs fell into "certain and probable/likely category" (40 & 18; 55.55% & 36.7%). After assessment for seriousness of the reactions, a few ADRs were categorised as serious (14; 19.44%) out of which1 case of mortality occurred (inj. Diclofenac;0.02%). maximum number of ADRs were due to antibiotics (26, 36.1%) and contrast-induced (25, 34.7%) drugs. Conclusion: focused training on ADR reporting and timely causality assessments can enhance reporting accuracy, promote early detection of serious ADRs, and improve overall pharmacovigilance outcomes. **Keywords:** pharmacovigilance, adverse drug reaction, causality assessment, ADR monitoring centre.

Medical device related adverse event: a case report

Pratiksha Ingle[1], Deepak Bhosle[1], Jyoti Bobde[1]
[1]MGM medical college & hospital, Aurangabad

Introduction: A femoral sheath catheter is a flexible tube inserted into the femoral artery or vein during cardiac catheterization to guide a catheter into the heart. It provides femoral arterial access, with the sheath temporarily in place to reduce bleeding. The femoral artery is preferred for its size and compressibility, and closure devices seal the port post-procedure. **Case summary:** A 72-year-old male patient of cad with inferior wall acute myocardial infarction was admitted for PTCA. Procedure was without complication sand all the procedures were done by trained personnel under the guidance of cardiac surgeon. Patient was shifted to ICU. Patient had bleeding and had femoral sheath removal. It was observed that the femoral sheath was broken. **Management:** Imaging revealed presence of broken sheath in femoral artery. Exploratory procedure was done to remove the broken sheath. **Outcome:** Patient was on ventilator support and was extubated after 3 days. **Discussion:** This case highlights the need to recognize and

report rare complications like femoral sheath fractures to the Materiovigilance program of India (MvPI) to enhance device safety, guide clinical practice, and improve patient outcomes. **Conclusion:** Reporting rare complications like femoral sheath fractures to the Materiovigilance program of India is essential for improving device safety and clinical outcomes. Such vigilance ensures better management and prevention of similar incidents.

Keywords: PTCA, femoral sheath, embolization, MvPI.

Assessment of medication regimen complexity and its impact on medication adherence in a tertiary care setting

Raihana Nilofar[1], Pascal Immanuel[1], Rajendran Priyadharsini[1]

[1]Department of Pharmacology, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry

Introduction: Medication regimen complexity (MRC) significantly influences patient adherence to prescribed treatments, with higher complexity often leading to poorer adherence and suboptimal therapeutic outcomes. This study aims to assess medication regimen complexity using the medication regimen complexity index (MRCI) and evaluate its impact on adherence through the medication adherence rating scale (MARS). Also, this study seeks to identify patterns of adherence, analyse the relationship between MRC and adherence levels and explore risk factors associated with high MRC. **Materials and methods:** This prospective observational study was conducted over two months (November–December 2023) at a tertiary care centre. Data were collected from 120 adult patients (≥18 years) visiting the general medicine OPD, with at least one prescribed medication. The MRCI assessed regimen complexity, while adherence was measured using mars. Sociodemographic and clinical characteristics were analysed using SPSS software, with significance set at $p< 0.05$. **Results: Mean MRCI score:** 27.19 ± 12.56 (range: 4–64).**Key contributors to MRC:** polypharmacy (63.3%), potential drug-drug interactions (72.5%), and high-alert medications (37.5%).**Adherence rates:** 88.4% adherent, 11.7% non-adherent. **Factors influencing high MRC:** older age (>75 years), unemployment, higher socioeconomic status, and comorbidities. On-adherent patients had significantly higher MRCI scores (mean: 38.2 ± 14.3) than adherent patients ($p< 0.05$). **Conclusion:** Medication complexity significantly impacts adherence. Factors such as polypharmacy, drug-drug interactions, and high-alert medications contribute to higher MRCI scores, which are associated with non-adherence. Simplifying medication regimens should be a priority for healthcare providers to improve adherence, especially in patients with multiple chronic conditions.

Keywords: Medication regimen complexity, MRCI, medication adherence, polypharmacy, MARS

Pharmacoeconomic Study of Biologicals Used for Rheumatoid Arthritis in India

Sapna A. More[1], Pallav Hetawal[2]

[1]MGM Medical College, Indore, Madhya Pradesh, India, dr.sapnagajbhiye@gmail.com

[2]LNCT Medical College, Indore, Madhya Pradesh, India, prhetawal1994@gmail.com

Introduction: Rheumatoid Arthritis is a chronic autoimmune disorder requiring prolonged treatment, often involving high-cost biologicals. This study evaluates the cost variation among biologicals approved in India as per the national formulary of India (NFI, 2021), including TNF antagonists—infliximab, adalimumab, and etanercept—and the b-cell-depleting agent rituximab.

Methodology: a cross-sectional study was conducted using cost data for different brands of the same drug, strength, and dosage form, from the current index of medical specialties (CIMS) India (July–October 2024). Injectable prices were Standardized to per ampoule or vial. Formulations manufactured by single company or with incomplete cost data were excluded. Mean cost, cost ratios, and percentage cost variations were calculated, with price variations Categorized into five groups: <24.99%, 25–49.99%, 50–99.99%, 100–499.99%, and >500%. **Results**: Four drugs and 14 dosage forms were Analyzed, five of which were single-brand formulations. rituximab 500 mg/50 ml exhibited the highest cost ratio (5.44) and percentage cost variation (444.65%), while rituximab 600 mg/60 ml showed the least cost ratio (1) and cost variation (0.0005%). The mean costs ranged from ₹2,500 for adalimumab 20 mg/0.4 ml to ₹65,900 for rituximab 1400 mg/11.7 ml. Three formulations fell in the <24.99% category, three in the 25–49.99% range, one in the 50–99.99% range, and two in the 100–499.99% range. **Conclusion**: Significant cost disparities exist among biologicals for RA in India, with rituximab showing the highest variability. regulatory measures are needed to enhance price uniformity and accessibility, with further research necessary to evaluate the clinical implications of these variations.

To evaluate the outcome of sensitization sessions for medical and paramedical staff on ADR reporting in a tertiary care hospital

Shirish Kumar Tiwari[1], Sanjib Das[1], Dr Mohit Kulmi[1]
[1]Department of Pharmacology, GMC Ratlam (MP)

Introduction: adverse drug reactions (ADRs) significantly contribute to morbidity, mortality, and increased healthcare costs. The pharmacovigilance programme of India (PvPI) aims to enhance patient safety and well-being by monitoring the safety of medications and minimizing risks associated with their use. Our center is the first PvPI reporting centre among the newer Medical Colleges In Madhya Pradesh. Challenges such as underreporting due to communication gaps, a lack of reporting culture, and insufficient awareness hinder effective ADR reporting. Sensitizing postgraduate students, interns, and nurses—who maintain close interactions with patients—can potentially improve ADR reporting. **Methodology:** a total of 100 participants, including postgraduate students, interns, and nurses, underwent sensitization sessions on ADRs and the PvPI during October 2024. ADR reporting data were Analysed at monthly interval for two months before and after the sensitization sessions by comparing documentary evidence. **Results:** pre-sensitization, three ADRs were reported each month in September and October 2024. Following the sensitization program, the number of ADR reports increased to six in November and seven in December *2024.*paired t- test revealed statistically significant increase in ADR reporting ($p < 0.05$). **Conclusion:** a structured sensitization program for medical and paramedical staff significantly improved ADR reporting at GMC Ratlam, highlighting the effectiveness of targeted sensitization initiatives in increasing the ADR reports at GMC Ratlam.

Keywords: pharmacovigilance, adverse drug reactions, ADR reporting.

Nimesulide induced steven Johnson Syndrome-Toxic Epidermalnecrolysis overlap: a case report

Kavita Jaiswal[1], Piyush Nama[1], Ankush Bhad[1]

[1]Department Of Pharmacology, Government Medical College and Hospital, Nagpur

Background: Stevens-Johnson Syndrome (SJS) is a life-threatening adverse drug reaction characterized by extensive mucocutaneous exfoliation. Though rare, nonsteroidal anti-inflammatory drugs like nimesulide have been implicated in SJS. **Case presentation:** we report a case of a 52-year-old female presenting with widespread skin peeling, following a two-day history of nimesulide intake for flu-like symptoms. Initial symptoms included pruritus and fluid-filled bullae, progressing to extensive skin erosion involving 30% of the body surface area. Clinical examination revealed pseudo-nikolsky sign positivity, flaccid bullae, and erythematous oral lesions. Laboratory findings on admission demonstrated acute kidney injury (urea: 101 mg/dl, creatinine: 4.6 mg/dl), hyperglycemia (>600 mg/dl), and severe electrolyte derangement. Despite initial management with systemic corticosteroids, intravenous immunoglobulin (ivig), and meticulous supportive care, her condition rapidly deteriorated with severe anaemia (haemoglobin drop from 13.2 to 5.8 g/dl) and respiratory failure, culminating in cardiopulmonary arrest on day two. **Discussion:** this case highlights the severe clinical trajectory of nimesulide-induced sjs, exacerbated by comorbidities like uncontrolled diabetes mellitus and chronic kidney disease. The diagnosis was established based on clinical and laboratory criteria, with a scorten score predicting high mortality (>35.8%). Management controversies in SJS persist, particularly regarding early corticosteroid use. In this patient, systemic steroids and IVIG were employed to modulate immune-mediated keratinocyte apoptosis. **Conclusion:** This case underscores the need for cautious prescription of nimesulide and heightened awareness of its potential to induce fatal SJS. Prompt recognition, drug discontinuation, and aggressive supportive care remain pivotal in management. Further research is essential to optimize treatment protocols for SJS-Ten overlap syndromes.

Febrile reactions following intravenous administration of ceftriaxone: a case series

Monika Suryawanshi[1], Bijoy Kumar Panda[1], Anjali Shinde[2]

[1]Krishna Institute of Pharmacy, Krishna Vishwa Vidyapeeth, Karad, Satara, Maharashtra

[2]Adverse Drug Reaction Monitoring Centre, Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth, Karad, Satara, Maharashtra

Background: Ceftriaxone, a broad-spectrum cephalosporin antibiotic, is generally well-tolerated, however adverse drug reactions (ADRs) such as fever with chills are infrequently reported and poorly documented. This case series aims to highlight the clinical presentation and resolution of febrile reactions in patients receiving ceftriaxone iv. **Case summary**: a retrospective analysis was conducted from the spontaneous ADR reports submitted to our ADR monitoring Centre under PvPI of our institution on seven patients admitted in cardiac ward who developed febrile reactions following intravenous administration of ceftriaxone. all seven patients developed fever with chills within hours of receiving intravenous ceftriaxone of a specific brand and manufacturing batch on the same day and date. No other significant systemic complications were observed. The febrile reactions resolved spontaneously within 4-5 hours of discontinuation of the implicated generic branded drug. Clinical investigations suggested a potential link between the specific drug batch or excipients and the observed reactions. The Naranjo causality assessment algorithm indicated a probable relationship between ceftriaxone iv and the febrile reactions in all cases. **Management and treatment:** paracetamol(*iv*) was administered to reduce febrile illness. Ceftriaxone was replaced by iv Augmentin during subsequent treatment process. **Outcome and follow up**: Dechallenge resulted into positive

outcome with no harm. The batch of the manufacturer was returned back with complaints of adverse effect seen in patients. **Conclusion**: this case series emphasizes the importance of vigilant ADR monitoring and reporting in clinical practice. Further investigation into the role of drug formulation and excipients in triggering such reactions is warranted to ensure patient safety.
Keywords: ceftriaxone, febrile reaction, adverse drug reaction, causality assessment, patient safety

A case of periorbital inflammation induced by Deroben® Ointment: unveiling dithranol's irritative potential in psoriasis treatment

Smita Gaikwad[1], Bijoy Kumar Panda[1], Anjali Shinde[2]
[1]Krishna Institute of Pharmacy, Krishna Vishwa Vidyapeeth, Karad, Satara, Maharashtra
[2]Adverse Drug Reaction Monitoring Centre, Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth, Karad, Satara, Maharashtra

Introduction: Psoriasis is a chronic inflammatory skin condition treated with various topical agents. Deroben® ointment, comprising dithranol 1.15%, salicylic acid 1.15%, and coal tar solution 5.3%, is indicated for the treatment of psoriatic plaques. **Case summary:** A 17-year-old male presented to a tertiary care hospital with complaints of swelling, redness, and itching around the right eye socket that had spread to the left eye. The patient had applied deroben® ointment for psoriatic plaques on his forehead as advised by the local community pharmacist. The patient exhibited marked periorbital swelling, redness, and pruritus, suggestive of a local inflammatory reaction. Based on the temporal association and the application site, the reaction was attributed to dithranol. **Management:** the patient was advised to discontinue the ointment immediately and treatment with topical corticosteroids and antihistamines was initiated. **Outcome and follow up**: symptoms subsided within three days, confirming the diagnosis of a topical adverse reaction to dithranol. No systemic involvement was noted. **Discussion:** Dithranol is a keratolytic agent effective in psoriasis treatment but often causes local irritation, which may extend beyond the application site due to inadvertent transfer. Evidence suggests that dithranol's oxidative properties can damage epidermal cells, leading to irritation and inflammation. Coal tar and salicylic acid, though generally well-tolerated, may exacerbate these effects when combined with dithranol. **Conclusion**: This case underscores the importance of vigilance in the use of deroben® ointment for psoriasis. Patients and clinicians must be aware of its potential to cause significant irritation and inflammation. Strategies such as patch testing and precise application can prevent risks. **Keywords:** Dithranol, salicylic acid, periorbital erythema, infraorbital erythema, self- medication

Fluoroquinolones induced fixed drug eruption

Avani Shakalya[1], Ruchi Baghel[1], S.P. Dhaneria[1], Neer Arora[1], Madhav Saxena[1]
[1]RD Gardi Medical College and Hospital, Ujjain

Introduction: Fixed Drug Eruption (FDE) is a cutaneous adverse drug reaction characterized by the onset of rash at a fixed location on the body each time a specific medication is administered. **Case summary:** An 18-year-old male presented with dark patches on the neck, ear, genital sand blisters on the hands, generalized itching and burning. Four days prior, he had fever and was prescribed tablets ofloxacin 500 mg, betamethasone 0.5 mg and cetirizine-phenylephrine-paracetamol combination. After taking these, he developed the described symptoms and sought

treatment at a government hospital and received injections of pheniramine and dexamethasone and also tablets of ampicillin and multivitamins but he did not get any improvement therefore, he resumed the initial medications and visited dermatology OPD of a tertiary care hospital. He also reported similar episodes of lesions in past six months for two times but could not recall the medications received. **Management and treatment:** The dermatologist of tertiary care hospital prescribed clobetasol cream, tablets prednisolone 16 mg, bilastineod for 10 days followed by same treatment with tapering dose of 8 mg of prednisolone and fusidic acid cream for next 10 days. **Outcome and follow up:** Patient reported marked improvement in lesion after 10 days of treatment and almost completely recovered after 20 days of treatment. **Discussion:** Ofloxacin, a second-generation fluoroquinolone, is widely prescribed for infections and generally well-tolerated. However, in 2004, the us-FDA mandated warnings on fluoroquinolones for risks like peripheral neuropathy, tendon damage, QTC prolongation, and severe dermatological Reactions. The cetirizine-phenylephrine-paracetamol combination is excluded as the suspected medication causing ADR because the patient previously received many times without any problem. According to who and Narajo's causality assessment this ADR comes under probable category. **Conclusion:** Recognizing the ADR due to medication and including in medication history of patient may prevent ADRs in future. Therefore, this patient was given "drug alert card" for reference to physician in future as a drug safety measure.

Robotics in drug delivery and pharmacovigilance: a revolutionary approach

Tanu Sharma[1], Vansh Agrawal[1], Bhavesh Chaurasiya[1], P. K. Singour[1], Vipin V Dhote[1]
[1]Department of Pharmaceutical Chemistry and Department of Pharmacology, VNS Group of Institutions-Faculty of Pharmacy, Neelbad, Bhopal

Brief introduction: Robotics in healthcare offers a promising solution to address issues such as adverse drug reactions, medication errors, and the irrational use of drugs. By integrating advanced technologies like artificial intelligence (AI) and machine learning, robotic systems can improve the accuracy of drug administration, ensuring correct dosages and timing while reducing the likelihood of human error. These systems can automate medication dispensing, monitor patient responses, and check for potential drug interactions, thereby minimizing adverse effects. **Methodology**: Nanorobots and microrobots, in particular, have gained attention for their potential to target specific cells or tissues at a molecular level, ensuring that the drug reaches its intended site with minimal systemic exposure. these systems can also control drug release rates, ensuring a continuous or on-demand delivery of therapeutics, which is particularly important for cancer patients requiring tailored and sustained treatment regimens. By responding to real-time feedback, robotic drug delivery systems can adjust to changes in the tumor's microenvironment, improving the overall efficacy of the treatment. These robots can also be engineered to release drugs at controlled rates, offering personalized treatment plans for patients with varying needs. In addition, the use of robotic systems can enhance the efficiency of drug administration in patients with chronic conditions, offering reduced human intervention and improved outcomes. **Conclusion:** In terms of preventing the irrational use of drugs, robotics can assist in clinical decision-making by analyzing vast datasets and suggesting evidence-based therapies. This reduces reliance on subjective clinical judgment and enhances treatment outcomes. As robotic technology continues to evolve, its role in medication management is set to transform healthcare by improving drug quality, reducing errors, and ensuring safer and more rational drug use.

Ultimately, robotic systems have the potential to enhance patient safety, improve therapeutic efficacy, and optimize overall healthcare delivery.

Keywords: Robotics; pharmacovigilance; anti-cancer, drug delivery.

A comprehensive exploration of clinicians' perspectives on the challenges and Barriers in implementing artificial intelligence in healthcare: a questionnaire-based Study from tertiary care hospital in central India

Supriya Devidas Khade[1], Mohini Mahatme[1], Purvastadhargave[1], Ravi Gaikwad[1]

[1]Department Of Pharmacology, Government Medical College, Nagpur

Introduction: Artificial intelligence (AI) has the potential to transform healthcare in various ways. It can turn large amounts of patient data into actionable information, improve public health surveillance, accelerate health responses and produce faster and more targeted research and development. This study examines evidence on the barriers to the adoption of artificial intelligence in healthcare in India. It can scan populations, identifying risk factors and predicting outbreaks before they erupt. This foresight allows for targeted resource allocation and preventive measures, mitigating outbreak impact. Ai can even personalize healthcare, shaping treatment plans based on a patient's unique lifestyle and medical history.in high-income countries, AI is gradually improving public health services. In the USA, ai applications are saving up to USD 150 billion in healthcare costs. In context of developing countries, the potential of ai in public health needs to be assessed. This study enables a comprehensive exploration of clinicians' views, aiming to identify actionable insights for addressing barriers to ai implementation in healthcare systems. **Objectives:** to identify the challenges & barriers to the successful implementation of artificial intelligence in healthcare **Methodology:** It is a cross-sectional study in which a pre-validated questionnaire developed. purposive sample of 100 clinicians from various specialties taken in the study. Data is collected using a structured questionnaire designed after an extensive literature review and expert consultation. Data will be analyzed using appropriate statistical test. **Results &conclusions:** as the data collection is ongoing, results &conclusions will be presented at the time of presentation.

Adverse event related to blood pressure monitor: a cross-sectional study

Alfiya Perween[1], Vijay Aherwar[1], Avinash Singh Mandoli[1], Vipin Dhote[1]

[1]VNS Group of Institutions, Faculty of Pharmacy, Neelbud, Bhopal

Aim and Objective: Materiovigilance is the concept of closely monitoring any unfavorable changes in a medical device's performance or characteristics using a system that can detect, report, and estimate unfavorable occurrences and respond to them with on-the-ground safety corrective actions or device recalls during the post-marketing phase of a medical device. the study aimed to investigate adverse events related to blood pressure monitors through a cross-sectional design. **Material and methods**: the study setting at Sri Aurobindo Medical College and Pg Institute, Indore, provided a suitable environment to conduct the research and gather valuable insights into adverse events associated with blood pressure monitors in a real clinical setting.it took3 months (from [start date] to [end date]). **Result:** the mean age of all patients in the study was 48,84 years, with a standard deviation of 17.29. This suggests that the study population had a wide age range, with an average age close to 48.84 years. The standard

deviation indicates that there was some variability in the ages of the patients, with some being significantly younger or older than the mean age. **Conclusion**: this cross-sectional study target to explore adverse events related to blood pressure monitors and shed light on various aspects of their usage, maintenance, and associated challenges. The findings provide valuable insights into the current practices and highlight areas that require attention for improvement.

Key words: Materiovigilance, cross sectional study, blood pressure monitor

To study the effect of wound healing activity of MUSA balbisiana SP. peel as anti-inflammatory activity on Wister rats

Mohan Pethe[1], Aashish Singh Rajput[1], Sushil Kumar Varma[1], Babita Jadhav[1]

[1]Department of Pharmacology, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra

Background: Herbal medicines are widely used for their affordability and minimal side effects. *Musa balbisiana* peel, though traditionally utilized, remains underexplored for its therapeutic potential. This study evaluates the anti-inflammatory and wound-healing properties of its hydroalcoholic extract (HEMB) in a rodent model. **Objective:** To assess HEMB's anti-inflammatory effects using carrageenan-induced paw Edema and cotton pellet-induced granuloma models and its wound-healing effects via excision and incision wound models. **Methodology:** This experimental study was conducted at JNMC, Wardha, with Wistar rats (180-250 g). The study duration was 14 days for acute toxicity and 7-21 days for anti-inflammatory and wound healing tests. Musa balbisiana peel extract was prepared using 70% ethanol. Toxicity was assessed at 200, 400, and 800 mg/kg. Anti-inflammatory activity was evaluated using carrageenan-induced paw Edema and cotton pellet-induced granuloma. Wound healing was tested via excision and incision models. Data were analyzed using one-way anova and student's t-test ($p<0.05$, $p<0.01$, $p<0.001$). **Results:** Hemb significantly reduced granuloma weight by 20.24% (200 mg/kg, $p<0.01$) and 46.8%-66.73% (400-800 mg/kg, $p<0.001$) compared to indomethacin (78.61%, $p<0.001$). In paw edema, hemb (800 mg/kg) reduced edema by 30.90% and 28.90% at 2 and 3 hours ($p<0.001$), comparable to aspirin. Hemb ointments (10%-20%) significantly improved wound contraction, epithelialization, and tensile strength ($p<0.001$), comparable to soframycin. **Conclusion:** Hemb demonstrated significant anti-inflammatory and wound-healing properties in rats, likely due to its bioactive compounds. It offers potential as a cost-effective alternative for managing inflammation and wounds, warranting further exploration.

Phenotyping of intravenous (IV) fluid therapy in critical care unit (CCU)

Het Desai[1], Smruti Patel[1], Rahul Patel[1], Abhishek Prajapati[2], Anita Mehta[1]

[1]Anand Pharmacy College, Anand, Gujarat [1]

[2]Shree Krishna Hospital and Pramukhswami Medical College, Bhaikaka University, Karamsad[2]

Introduction (background and objective): Variations in patient responses to intravenous (IV) fluid therapy in critical care necessitate individualized approaches to optimize outcomes. Up to 20% of patients receive inappropriate iv fluids, resulting in increased morbidity and mortality. The ros-d model, proposed by vincent and de backer, categorizes iv fluid management into four stages—rescue, optimization, stabilization, and de-escalation—emphasizing the need for tailored fluid management strategies. This review aims to assess the consequences of phenotyping iv fluid therapy in critical care and its potential to improve outcomes by integrating goal-directed,

personalized treatment approaches. **Methodology:** a comprehensive literature search was conducted using pubmed, cochrane library, british medical journals, springer nature, nature, and the society of critical care medicine databases. Search terms included "iv fluid therapy," "phenotyping," and "critical care." Studies published in english within the last 15 years focusing on adult icu populations were included. The screening process involved reviewing titles, abstracts, and full texts to identify 10 relevant studies for synthesis. **Results:** Key findings from the selected studies indicate that inappropriate fluid administration affects up to 20% of patients, contributing to increased complications. Excessive cumulative fluid balance, particularly in sepsis, is associated with higher mortality. Regional variations in fluid choice were noted, with colloids often preferred despite limited supporting evidence and higher costs. Survivors and non-survivors initially exhibited similar fluid balances; however, a positive fluid balance on the second day independently predicted icu mortality. These findings underscore the importance of phenotyping in iv fluid therapy to guide individualized care. **Conclusion:** Integrating the ros-d framework into iv fluid management enables personalized, disease-oriented treatment approaches that address the risks associated with inappropriate fluid administration. By tailoring fluid therapy to individual patient needs, this approach has the potential to improve outcomes in critical care settings, particularly by mitigating complications such as excessive fluid accumulation and its impact on mortality.

Keywords: intravenous (iv) fluid therapy, critical care unit (CCU), fluid overload, individualized fluid therapy, phenotyping, hemodynamic stability, patient-centered care

Impact of Certain Educational Interventions on Adverse Drug Reaction Reporting by Health Professionals

Deepika Singh[1], Surendra Kumar Bouddh[1]

[1]Dept. Of Pharmacology, Govt. Medical college, Datia

BACKGROUND: Spontaneous or voluntary reporting of suspected adverse drug reactions (ADRs) is one of the vital roles of all health professionals. In India, under-reporting of ADRs by them is recognized as one of the leading causes of poor ADR signal detection. The present study was planned to assess the impact of an educational intervention on ADR reporting. **OBJECTIVES:** 1.To evaluate the effectiveness of structured educational interventions on the ADR reporting rates. 2.To identify barriers and potential solutions to underreporting in pharmacovigilance. **METHODOLOGY:** An educational intervention in the form of sensitization programme, including basic knowledge of pharmacovigilance, monitoring system for pharmacovigilance and case-based ADR reporting was conducted among the healthcare professionals in a tertiary care Hospital in Central India. Number and quality of ADR reported by the healthcare professionals in pre-intervention (3 months), intervention (01 month), and post-intervention (3 months) phase were compared. **RESULT:** Only 01 ADR was reported in pre-IP Phase, 07 ADRs in the intervention phase and 12 ADRs in the post-IP Phase. Maximum ADRs (12) were reported after the workshops. Most of the participants agreed that reporting ADR improves drug safety and frequent sensitization programmes should be conducted. **CONCLUSION:** The study reveals that the deficient ADR reporting indicates strong need for the conduction of repeated training/sensitization programmes and other suitable methods for encouraging ADR reporting.

Evaluating prognostic scoring systems for predicting invasive fungal infections in critically ill patients

Maitri Patel[1], Sakshi Desai[1], Karishma Tekchandani[1], Samir Patel[2], Tejal Gandhi[1], Chirag Modi[2], Juliet Joy Joseph[1]

[1]Anand Pharmacy College, Anand, Gujarat

[2]Shree Krishna Hospital and Pramukhswami Medical College, Bhaikaka University, Karamsad

Introduction (Backgroud): Addressing the challenges posed by invasive fungal infections (IFIs) in critically ill and immunocompromised patients necessitates tailored approaches due to high morbidity and mortality rates. Suboptimal diagnostic methods, delayed identification, and inadequate treatment options further worsen outcomes, emphasizing the importance of early disease severity and mortality prediction. **Methodology:** This review synthesized findings from numerous articles accessed through databases such as springer, PubMed, NCBI, Scopus, wiley online library, and science direct. The search employed keywords like invasive fungal infections, apache II, SOFA , MODS, CCI , SAPS II , prediction and intensive care units. Studies identified scoring systems, including apache ii, sofa, and saps ii, as critical tools for monitoring and predicting mortality. **Result:** The combination of the sofa and charlson comorbidity index (cci) demonstrated superior predictive accuracy for candidemia, with sofa scores ≥5 and cci scores ≥3 as independent predictors of mortality. Tools such as the leon score (AUC: 0.946) and IFIRS stratified ICU patients into low-risk (5.2%), intermediate, and high-risk (63.2%) categories to enhance the precision of clinical interventions. Notably, inappropriate fluid administration and excessive cumulative fluid balance were linked to higher mortality, highlighting the need for condition-specific management strategies. **Conclusion:** This review highlights the potential of integrated scoring systems to inform timely, individualized care and improve outcomes for critically ill patients. A comprehensive and holistic approach is important for enhancing critical care practices and effectively managing IFIS

Keywords: invasive fungal infections, intensive care units, Apache II, SOFA , MODS , CCI , MPM , SAPS II, LODS , ODIN , TRIOS, prediction

Understanding the risks: ADRs associated with over-the-counter drug use

Neer Arora[1], S.P. Dhaneria[1], Ruchi Baghel[1], Avani Shakalya[1], Madhav Saxena[1]

[1]Department of Pharmacology, R.D. Gardi Medical College and Hospital, Ujjain (MP)

Background- over the counter (OTC) drugs are the ones which can be obtained from retail pharmacies without prescription from a physician. use of over-the-counter drugs without medical guidance leads to inappropriate or undue therapy, adverse drug reaction, antimicrobial resistance& delay in appropriate treatment, that may increase morbidity. **Objectives**- To analyse adverse drug reaction from over-the-counter medication. **Methodology**- a cross-sectional study was carried out at community level. The data was collected by face-face interview of eldest member of the family available using a semi structured questionnaire which had both closed and open-ended questions. Informed written consent was taken from study subjects, confidentiality was maintained and approval from EC was taken. **Result-** out of the 70 families interviewed, 83% consumed OTC drugs, 35% consumed with their own knowledge and 19% used older prescription. The commonest cause for consumption was fever 40%, cold and cough 39% followed by gastritis and other minor ailments. Most used OTC drug were paracetamol (30%) and diclofenac (15%). Instructions related to administration of the drugs were not explained by the pharmacist. None were aware about the possibility of adverse drug reaction occurring due to

drugs at the start of the treatment. How-ever 20% of the interviewee mentioned about some undesirable effect occurring after intake of drugs, mostly gastric upset due to norfloxacin. 35% also used home remedies for their health problems. None of the interviewee were aware about reporting of ADRs by patients/relatives under PvPI. **Conclusion**: this pilot study highlights the lack of adequate knowledge in common men in respect of ADRs and it's reporting system. To address this, we have developed an educational module on common OTC drugs to promote its rational use through awareness about 'when to use the drug', 'how to use', when not to use', 'common side effect associated with use of the drug'. Which will be used at next visit. Aim of this educational intervention is to increase awareness about safe and effective use of medicines in society.

Cost analysis study of proton pump inhibitors and H2-receptor antihistaminic drugs – a pharmacoeconomics study

Nitin Verma[1], Ashutosh Tiwari[1], Pooja Solanki Mishra[1]
[1]Department Of Pharmacology, Mahatma Gandhi Memorial Medical College Indore

Introduction: this study involves a cost analysis of proton pump inhibitors (PPIs) and H1 antihistamines in India, examining their prices, brand variability, and implications for long-term and short-term treatment costs. PPIs, including omeprazole, pantoprazole, and esomeprazole, are essential for managing chronic conditions such as GERD and peptic ulcers. In contrast, H1 antihistamines like ranitidine, famotidine addresses short-term acid reflux. **Objective:** 1. To evaluate the cost of proton pump inhibitors vs H1 anti-histamine drugs of different generic classes and different brand names of one compound. 2. To evaluate the difference in cost of different brands of the same active drug by calculating percentage variation of cost. **Methodology:** The analysis utilized data from CIMS and IDR 2024(issue 5) to calculate the cost per defined daily dose (DDD) and percentage cost variation between different brands. **Results:** Indicate that PPIs incur higher costs, with daily expenses ranging from ₹4.50 to ₹7.20 per DDD and monthly costs from ₹135 to ₹600. Antihistamines are more economical, with daily costs between ₹3.00 and ₹4.00 per DDD and monthly costs of ₹90 to ₹150. Notably, PPIs exhibit significant price variability across brands, while antihistamines show more consistent pricing. **Conclusion:** The findings suggest that although PPIs are indispensable for chronic conditions, their long-term use results in higher expenses. Antihistamines, with lower costs and minimal price variability, are more cost-effective for short-term or conditions. This study underscores the importance of cost considerations in drug selection, particularly in resource-limited settings like India.

Assessment of The Gap Between Prescribing Practices and Pharmacogenetic Recommendations

Ajay Shukla[1], Srijan G Shetty[1], Florance Joy[1], Shubham Atal[1], Ratinder Jhaj[1]
[1]Department of Pharmacology, AIIMS Bhopal

Introduction: Pharmacogenomics is essential for optimizing drug therapy by ensuring the safe and effective use of medications, especially for drugs where genetic testing is recommended or required. PharmGKB is an online database that compiles pharmacogenetic recommendations from regulatory bodies like the FDA, ema, and HCSC. Drugs are categorized based on the level

of pharmacogenetic testing required: testing required and testing recommended. Despite growing awareness of pharmacogenomics, there remains a gap in its clinical adoption. This study aims to assess the prevalence of prescriptions in a tertiary care setting for drugs that either require or recommend pharmacogenetic testing according to pharmGKB, based on guidelines from the FDA, ema, and HCSC. **Methodology:** this cross-sectional study analyzed 5,177 prescriptions from the outpatient departments of a tertiary care hospital. PharmGKB was used as the primary source to identify drugs with testing required or testing recommended recommendations, according to FDA, EMA, and HCSC guidelines. Prescriptions were reviewed to determine the number and proportion containing these drugs and to identify any gaps in adherence to pharmacogenetic guidelines. **Results:** out of 5,177 prescriptions analyzed, 87 prescriptions (1.68%) contained drugs for which pharmacogenetic testing is required (8 drugs), and 50 prescriptions (0.97%) contained drugs for which testing is recommended (5 drugs). In total, 137 prescriptions (2.65%) included drugs for which pharmacogenetic testing is either required or recommended, highlighting a potential gap in adherence to pharmacogenetic guidelines. **Conclusion:** the study identifies GAPS in prescribing practices related to pharmacogenetic testing. Integrating pharmacogenetic testing into clinical practice could optimize drug therapy, enhance patient safety, and improve outcomes. Addressing barriers such as the complexity, cost, and accessibility of genetic testing will be essential for broader implementation

Case report: community-acquired klebsiella aerogenes UTI in central India—challenges and strategies in an XDR scenario

Vikrant Katara[1], Vikalp Tiwari[1]

[1]Mahatma Gandhi Memorial College, Indore (M.P)

Introduction: Urinary tract infections (UTIs) are a common health issue, exacerbated by rising antibiotic resistance, especially in hospital-acquired infections. klebsiella aerogenes, traditionally associated with nosocomial infections, has recently been reported in community-acquired UTIs, particularly in immunocompromised patients. This case presents the management of a community-acquired UTI caused by extensively drug-resistant (XDR) *k.* Aerogene*s* in a diabetic patient. **Case summary:** a 71-year-old woman with type-2 diabetes and hypertension presented with fever, dysuria, and abdominal pain. Despite empirical treatment with ceftriaxone, her symptoms persisted. Urine culture identified k. Aerogenes, resistant to most antibiotics but sensitive to carbapenems and polymyxins. **Management and treatment:** based on susceptibility testing, the patient was switched to meropenem (500 mg every 8 hours) for 10 days. Diabetes management with metformin and telmisartan was continued. **Outcome and follow-up:** after 7 days of meropenem therapy, the patient's symptoms resolved. She was discharged on day 25 with instructions to complete the full antibiotic course. Follow-up cultures at 15 days post-discharge were negative, and monthly urine cultures over the next 3 months showed no recurrence. **Discussion and conclusion:** This case highlights the importance of accurate pathogen identification and tailored antibiotic therapy in managing resistant infections. Targeted treatment with meropenem successfully resolved the infection, emphasizing the need for antibiotic stewardship and vigilant follow-up, particularly in high-risk patients with diabetes.

CAR-T therapy-induced secondary malignancies: a narrative review and Pharmacovigilance call to action

Avani Patel[1], Dr. Akshay Shah[1]
Anand Pharmacy College, Anand, Gujarat

Background: Car t-cell therapy offers hope for relapsed hematologic malignancies but necessitates enhanced post-marketing surveillance to address secondary malignancies. Nexcar19, an affordable Indian car t-cell therapy targeting cd19, shows promise but requires rigorous monitoring to ensure. **Introduction:** A patient's immune cells to target and destroy cancer cells. This novel approach has shown efficacy in treating hematologic malignancies like Leukemia and lymphoma. This review determines the association between car-t cell therapy and risk of secondary malignancies. **Methodology:** This review explores available clinical data, regulatory evaluations, and reported cases of secondary malignancies following car t-cell therapy. A comprehensive analysis of patient outcomes, mechanisms of action, and genetic modifications was conducted, incorporating findings from the FDA adverse event reporting system (FAERS), PRAC evaluations, and academic publications. Additionally, clinical trial data for nexcar19, an indigenous car t-cell therapy targeting CD19 antigens, were reviewed **Results**: Secondary tumors, including t-cell lymphoma and myelodysplastic syndromes, have been reported in a subset of patients' post-car t-cell therapy. Mechanistic investigations suggest the involvement of insertional oncogenesis due to random integration of car constructs into the host genome. PRAC documented secondary tumors in 38 out of 42,500 cases, while FAERS identified malignancies in 4.3% of adverse event reports. No evidence of secondary tumors observed during the trial period of nexcar19 **Conclusion:** Safety. Transparent communication and vigilant oversight are essential to maximize its potential while minimizing risks.

Keywords: Car-t cell therapy, secondary tumors, t cells, pharmacovigilance, post marketing surveillance, PRAC, malignancies, nexcar19

COVID-19 Vaccine-Induced Thrombotic Thrombocytopenia: A Narrative Review Through the Lens of Pharmacovigilance

Prina Patel
Anand Pharmacy College, Anand, Gujarat

Introduction (background and objective): Vaccine-induced immune thrombotic thrombocytopenia (VITT) is a rare but serious adverse event linked to COVID-19 vaccines. VITT is characterized by thrombocytopenia and involves anti-platelet factor 4 (PF4) antibodies, platelet activation, and thrombus formation, leading to complications like cerebral venous sinus thrombosis (CVST) and pulmonary embolism. In this systematic review, we critically evaluated the published literature on VITT highlighting its incidence, clinical presentation, diagnosis, and the critical role of pharmacovigilance in ensuring vaccine safety. **Methodology:** Articles were sourced from databases like PubMed, SciELO, and Google Scholar using terms such as "VITT," "COVID-19 vaccine," and "thrombocytopenia" with duplicates removed and relevant results manually reviewed. Abstracts and titles were screened for review inclusion, and full articles were accessed when their relevance was uncertain. **Results:** Comparative risks between adenoviral vector and mRNA vaccines were evaluated along with incidence. Adenoviral vector vaccines were associated with a higher VITT risk compared to mRNA vaccines. The incidence of VITT ranged from 1 case per 26,500 to 127,300 first doses of ChAdOx1 and 1 case per

518,181 second doses. For Ad26.COV2.S, the incidence was 1 case per 263,000 doses administered (as of 2022). Most cases occurred in younger adults, particularly women, within 4–30 days post-vaccination. Pharmacovigilance interventions, including age restrictions, risk-benefit analyses, and revised vaccination protocols, effectively mitigated VITT. **Conclusion:** The emergence of VITT underscores the importance of pharmacovigilance in vaccine safety. Advanced technologies and interdisciplinary efforts are vital for detecting and managing rare adverse events, ensuring safer vaccine deployment and maintaining public trust.

Keywords: Vaccine-induced immune thrombotic thrombocytopenia (VITT), Pharmacovigilance, COVID-19 Vaccine, Adenoviral vector vaccines, incidence

To assess the knowledge, attitude & practice of look alike sound alike (LASA) drugs among health care providers at a tertiary care hospital

Nancy[1], Akash Khobragade[1], Sanjeevani Chawre[1], Aditya Bawne[1]
[1]Pharmacology, Grant Government Medical College, Mumbai

Background: look-alike sound-alike (LASA) drugs are a significant cause of medication errors, posing risks to patient safety. Despite their importance, there is limited data on healthcare providers' knowledge, attitude, and practices (KAP) regarding LASA drugs, especially in indian tertiary care settings. **Objectives**: this study aims to assess the KAP of LASA drugs among healthcare providers in a tertiary care hospital and identify gaps to improve medication safety practices. **Methods**: a cross-sectional observational study with convenience sampling (minimum sample size 100) with study duration of 2 months is ongoing at a tertiary care hospital in india. A structured questionnaire, validated through a pilot study, was administered to healthcare providers, including doctors, nurses, and pharmacists with cronbach's alpha value of 0.9. descriptive analysis will be done. (IEC number: IEC/pharm/RP/335/oct/2024) **Results**: interim analysis. **Conclusion**: it will be made after completion of study.

Keywords: LASA drugs, medication errors, healthcare providers, KAP study, patient safety. Results & conclusion will be completed by the time of submission of poster.

Paronychia and pride: unmasking a hidden side effect of EGFR inhibitors in lung cancer treatment

Divyashanthi CM[1], Geethanjali Sahadevan[2], Kalaimani S[3]
[1]Pharmacology, JIPMER, Karaikal
[2]Dermatology, JIPMER, Karaikal
[3]Medicine, JIPMER, Karaikal

Background/introduction: Lung cancer remains a leading cause of cancer-related mortality worldwide. Epidermal growth factor receptor inhibitors (EGFRIs) have revolutionised the treatment of non-small cell lung cancer (NSCLC). These targeted therapies are associated with a spectrum of dermatologic toxicities that complicate management. This case report details a 65-year-old male with stage iv NSCLC who developed paronychia and other manifestations of pride syndrome- from EGFRIs treatment with dacomitinib. **Case summary:** The patient, 65 a 65-year-old male who has hypertension and diabetes mellitus, was diagnosed with stage IV NSCLC and treated with dacomitinib. Within 4–8 weeks of treatment, the patient had developed paronychia manifested by tenderness, onycholysis, and crusted lesions along the nail folds. The patient had other manifestations of the disease, such as a papulopustular rash and diarrhoea, indicative of

PRIDE syndrome. **Management:** The paronychia was managed with local treatments, as it was non-infectious aetiology. Even though dacomitinib was continued, the paronychia was at a plateau with minimal progression. Dose reduction of dacomitinib was considered as part of the treatment plan to help manage symptoms. **Outcome and follow-up**: The patient was continued on EGFRIs therapy with observed paronychia and other pride syndrome symptoms. Local treatment did control the paronychia, and there was no significant worsening of symptoms to allow continued cancer therapy. **Discussion and conclusion:** This case highlights a rare but significant occurrence of paronychia within the pride syndrome in a patient treated with dacomitinib for lung cancer. The constellation of symptoms underscores the importance of recognising and managing EGFRI-induced cutaneous adverse reactions. Enhanced awareness and vigilant monitoring are crucial for patients undergoing EGFRI therapy.
Keywords: epidermal growth factor inhibitor (EGFRI)

Retrospective Study of Adverse Drug Reactions (ADRs) induced by antihypertensive drugs at tertiary care hospital Bhopal

Nitendra Singh[1], Sonali Meshram[1], Rahul Bhalsinge[1], Priyanshi Singh[1]
[1]LN Medical College & Research Centre Bhopal

Background: Hypertension is one of leading cause of morbidity & mortality in the world. Monitoring of ADRs through pharmacovigilance is useful to improve the safety of each patient. **Method:** The information collected includes patients information(initials,age,sex,height,weight) onset date/ stop date, dose, frequency, route of administration, medical history, concomitant medication. Causality assessment was done by Naranjo scale, used to evaluate nature of ADRs. **Result:** During study period total of 150 patients visited jk.hospital bhopal. Among them 48 ADRs reported. Male patients reported 27(56.25%) while female patients reported 21(43.75%) ADRs. The patients most frequently impacted between the ages of 40 and 70. In terms of age distribution, elderly patients were more accounted. Only 20(41.66%) type- a ADRs were reported but not type- b ADRs. Out of 150 patients 12(25%) ADRs effected cns, 11 (22.91%) reported from cvs, 06(12.5%) ADR involved eye, 10(20.83%) effected respiratory system and 09(18.75%) effected musculoskeletal system. Most frequently prescribed medication was amlodipine (34.8%), followed by thiazide (4.9%) ramipril (6.1%), metoprolol (23.5%), enalapril (12.6%), atenolol, telmisartan, nifedipine (6.9%,5.7%,5.5%respectively). On causality assessment done by naranjo scale found 06 ADR(12.52%) certain, 11 probable(22.91%), 10 possible(20.83%), 05(10.41%) conditional, 07(14.58%) represented unlikely and 09(18.75%) unacessible**.** **Conclusion:** According to our research, antihypertensive medications are frequently prescribed in tertiary care hospitals, necessitating close monitoring of ADRs and encouraging healthcare professionals to report ADRs and increase ADR reporting rates.

Safety of prescribed fixed drug combinations: rationality assessment

Florance Joy[1], Srijan Shetty[1], Ajay Shukla[1], Ratinder Jhaj[1], Balakrishnan S[1]
[1]All India Institute of Medical Sciences, Bhopal

Introduction: the irrational use of fixed-dose combinations (FDCs) in india is a significant public health issue, leading to adverse drug reactions, higher healthcare costs, and reduced therapeutic efficacy. In response, the CDSCO has banned several FDCs, and the who has

published a not recommended list under its aware classification. This study aims to evaluate FDC utilization patterns, assess their rationality, and promote rational prescribing practices, while ensuring alignment with the **NLEM 2022** and **WBO-edl 2023** guidelines **Methods:** a cross-sectional study was conducted to analyze prescriptions from outpatient clinics of a tertiary care hospital. All prescribed FDCs were assessed for rationality and approval status. FDCs were checked for irrationality or banning based on reference lists from regulatory authorities, including the not recommended list (aware classification), NLEM 2022, and WHO-EDL 2023. **Results:** Out of 2,238 prescriptions analyzed, 700 (49.7%) included at least one FDC, with over 350 distinct FDCs. Among them, 241 were rational and listed in NLEM, 10 were irrational, 7 were on the not recommended list, 14 required further data, and 96 could not be categorized. Common FDCs included vitamins/minerals, antibiotics, and medications for GERD/peptic ulcers. **Conclusion:** the gazette issued by government of India is formulation and drug specific. This loophole is often misused by drug manufactures by either by changing the formulation or by minor changes in the content of the FDC. The presence of irrational FDCs in prescriptions highlights the need for a rigorous, consistent evaluation process for fdc approval and periodic updates for healthcare providers on banned FDCs. Such measures will promote safer, more effective prescribing practices.

Keywords: Fixed drug combinations, adverse drug reaction, irrationality

Bullous fixed drug eruption induced by tapentadol: a rare case report

Chaudhary Deepa,[1] Jhaj Ratinder,[1] Balakrishnan S[1], Singh Jyoti[2]
[1]Department of Pharmacology, [2]Department of Dermatology, AIIMS Bhopal

Introduction: Fixed drug eruption (FDE) is a special type of cutaneous adverse drug reaction, which characteristically recurs in the same site after re-administration of offending drug. Occasionally, vesicles or bullae may be formed when it is referred to as bullous FDE. analgesics and antibiotics are the most common drugs causing FDE. Tapentadol is an analgesic that acts at mu opioid receptors. Here, we report a rare case of fixed drug eruption caused by Tapentadol. **Case summary:** A 46-year-old female patient presented at a private clinic in Bhopal with chief complaint of joint pain. Katridol tablet (Tapentadol) 50 mg, OD (Once in a day) was prescribed for the treatment of joint pain. About one hour after taking the medication, the patient experienced bullous FDE (bullous fixed drug eruption) **Management and treatment:** Tablet omnacortil (prednisolone), cream metdeal (mometasone furoate) were prescribed to treat the reaction. **Outcome:** The lesions resolved after 21 days of withdrawal of Tapentadol along with the above treatment of reaction. **Conclusion:** Literature search revealed no case of bullous FDE or FDE induced by Tapentadol reported so far. Hence our case may be the first case report of bullous FDE induced by Tapentadol. We suggest being aware of such reactions during tapentadol usage.

Rationality assessment of prescribing practices at outpatient departments of a tertiary care hospital

Srijan Shetty[1], Florance Joy[1], Ajay Shukla[1], Ratinder Jhaj[1], Balakrishnan S[1]
[1]Department of Pharmacology, AIIMS Bhopal

Introduction: Essential medicines are drugs selected to meet the key health needs of a population, based on their effectiveness, safety, and cost-efficiency. Both the government of

India and who periodically update their essential medicines lists. The national list of essential medicines (NLEM) has been revised in 1996, 2003, 2011, 2015, and most recently in 2022, while the who essential medicines list (WHO-EDL) was updated in 2023. This study aims to evaluate the rationality of prescribed drugs in accordance with the NLEM 2022and WHO-EDL 2023. **Methods:** this study was a cross-sectional analysis of prescriptions from the outpatient departments of a tertiary care hospital. A total of 2,012 prescriptions were reviewed to determine whether the prescribed drugs were included in the NLEM 2022 and WHO-EDL 2023. Additionally, the rationality of each prescribed drug was evaluated based on its indication and potential drug-drug interactions**. Results:** data from the analysis will show the proportion of prescribed drugs listed in the NLEM 2022and WHO-EDL 2023. Rationality will be assessed by reviewing the appropriateness of drug choices, including their therapeutic indication and risk of drug-drug interactions. **Conclusion:** The study highlights the presence of irrational prescriptions. To address this issue, it is essential to implement strategies to improve prescribing practices, ensure better adherence to established essential medicine lists, and promote rational drug use in clinical settings.

Keywords: Prescription audit, Rational Drug Use, Essential medicines

Self-medication: an alert for Indians

Munajir Rajja
School of Pharmaceutical Sciences, Jaipur National University, Jagatpura, Jaipur

Introduction: Self-medication is defined as use of medications by people to address conditions or symptoms they have self-diagnosed. Self-medication is defined as buying or using drugs without a prescription. Peoples choosing self-medications due to a lack of time, a lack of health services, the high cost of consultations, and the easy availability of drugs. **Methodology**: This study is a single centred study where 96 subjects were observed and studied to assess self-medication practice at the Jaipur national university for medical sciences and research centre, Jaipur. **Result:** Self-medication can cause health problems. Self-medication has a positive impact on 33.33% of the population while having a negative impact on 66.67% of the population. The author of this brief study on some of the most significant risks associated with self-medication behaviours, specifically: drug interactions and polypharmacy, pharmaceutical misuse or dependence, misdiagnosis, treatment selection errors and abuse. The author additionally suggests actions that might be implemented to address or enhance these problems. **Conclusion:** This research focused on the practice of self-medication, its use, its safety, and the reasons for its use. Self-medication has a positive impact on 33.33% of the population while having a negative impact on 66.67% of the population. It is safe if the people who use it having sufficient knowledge of its dose, frequency, route and side effects.

Keywords: Self-medication, Drug interaction, Polypharmacy, Abuse.

Cost variation analysis of immunosuppressant drugs available in the Indian market for the management of autoimmune diseases or organ transplantation

Radhika Mittal[1], Tejal Patel[1]
[1]HBT Medical College & Dr. RN Cooper Hospital, Juhu, Mumbai

Introduction: immunosuppressants are a class of medications that suppress cellular, humoral, or both types of immune responses. The cost variation among different brands of immunosuppressants is an important issue. Expensive drugs can reduce patient compliance, negatively impact the physician-patient relationship, and cause psychological stress for patients. **Objective:** To find out the maximum and minimum price of various immunosuppressant drugs available in Indian market and to compare their cost variation in terms of cost ratio and percentage cost variation. **Methodology:** the prices in Indian rupees of all immunosuppressant drugs and their fixed dose combinations with other immunosuppressants, of same strength manufactured by different pharmaceutical companies were obtained from current index of medical specialities 3rd update 2024, Indian drug review 2024 issue, and national pharmaceutical pricing authority-pharma Sahi Daam. Cost ratio = price of the costliest brand/price of the least costly brand and Percentage cost variation = maximum cost - minimum cost x 100 / minimum cost **Results:** a total of 966 brands of 18immunosuppressant drugs available in the Indian market were analysed. The maximum percentage cost variation and cost ratio was found for injection triamcinolone 40 mg and minimum was found with injection Antithymocyte globulin 25 mg. **Conclusion:** there is significant price variations among different brands of immunosuppressants available in the Indian market. If a costly brand is prescribed, the patients end up paying more for the same treatment. Furthermore, these price disparities underscore the need for regulatory measures to ensure more equitable pricing.

Adverse drug reaction to injection paclitaxel nanoparticles with a patient of adeno carcinoma lung cancer: a case report

Urmaliya Shambhavi[1], Jhaj Ratinder[1], Deepa Chaudhary[1], Akansha Choudhary[1]
[1]Department of Pharmacology, Department of Oncology, AIIMS Bhopal

Introduction: Paclitaxel is a first-line Taxane-based chemotherapeutic agent treated for various malignancies such as breast, ovarian, and non-small cell lung cancers. Neuro protective effects against paclitaxel-induced neurotoxicity both in vivo and in vitro but progressed into tachycardia and hypotension at high dosages. Besides, adverse effects such as hypertrichosis, lower-limb edema, and so forth have been regularly reported in the post-treatment assessment of oral minoxidil. **Case summary:** A 61years old male Patient with adeno carcinoma lung cancer was treated on 16/07/24 with injection paclitaxel nano particles with a dose of 330mg iv in 5/dx*1hr, after 10 days with a complaint of peripheral neuropathy (unable to walk, weakness) **Management and treatment:** The dose was changed paclitaxel to pemetero. **Outcome:** After management and treatment, the patient is still resolving. **Discussion:** Study demonstrates a significant incidence of the effect with the majority consisting of mild to moderate cases. We reinforce the importance of multidisciplinary assessment for early diagnosis and adequate follow-up. **Key words:** Taxol, carcinoma, peripheral neuropathy

Cost variation analysis of agents used to treat hyperpigmentation that are available in the Indian market- a pharmacoeconomic study

Neel Pandit[1], Prasad Pandit[1]
[1]HBTMC & Dr. RN Cooper Hospital

Introduction: Hyperpigmentation is a condition in which patches of skin become darker in

colour; usually treated by various topical, oral and injectable agents. Very few studies have been done to analyse their cost variation, despite a number of agents in various dosage forms (including cosmeceuticals and phytochemicals) being freely available over the counter. Thus, this study was designed to find out the variation in cost, which will guide the treating doctors in selecting the agent of choice. **Objective:** To compare cost ratio and percentage cost variation of various agents used to treat hyperpigmentation that are available in Indian market. To find out the maximum and minimum price of the same. **Methodology:** The maximum and minimum price of each brand of the agents used to treat hyperpigmentation, in INR, will be noted by using latest edition of CIMS 2024, Indian drug review 2024 and NPPA's GOI 'Pharmasahidaam' website. All dosage forms and routes mentioned will be analyzed. The cost ratio and percentage cost variation for individual drug brands will be calculated and compared. **Results:** around 500 brands of agents were analyzed. Across all dosage forms, the percentage cost variation and cost ratio were maximum for injection glutathione500mg and minimum for tranexamic acid 3% gel. **Conclusion:** this study highlights the disparity in cost of the agents. Despite a huge variety of dosage forms in different combinations being available, information about the exact percentage composition of many of these is missing. This may lead to their inappropriate prescription & use.

Cost variation analysis of diuretic drugs available in the Indian market

Ankita Dhakne[1], Kiran Bhave[1]
[1]HBTMC & Dr. RN Cooper Hospital

Introduction: Diuretics, are medications that promote increased production of urine. They are primarily used for hypertension, heart failure, and edema associated with renal or hepatic disorders. understanding the cost dynamics of diuretic prescriptions is essential given the wide variability in pricing and adherence. Hence this study is being done to understand the cost variance of various diuretic agents along with their FDCs. **Objective:** to compare cost ratio and percentage cost variation of various diuretic drugs available in Indian market. To find out the maximum and minimum price of the same. **Methodology:** The maximum and minimum price of each brand of all diuretic drugs including FDCs in INR will be noted by using latest edition of CIMS, Indian drug review and NPPA's-GOI 'Pharmasahidaam' website. All dosage forms except topical preparations will be analyzed. The cost ratio and the percentage cost variation for individual drug brands will be calculated and compared. **Results:** A total of around1000 brands of anti-diuretic drugs available in the Indian market were analysed. The cost variation and cost ratio was maximum for tablet torsemide10 mg and minimum forinjectionfrusemide10mg. **Conclusion:** the findings showed that there is a difference in the cost of medications, with some brands being more expensive than others.by examining the factors influencing cost variance, healthcare systems can implement strategies to optimize treatment protocols, ultimately improving patient outcomes and reducing financial burdens on both patients and providers.

Evaluation of knowledge, attitude and practices of Pharmacovigilance in resident doctors of tertiary care teaching institute in central India

Divya Dhaked[1]**,** Kavita Jaiswal[1]
[1]Department of Pharmacology, GMC, Nagpur

Background: Adverse Drug Reaction (ADR) is defined by the world health organization (WHO) as "a noxious, unintended effect of a drug that occurs in doses normally used in humans for the diagnosis, prophylaxis and treatment of disease". ADRs are global problems of major concern. ADR reporting also forms a part of health care. the resident doctors worldwide should report on ADRs as it can save lives of their patients. **Aim and objectives:** 1**.** Todetermine the knowledge, attitude, practices (KAP) on spontaneous ADR reporting and factors affecting the reporting process in resident doctors2.to correlate these findings with their professional `characteristics **Material and methods:** Across-sectional, questionnaire-based study conducted among resident doctors in tertiary care teaching hospital of central India. **Statistical analysis**: data was expressed as counts and percentages using MS excel. **Results:** data analysis is under process and will be presented at the time of conference **Conclusions:** the knowledge attitude and practices of doctor participants was good as compared to nurses and pharmacists. Inaccessibility to ADR form is the major hindrance in reporting of ADRs. Managing the patients is more important, lack of time, did not know how to report are the discouraging factors.

Key words: pharmacovigilance, ADR

Awareness and practices of adverse drug reaction reporting amongst doctors and physicians: a cross-sectional study

Prachi Singh
Rohilkhand Medical College, Bareilly

Background: Adverse Drug Reactions (ADRs) are a significant concern in healthcare, causing morbidity, mortality, and even sometimes more fatal situation for the patient and the physician and even increased healthcare funds not reporting of ADRs is a major issue, hindering the identification and the subjective matter of the drugs efficacy. **Objective**: to assess the awareness, knowledge and the reporting system and practices of ADR reporting amongst doctors and physicians. **Methods**: a brief study was conducted amongst 500 doctors and physicians using a pre-validated and common questionnaire. The questionnaire were assessed about the demographics, awareness of ADR reporting, knowledge of reporting procedures, and practices of reporting ADRs. And even knowing that ADR is being reported the methods and procedures it's different platforms and sites **Results**: the response rate was 70% although 85%of respondents were aware of the importance of ADR reporting, only 40% knew the correct reporting procedures. The most common reasons for underreporting were lack of awareness about reporting procedures (60%) and lack of time (40%). Only 20% of respondents reported ADRs regularly. Results have shown that even doctors and physician have less knowledge about the reporting system of ADR they don't know how to even proceed for ADR which may be a bad sign for the medical ethics and rules and can be considered as fatal if any ADR of drug will be circulated among heavy population. **Conclusion**: despite high awareness of the importance of ADR reporting, knowledge and practices of reporting ADRs amongst doctors and physicians are suboptimal. Educational programs and brief discussion of reporting procedures are necessary to improve ADR reporting rates. There should be more awareness about the ADR among the people too local Practisoners; Physcisian; tertiary care centres and the well experienced doctors should be highly aware about the ADR monitoring

Evaluation of drug reutilization strategies for unused drugs to analyse cost conserved and prevention of drug waste in healthcare settings

Anushka B. Thombare[1], Vishakha V. Karanjule[1], Payal S. Khape[1], Tallini D. Lokhande[1]
[1]Modern College of Pharmacy Nigdi, Pune

Introduction: Medication waste poses a global challenge to healthcare sustainability and cost efficiency, driven by factors like early treatment discontinuation, incorrect prescriptions, improper storage, and non-compliance. Strategies like vial sharing, pulverization, and stability improvement have emerged to reduce waste, enhance efficiency, and lower costs. This study evaluates strategies such as vial sharing and stability enhancement, emphasizing their role in reducing waste and supporting sustainable healthcare practices. **Objectives:** 1. To estimate the quantity of unutilized oral and parenteral medications. 2. To monitor individual dose adjustment, vial sharing technique and preparation of oral medication through pulverization technique. 3. To evaluate sustainability improvement techniques used for parenteral drugs. 4. To analyse total cost cut down per patient by using drug reutilization strategies. **Methodology:** This prospective observational study was conducted in the clinical pharmacy department of a tertiary care hospital over one year. A specially designed data collection form recorded demographics, department, medication details, lab reports, administration information, drug waste prevention, reasons for unused drugs, and cost savings from strategies like vial sharing and pulverization of oral medicines. Data was digitized in MS excel for evaluation. **Result:** The study showed a higher proportion of males than females, with children and adults enrolled. Parenteral drugs outnumbered oral drugs, and anaesthetics ranked highest in drug classification, followed by anti-hypertensives. Anti-histamines and antihyperlipidaemics had the lowest counts. Mephenteramine sulphate was primarily reused via vial sharing. Pulverization led to significant drug reuse and discard in children, with minimal impact in premature neonates. Stability improvement techniques preserved more drugs than discarding, and prevention methods effectively reduced costs for both oral and parenteral drugs**. Conclusion:** Optimizing drug utilization in hospital settings is crucial for improving patient care and reducing healthcare costs. By implementing strategies such as vial sharing, stability improvement, and minimizing prescription errors, hospitals can effectively reduce medication waste.

Evaluation of the Antidepressant Activity of Emblica officinalis in Albino Wistar Rats Using the Forced Swim Test

Shariq Ahmad Azmi[1], Syed Ziaur Rahman[1], Mehtab Parveen[1]
[1]Jawaharlal Nehru Medical College, AMU, Aligah

Introduction: Depression is a globally prevalent disorder with considerable morbidity. Conventional antidepressants, such as tricyclics and SSRIs, often have limitations involving side effects and inconsistent efficacy. Emblica officinalis (amla), traditionally recognized in ayurveda for its antioxidant and anti-inflammatory properties, remains insufficiently explored for potential antidepressant effects. **Aim and objective:** This study aimed to investigate the antidepressant-like properties of *e*. Officinalis fractions (petroleum ether, benzene, ethyl acetate, acetone, and methanol) in albino Wistar rats using the forced swim test (FST), with imipramine serving as a standard comparator. **Methodology:** Forty rats were randomized into eight groups (n=5 each). Group 1 received normal saline (1 ml/100 g), and group 2 was given imipramine (10 mg/kg). Groups 3–8 each received a distinct *e. Officinalis* fraction (500 mg/kg) orally for 10 days, followed by the FST. Immobility time was recorded during the final four minutes of a six-minute

session. Statistical significance was determined via one-way Anova ($p<0.05$). **Results:** All *e. Officinalis* fractions decreased immobility relative to control. Notably, the methanol and ethyl acetate fractions elicited the most pronounced reduction, approximating the effect of imipramine. No significant adverse effects were observed in any group. **Conclusion:** Methanol and ethyl acetate fractions of Emblica officinalis demonstrate promising antidepressant-like activity in the FST. These findings warrant further research to isolate active components and elucidate their mechanisms, potentially offering novel treatment avenues for depression.

Keywords: Emblica officinalis, amla, antidepressant, forced swim test, imipramine

A comprehensive review on integrating technology in pharmacovigilance and Materiovigilance

Shashiranjan Choudhary[1], Amulya Agrawal[1]

[1]Lakshmi Narain College of Pharmacy, Bhopal

Introduction: the integration of advanced technologies in pharmacovigilance and Materiovigilance marks a significant transformation in healthcare safety monitoring. As the pharmaceutical and medical device industries expand exponentially, traditional safety surveillance systems struggle to manage large-scale, real-time data. Advanced tools like artificial intelligence (AI), machine learning (ml)and big data analytics provide innovative solutions to identify adverse drug reactions (ADRs) and device-related complications with enhanced efficiency and accuracy India's advancements in information technology present an opportunity to leverage tools such as electronic health records and mobile health applications for real-time data collection and patient engagement. **Methodology:** The presentation examines successful implementations of advanced technologies in pharmacovigilance and Materiovigilance. It analyzes their impact on enhancing automated data mining, predictive modeling, and risk assessment, while addressing challenges such as regulatory alignment, and ethical considerations. **Results:** technologies like blockchain ensure data integrity and security, addressing issues of privacy and compliance with regulatory standards. Ai and ml improve signal detection and reduce manual errors, while EHRS and M health applications facilitate proactive monitoring and reporting. **Conclusion**: pharmacy professionals in India play a crucial role in bridging technology and healthcare safety. By overcoming barriers to adoption and ensuring regulatory compliance, technology-driven approaches can significantly enhance therapeutic and device safety, ultimately improving patient outcomes.

Oral toxicity of Nyctanthes arbor-Tristisleaves fraction and elucidation of its hypotensive activity in vivo

Akanksha Chaturvedi[1,2], Kanika Verma[2], Smita Jain[2], Pragya Sharma[2], Vartika Paliwal[2], Sarvesh Paliwal[2], Swapnil Sharma[2]

[1]Department Of Pharmacology, All India Institute of Medical sciences, Bhopal, India

[2]Department of Pharmacy, Banasthali Vidyapith, Banasthali, Rajasthan

Background: Nyctanthesarbor-Tristisis an ethnomedicinally important plant that mitigates various pharmacological ailments. However, its pharmacological effect on the management of hypertension is unclear. This study explores the toxicity and antihypertensive effects of *n. Arbor-tristis* leaves (NAL) in rats. **Methodology**: male Wistar rats (200–250 g) were used for the study. Acute oral toxicity of the selected fraction was assessed per OECD guideline 423. Rats were

divided into four groups and administered fraction doses of 5, 50, 300, and 2000 mg/kg orally. Behavioral and physiological changes were monitored for two weeks, and any abnormalities or mortality were recorded. Subsequently, in vivo studies using a DOCA-salt-induced hypertension model in Wistar rats and molecular analyses (RT-PCR) were conducted to validate the antihypertensive potential of n. Arbor-tristis. **Results**: no mortality or morbidity was observed with NAL up to 2000 mg/kg. Doses of 200 mg/kg and 400 mg/kg were selected for hypotensive activity. Nal (400 mg/kg) significantly reduced blood pressure, improved cardiac function, and restored body weight, organ weights, and water intake. It reduced cardiac hypertrophy, inflammation, oxidative stress, and elevated antioxidant biomarkers (GSH, SOD, catalase). Histopathology confirmed improved tissue architecture. Gene expression analysis showed reduced il-6, mpges-1, MCP-1, and NF-KB, decreasing sympathetic activity and arterial stiffness, while increased ENOS, PGC-1α, and SGC enhanced no bioavailability, supporting endothelial function and hypotension. **Conclusion**: This study is the first to support the use of *n. Arbor-tristis* leaves for treating high blood pressure. However, further research is needed to isolate arborside c and other bio actives and evaluate their safety and hypotensive effects in robust hypertension models.

Haemovigilance as a safety tool for blood transfusion

Saransh Kesarwani[1]

[1]Rohilkhand Medical College and Hospital

Introduction: It deals with the quality improvement of the transfusion chain through different action to ensure patient safety and outcomes, it enhances safety of the donor and reduce wastage. It aims towards blood safety and self-sufficiency in the community to improve public confidence in the secure blood supply. **Objective:** To improvise the blood transfusion techniques, ensuring safety without any unexpected or undesirable effects. To manage the blood transfusion programs occurring in whole of the nation. **Methodology:** To study events causing adverse reaction or complications occurred due to donation, selection, and management of donor that may cause harmful effect to donor or deteriorate the quality of product, putting the recipient at higher risk. Study of 2 components “immune haematology” and “transfusion medicine” are used by medicine specialists that help them in procedures like massive transfusion, difficult/ incompatible transfusion and rational use specialised blood product therapy like irradiated blood / washed blood products. **Result:** The Haemovigilance program HvPI aims at reduced adverse reaction, increased reporting of ADR, improved collaboration and awareness among medical practitioners regarding procedures of blood transfusion. In developed countries like united states and UK, aemovigilance program is quite well developed and regarded as the Haemovigilance module in the bio vigilance component of the national health care safety network (NHSN) and serious hazards of transfusion (short). **Conclusion:** it is recommended by who that HAEM vigilance should be incorporated for rectifying ADRs and simplify blood transfusion procedures

Materiovigilance- a Protection from the unexpected use of medical devices

Saksham Saxena[1]

[1]Rohilkhand Medical College and Hospital, Bareilly, U.P.

Background: the Materiovigilance program of India (MvPI) is a program that investigate and

manage the safety of medical devices in India to individual Organization that are central drugs standard control organization (CDSCO) and Indian Pharmacopoeia Commission IPC along with national collaborating Centre Shree Chitra Tirunal Institute of Medical Sciences and Technology, (STIMST). MvPI program was launched by the drugs controller general India.

Objective: To scrutinize and prevent the harmful effects associated with use of medical devices. To identify, register, collect ADR reports and submission of medical devices report to the medical device regulator.

Methodology: different events reported through materiovigilance are device breakage and malfunction, entry and exit site infection, organ perforations or injuries, need for surgery and even death, and life cycle assessment of devices. This reporting framework and the significance of materiovigilance helps in ensuring safe protocols of use of medical devices and getting used with reporting procedures and applying action plans in case of a device induced adverse event. **Result:** MvPI monitors the safety of medical devices in the nation and helps withdrawing dangerous or potentially hazardous devices from the market and removes malfunction to improve their quality and effectivity. **Conclusion:** We can finally conclude that it is a practice that monitors the performance and features of a medical device for any unexpected and harmful effects. Enabling and educating all relevant parties on the value, necessity medical devices adverse event reporting.

To study the effect of sex, age, and route of administration on adverse effects of opioid treatment

Tejas Kocher[1]

[1]Rohilkhand Medical College and Hospital, Bareilly, U.P.

Background: Opioids are drugs that comprises of chemicals that relives pain. These are also used to relax the body and relieve the symptoms of illness or injury and pain after the surgical procedures. **Objective**: to study the adverse effects of opioids treatment in age, sex, and route of administration. **Methodology:** Electronic records including PubMed / national library of medicine were searched to identify articles. Adverse effects included: nausea/vomiting, hypotension and oxygen saturation <92% and respiratory rate. **Result:** In the study conducted, it comprised of 31,750 patients who were treated with opioids, of which % were females. The overall adverse drug events reported were 12%. These were associated more with the female sex, and much prevalent in the age groups of greater than 65 years. These were seen more commonly in intravenous route and then lesser I subcutaneous route and least in oral route. **Conclusion**: the abstract presents that the incidence of adverse drug events related to opioids treatment is low in association with age, sex, and route of administration.

Benzyl benzoate from nature to Therapy: gabaa receptor-mediated sedative hypnotic efficacy & its mechanism in SWISS albino mice

Gauri R. Chaudhari[1], S. R. Tambe[1], R.S. Patil[1]

[1]MGV's College of Pharmacy, Nashik

Benzyl benzoate, a compound found in various flowering plants and spices, has gained attention

for its potential therapeutic properties. This study aims to explore its sedative-hypnotic effects through network pharmacology, molecular docking, and in vivo efficacy evaluations. The objective was to investigate its mechanism of action, particularly its interaction with the GABAa receptor, elucidated by flumazenil, and its efficacy study using benzyl benzoate microemulsion formulation. Network pharmacology analysis identified key targets and pathways involved in benzyl benzoate's action, revealing its potential to modulate GABAa receptor activity. Molecular docking studies further supported these findings, demonstrating strong binding affinity of benzyl benzoate to the GABAa receptor, suggesting a possible sedative-hypnotic mechanism. Based on this further. In vivo studies using swiss albino mice showed that benzyl benzoate significantly induced sedative and hypnotic effects, as evidenced by reduced locomotor activity and increased sleep latency as compared with standard drug diazepam. Additionally, the study explored the efficacy of benzyl benzoate in a microemulsion formulation, enhancing its bioavailability and providing a more efficient delivery system. The formulation showed improved therapeutic outcomes, with the compound displaying potent sedative and hypnotic properties. In conclusion, benzyl benzoate exhibits promising sedative-hypnotic effects through GABAa receptor modulation with no adverse effects. The microemulsion formulation further enhances its efficacy, highlighting its potential as a therapeutic agent in the management of sleep disorders and related conditions. Further studies are warranted to explore its long-term safety and clinical applicability.

Keywords: Aroma therapy, sedative-hypnotic, flumazenil, GABAa, benzodiazepines

Evaluation of the impact of knowledge, practice, and counselling regarding the use of inhalers in patients with asthma and COPD

Aaska Patel[1], Trusha Prajapati[1], Zankhana Amin[1], Kinjal Pal[1], Anita Mehta[1], Angha Apte[1]

[1]Anand Pharmacy College, Anand, Gujarat

Objective: the objective of our study is to check the understanding of patients regarding the use of inhalers and measure the effect of counselling interventions on various aspects of health-related quality of life such as symptom control and patient satisfaction. **Method**: it was a randomized control trial conducted at Shree Krishna Hospital, Karamsad. Education regarding the use of inhaler was provided to the patients of the case group. They were assessed before and after the follow-up (after 1 week) on their inhaler technique based on a validated knowledge assessment questionnaire and checklist, symptoms control based on quality of life. **Result**: patients who were suffering from COPD and asthma were recruited in the study considering exclusion and inclusion criteria. The difference between before and after peak flow was highly significant in the case group (p= 0.000283). At follow-up patient using synchro breath, revolizer and Lupi haler showed significant result in the case group. Patients, who were using Lupi haler made 0% error after training. QoL score was significantly improved in both groups for physical functioning and role limitation due to physical heath domain. **Conclusion**: it was concluded that after providing counseling regarding appropriate use of inhaler, certain aspects including per, signs and symptoms and health related quality of life of patients with asthma and COPD got improved. **Keywords**: Asthma, COPD, mdi, synchro breath, lupihaler, revolizer, QoL, peak flow.

A review article: reviewing chemotherapy administration sequencing and designing sequencing chart

Patel Ritika[1], Patel Aaska[1], Nisarg Hazariwala[1]

[1]Anand Pharmacy College, Anand

Background: In 2009, Mancini and MODL in conducted a literature review on FDA-approved intravenous chemotherapy to aid oncology professionals. Since then, many new intravenous chemotherapy agents and monoclonal antibodies have received FDA approval. Of these, many are sanctioned for use in combination with another intravenous agent. **Objectives**: to identify FDA-approved intravenous chemotherapy and monoclonal antibodies from 2020, review literature for sequence recommendations, and update the chemotherapy sequencing chart with new medications used in combination. **Methods**: Initially, list of FDA-approved intravenous chemotherapy and monoclonal antibodies from January 2020 to November 2024 was compiled. Clinical trials with human participants assessing drug administration sequences were included, excluding monotherapy agents. Subsequently, we examined medication compatibility via y-site co-infusion using Micromedex, drugs.com, and Medscape. Additionally, we assessed base-solution compatibilities for individual chemotherapy agents. Finally, we consulted Micromedex online for recommended drug sequences. **Results**: total of 40 intravenous chemotherapy or monoclonal antibodies received FDA approval from January 2020 to November 2024. After excluding single-agent intravenous drugs, 35 agents were approved for combination therapy. A comprehensive literature review revealed no data supporting a preferred Administration sequence based on the exclusion criteria. Furthermore, literature review of new studies published from January 2020 to November 2024 on Previously investigated agents found no new evidence to modify earlier recommendations. **Conclusion**: 18 FDA-approved intravenous chemotherapies or monoclonal antibodies from January 2020 to November 2024 lack studies on sequencing safety and efficacy. Therefore, in the absence of clear supporting studies, it is recommended that adhering to original drug regimen's administration sequence.

Role of vitamin d in modulating inflammatory bowel disease

Mohamed Fiyas Konnola

BRD medical college Gorakhpur

Background: Inflammatory bowel disease (IBD), encompassing Crohn's disease and ulcerative colitis, is characterized by chronic inflammation of the gastrointestinal tract. The pathogenesis of IBD is complex and involves an interplay of genetic, environmental, and immunological factors. Vitamin d, a fat-soluble vitamin with immunomodulatory properties, has emerged as a potential factor influencing IBD development and progression. **Objective:** To investigate the role of vitamin d in modulating inflammatory bowel disease (IBD) by examining its impact on disease pathogenesis, progression, and therapeutic outcomes. **Methodology:** A comprehensive literature search was conducted using PubMed, google scholar, and Cochrane library databases. Studies investigating the association between vitamin d levels, IBD susceptibility, disease activity, and response to therapy were included. Keywords used in the search included "vitamin

d," "inflammatory bowel disease," "Crohn's disease," "ulcerative colitis," "inflammation," "immunomodulation," and "therapy." **Results:** The literature review revealed that: * Vitamin D deficiency is prevalent in IBD patients: studies consistently show that individuals with IBD often have lower Vitamin D levels compared to healthy controls. * Vitamin D may influence disease susceptibility: some studies suggest that low vitamin d levels may increase the risk of developing IBD, though more research is needed to confirm a causal relationship. * Vitamin D may affect disease activity: evidence indicates an association between vitamin d deficiency and increased disease activity, including more frequent relapses and hospitalizations. * Vitamin D may modulate immune responses in IBD: vitamin d exerts immunomodulatory effects by influencing the production of cytokines, regulating t cell differentiation, and enhancing intestinal barrier function. * Vitamin D supplementation may improve therapeutic outcomes: while research is ongoing, some studies suggest that vitamin d supplementation may improve response to conventional IBD therapies and reduce disease activity. **Conclusion:** Vitamin d appears to play a significant role in modulating IBD. Its deficiency is common in IBD patients and may contribute to disease susceptibility and progression. vitamin d's immunomodulatory effects suggest a potential therapeutic benefit. Further research, particularly large-scale clinical trials, is needed to establish optimal vitamin d supplementation strategies for IBD management.

Keywords: Vitamin D, inflammatory bowel disease, Crohn's disease, ulcerative Colitis, Inflammation, Immunomodulation, and Therapy.

Knowledge, Attitudes and Practices of medical professionals in central India regarding the Materiovigilance program and their role in reporting MDAEs

Vivek Kumar Singh

Dept. of Pharmacology, RKDF medical college & research centre, Bhopal

Background: Materiovigilance (MV) plays a critical role in patient safety by monitoring medical device adverse events (MDAEs). Despite the establishment of the Materiovigilance program of india (MvPI) in 2015, healthcare professional's awareness and participation remain suboptimal. Bridging the gap between policy and practice requires an in-depth understanding of their knowledge, attitudes, and practices (KAP). **Objective**: to evaluate the knowledge, attitudes, and practices of medical professionals in central India regarding the Materiovigilance program and their role in reporting MDAEs. **Methodology**: This observational, cross-sectional study utilized a google form survey shared through social networking platforms. The survey consisted of 22 questions addressing KAP related to Materiovigilance. Responses were collected from healthcare professionals in central India. Data analysis is underway to identify trends and GAPs in awareness and engagement. **Results**: Preliminary analysis indicates that many healthcare professionals are limited awareness with the Materiovigilance program and its reporting protocols. This highlights the need for focused awareness campaigns and capacity-building initiatives to enhance their involvement in mv activities. **Conclusion**: preliminary findings suggest limited awareness among healthcare professionals about MvPI and its reporting protocols. A significant GAP exists in their knowledge and practices, underscoring the need for targeted awareness campaigns and training to enhance reporting of MDAEs.

Keywords: Materiovigilance (MV), MvPI (Materiovigilance Program of India), Medical Device Adverse Events (MDAEs), knowledge, attitudes, and practices (KAP), healthcare professionals**,** patient safety.

Prospective observational study to assess prescription appropriateness in elderly patients by using beers criteria

Sayali Shivraj Bakale
PES'S Modern College of Pharmacy, Nigdi, Pune

Background: The aging population poses unique healthcare challenges. Age-related physiological changes alter drug metabolism, increasing the risk of adverse reactions, particularly with polypharmacy. The beers criteria helps clinicians identify and avoid high-risk medications, improving patient safety and quality of care. **Objective**: To improve the effectiveness and safety of prescription practices for geriatric patients. **Methodology**: This prospective observational study evaluated the prevalence of PIMs in hospitalized elderly patients. Data from approximately 300 patients was collected over a one-year period and categorized using the AGS beers criteria 2023. The study assessed prescription appropriateness, and presented findings through descriptive statistics and graphical representations. **Result**: This study found a high prevalence of comorbidities. A significant proportion (28.7%) received potentially inappropriate medications (PIMs), with 54.88% falling under category 1 PIMs, followed by category 2, category 3 and category 5 PIMs. **Conclusion:** This study reveals a significant prevalence (28.7%) of potentially inappropriate medication prescriptions among elderly patients, emphasizing the need for cautious medication management in this population.

Antifungal Resistance Patterns and Treatment Profiles in Yeast Infections: An Antifungal Stewardship Approach

Akshaya Suresh Meher[1], Siddhi Dhawade[1], Sharmada Dhonde[1], Yash Patil[1], Mayuri Khaparde[1], Bharat Purandare[1]
[1]Progressive Education Society's Modern College of Pharmacy, Nigdi, Pune

Introduction: Invasive fungal diseases represent a significant global health burden, with bloodstream yeast infections increasingly reported. This study aims to evaluate antifungal resistance patterns and treatment profiles in yeast infections to advocate antifungal stewardship. **Methodology:** A retrospective observational study was conducted in the Infectious Diseases Department of a tertiary care hospital over six months. Data on demographic details, susceptibility reports, and treatment profiles were collected using a structured data collection form, digitized in MS Excel 2013, and analyzed. **Results:** Data from 90 patients were analyzed, with 68 (76%) having comorbidities. Fifteen distinct species were identified, with *Candida auris* (36%) being the most prevalent, followed by *Candida glabrata* (15%) and *Candida tropicalis* (18%). *Candida parapsilosis* (6%) and *Candida albicans* (13%) were also observed, along with less common species such as *Trichosporon asahii*, *Candida rogusa*, *Cryptococcus neoformans*, and others. Non-*Candida albicans* species exhibited higher prevalence and resistance patterns, with notable resistance in *C. auris* and *C. parapsilosis*. **Conclusion:** The findings highlight the growing prevalence of non-*Candida albicans* species and their resistance to antifungal agents. The study underscores the critical role of susceptibility testing and the implementation of antifungal stewardship programs to optimize therapeutic outcomes. **Keywords:** Antifungal resistance, Yeast infections, Candida auris, Non-Candida albicans species, Antifungal stewardship, Invasive fungal diseases, Susceptibility testing, Treatment profile, Fungal comorbidities, Retrospective study.

Pre and Post-interventional study to evaluate awareness about rational pharmacy practice and pharmacovigilance in pharmacy students

Amit Dhok[1], Smita Sontakke[1]
[1]Department of Pharmacology, Shri Vasantrao Naik Government Medical College, Yavatmal

Introduction:

Background: There is a growing indifference among the pharmacy practitioners towards their duty as information providers to the patients. The patients do not always get enough desired information about proper use of medicines from the prescribers also. This contributes to improper use of medicines by the patients. **Objective**: 1. To evaluate awareness about rational pharmacy practice in final year B-Pharm Students 2. To study effect of intervention on awareness about rational pharmacy practice in final year B-Pharm students **Methodology:** This study is initiated after approval from the Institutional Ethics Committee. The final year students of Bachelor of Pharmacy (B. Pharm) from colleges of Yavatmal are enrolled for the study after informed consent. Their base knowledge will be assessed through a written test which will comprise of 27 objective questions related to rational pharmacy practice. This will be followed by a series of articles on rational medicine use, published in leading journals. The participants will be reminded to read them. Second intervention, a half day interactive session where series of lectures will be delivered to the participants on the right and wrong approaches in pharmacy practice. The session will be followed by a repeat test using the same pre-test to assess the change. Pre and post intervention data will be compared using Fisher's Exact test. **Results & conclusion:** The study is ongoing. Results and conclusion will be presented during the conference.

Nimesulide Induced Toxic Epidermal Necrolysis in a Pediatric Patient: A Case Report

Sadiyaakhtar S Kazi[1], Smita Borkar[1], Vijay Motghare[1], Vaishali Wankhade[1]
[1]Dept. of Pharmacology, Government Medical College, Chandrapur, Maharashtra, India.

Background: Adverse drug reactions (ADRs) represent a major challenge in medical practice, ranging from mild events to life-threatening conditions. Toxic Epidermal Necrolysis (TEN) is a rare but severe cutaneous adverse reaction frequently associated with medications such as non-steroidal anti-inflammatory drugs (NSAIDs). Although banned for pediatric use in India, Nimesulide continues to be prescribed, leading to rare instances of severe ADRs like TEN. This report highlights a case of Nimesulide-induced TEN in a pediatric patient, emphasizing its clinical presentation, management, and implications. **Case Summary** A 9-year-old male presented with generalized rash, febrile illness, and multiple raw areas affecting the oral mucosa, genitalia, and eyes after being prescribed Nimesulide alongside paracetamol, cefpodoxime, and ondansetron for fever. Examination revealed hyperpigmented plaques, bullae, and mucosal ulcerations. Based on clinical findings and medication history, Nimesulide-induced TEN was diagnosed. Note: Written consent from the patient was obtained. **Management and Treatment:** The patient was treated with systemic corticosteroids (Inj. Dexamethasone), gastric protection (Inj. Pantoprazole), topical therapies (Mucopain gel, liquid paraffin, and Soframycin), antiseptic gargles (Betadine), and close monitoring of vital signs. A multidisciplinary approach ensured

comprehensive care. **Outcome and Follow-Up** Within two weeks of intensive care, the patient showed significant clinical improvement, including healing of mucosal lesions and resolution of skin rashes. Causality assessment using the WHO-UMC system and Naranjo Scale yielded a score of 7, classifying the reaction as "Probable." **Discussion** TEN is a potentially fatal condition caused by immune-mediated epithelial damage. This case highlights the dangers of off-label Nimesulide use in pediatric populations. Despite its ban, Nimesulide is still used, often due to a lack of awareness and enforcement of regulations. This underscores the necessity of pharmacovigilance, proper prescribing practices, and awareness campaigns to mitigate the risk of such severe ADRs. **Conclusion** This report emphasizes the critical need for cautious drug prescribing in children and the importance of recognizing drug-induced ADRs like TEN. Early identification, withdrawal of the offending agent, and prompt, multidisciplinary intervention are essential for improving outcomes in patients with TEN. **Keywords** Toxic Epidermal Necrolysis; Nimesulide; Epidermal Detachment; Naranjo Scale

Systematic review of pharmacogenetic studies of DPYD gene influencing fluoropyrimidine toxicity and their frequency in Indian population

Gokul Aravind A[1], Shubham Atal[1], Balakrishnan S[1], Saiket Das[2], Akansha chaudary[3], Somya Singh[1], Florance Joy[1]

[1]Department of Pharmacology, AIIMS Bhopal

[2]Department of Radiation Oncology, AIIMS Bhopal

[3]Department of Medical Oncology, AIIMS Bhopal

Introduction Increased risk of severe and life-threatening toxicity in patients with DPYD deficiency, under treatment with fluoropyrimidines, has been widely studied. India's diverse genetic landscape underscores the importance of understanding how DPYD polymorphisms affect 5-fluorouracil and capecitabine metabolism and toxicity in the Indian population. This systematic review aims to consolidate data from multiple studies conducted in Indian population, allowing for a more accurate estimation of the frequency and association of DPYD variants and related toxicities. **Methodology** Protocol is developed following the Preferred Reported Items for Systematic Review and Meta-analysis Protocols (PRISMA) checklist, and the overview of systematic reviews will be reported in accordance with the PRISMA statement. PubMed, Google scholar will be searched from inception to December 2024. Studies conducted in India that analyse the association between DPYD polymorphisms and fluoropyrimidine toxicity will be considered. Results and conclusions will be drawn out and presented in conference.

Pharmacovigilance: Ensuring drug safety and patient wellbeing, as an elective in the CBME curriculum

Keyur Hirpara[1], Alpa Gor[1], Bharat Gajjar[1], Nazima Mirza[1], Ankit Patel[1]

[1]Department of Pharmacology, Pramukhswami Medical College, Karamsad, Anand

Introduction: The shift to competency-based medical education (CBME) has led to the introduction of targeted electives, such as pharmacovigilance, to enhance practical skills among medical students. This elective is vital for educating students on drug safety, therapeutic efficacy, and adverse drug reactions (ADRs). This study aims to evaluate knowledge, attitudes & practical skills and their importance in promoting patient safety and rational drug use among phase III part 1 medical students as an elective. **Methodology:** A descriptive cross-sectional

study was conducted in the Department of Pharmacology, Pramukhswami Medical College, Karamsad. A total of 26 students who had opted for pharmacovigilance as an elective were included in the study. Their knowledge, completeness score (out of 10) of ADRs reported, feedback on course content, teachers' effectiveness and overall training were evaluated. **Result:** All 26 students were evaluated through a multiple-choice question (MCQ) test, most of these students scored 8 or higher on the MCQ test. A total 36 of ADRs with an average completeness score of 8.81 ± 0.56 were found. The majority expressed favourable responses about the elective, indicating agreement or strong agreement. **Conclusion:** The elective posting effectively improves students' knowledge, attitudes and practical skills regarding the quality of ADR reporting in terms of completeness. Given the positive results, this elective could serve as a model for integrating pharmacological safety into medical curricula worldwide. This approach will help develop a new generation of medical professionals who are well-prepared to navigate the complexities of modern pharmacotherapy. **Keywords:** Elective, pharmacovigilance, ADRs

Dissemination of awareness, boosting public confidence and building ADR reporting culture through the Pharmacovigilance Week Celebration

Meghana Kava[1], Alpa Gor[1], Bharat Gajjar[1], Barna Ganguly[1], Nazima Mirza[1]
[1]Department of Pharmacology, Pramukhswami Medical College, Karamsad, Anand

Introduction: The pharmacovigilance mission to ensure drug safety has faced challenges such as limited awareness among healthcare professionals and the public, underreporting of adverse drug reporting (ADR), and the need for a cohesive reporting culture. Pharmacovigilance Week celebration under the aegis of the Pharmacovigilance Programme of India (PvPI) serves as a pivotal platform to address critical gaps in ADR reporting awareness and boost public confidence in pharmacovigilance practices. Department of Pharmacology, Pramukhswami Medical College, Bhaikaka University celebrated Pharmacovigilance Week i.e. from 17th to 23rd September of each year since2021. The four-year celebration of Pharmacovigilance Week sought to bridge these gaps through the themes of awareness, boosting public confidence, and encouraging a culture of ADR reporting. **Report Summary:** The comprehensive program incorporated sensitization sessions, awareness campaigns, panel discussions, and creative competitions (poster creation, essay writing, video-making) to engage diverse stakeholders, including healthcare professionals, students, and the community. The integration of ADR reporting forms into hospital systems and public outreach through multimedia displays and pamphlets ensured a multi-pronged approach to dissemination. Feedback from participants demonstrated an enhanced understanding of ADR monitoring, increased engagement in reporting practices, and a stronger alignment with PvPI goals. **Conclusion:** Pharmacovigilance Week celebrations foster a strong culture of Adverse Drug Reaction (ADR) reporting among patients, healthcare professionals, students from various disciplines and the community, which is crucial for enhancing patient safety and care quality. **Keyword**: Pharmacovigilance week, Pharmacovigilance programme of India, Adverse drug reaction

Reverse Pharmacology: A Paradigm Shift in Drug Safety Assessment

Aman Agrawal[1], Anju Saxena[1], Shalini Chandra[1], Sujata Singh[1]
[1]Rohilkhand Medical College and Hospital, Bareilly.

INTRODUCTION: Traditional medicine, developed over centuries through observation and

experimentation, represents a valuable repository of knowledge within communities. Plant-based remedies, described in ancient texts, provide cost-effective and promising options for drug development, often with better-known safety and tolerance profiles compared to entirely novel chemical entities. The current scenario does not show development of many new molecules with adequate safety profile and thus the scope of reverse pharmacology that represents a paradigm shift in the drug discovery process plays a tremendous role. **METHODOLOGY:** In 2024, a search for the term "reverse pharmacology" in Google Scholar yielded many articles. We identified a few articles related to the topic of drug discovery leading to drug safety and some articles were excluded which were unrelated to drug safety. We also included some articles from PubMed database. **RESULTS:** The number of annual new drug approvals has sharply declined, from 53 in 1996 to just 17 in 2007, but in last five years a figure consistent to 53 on an average in 2023, 55 new drug approved which was the second highest number approval in the past thirty years. Drug development requires 10-15 years and a lot of investment. In response, there is increasing recognition of the value of traditional medicine and holistic approaches. Embracing these approaches could lead to more sustainable, faster, and safer drug development processes. **CONCLUSION:** Reverse pharmacology represents a paradigm shift in the drug discovery process by inverting the traditional "bench-to-bedside" model into a "bedside-to-bench" approach. By optimizing and integrating **Ayurveda** with modern scientific frameworks, researchers can create a synergistic pathway for innovation and safe discovery of drugs ensuring that traditional knowledge remains a cornerstone of modern pharmacological advancements.

A cross-sectional survey of Knowledge, Attitude and Practices related to Adverse Drug Events (ADEs) reporting among the phase II medical students in a tertiary care teaching hospital of Gujarat

Ankit kumar Patel[1], Alpa Gor[2]

[1]Department of Pharmacology, Pramukh swami Medical College, Bhaikaka University, Karamsad, Gujarat, India.

[2]Department of Pharmacology, Pramukh swami Medical College, Bhaikaka University, Karamsad, Gujarat, India.

INTRODUCTION: To ensure drug safety, Pharmacovigilance Program of India (PvPI) has been established. Educating medical students pharmacovigilance is integral part of competency-based medical education. It is needed to assess how much students retained and their attitude towards such passive rewardless reporting. This can also help modify the teaching strategies of Pharmacovigilance to students which can produce a better impact. **METHODOLOGY:** As a part of the celebration of 'National Pharmacovigilance Week 2024', cross-sectional survey was conducted among phase-II medical students of Pramukh swami Medical College, Karamsad, India from 17th-23rd September 2024. A Google form containing 15 questions on knowledge, attitude and practices of ADE reporting was circulated among phase-II students. Data were extracted in MS Excel for further analysis. **RESULTS:** A total 193(93.2%) participants had correct knowledge of definition of pharmacovigilance. Total 135(65.2%) participants knew about banned drug. Out of total 215 participants, 81.86% (176) participants agreed that ADE reporting is a part of his/her professional responsibility, 83.72% (180) participants agreed that reporting ADEs makes significant contribution to patient safety. 'Fear of legal consequences (62.8%), 'Difficult to identify ADE' (58.5%) 'not knowing how to report' (58%) and 'lack of

time'(51.2%) were most stated reasons for less reporting of ADEs. **CONCLUSION:** Phase II medical students have good pharmacovigilance knowledge and a positive attitude towards ADE reporting depicting good teaching practices of pharmacovigilance in the current phase II medical curriculum. Frequent awareness programs, sensitization and incorporation of in-depth teaching of pharmacovigilance in various healthcare courses may help to develop a positive attitude towards ADE reporting.

Quantitative drug utilization evaluation of prescription with antifungal stewardship

Brinda Joshi[1], Dhrumil Kumar Chokshi[1], Yash Raval[1], Juliet Joy Joseph[1], Chirag Patel[1], Chaitali S Dabhi[2]

[1]Department of Pharmacy, Anand Pharmacy College, Anand, Gujarat

[2]Department of Microbiology, Pramukh Swami Medical College

Aim: Audit of clinical practice of prescribing antifungals in patients from antifungal stewardship perspective. Study Design: Retrospective Observational Study **Objectives**: To perform the quantitative drug utilization evaluation of prescription with antifungal stewardship. To evaluate the prescribing pattern of antifungal drug by treating physician in indoor patient. To assess the risk factor for developing fungal infection in patient. **Methodology**: This retrospective observational study was conducted at Shree Krishna Hospital, Bhaikaka University, Karamsad, to evaluate antifungal prescriptions from January 2020 to October 2023. Data were retrieved from inpatient medical records via the hospital information system (Solace) and documented in a Case Report Form. Medications were coded using the WHO Anatomical Therapeutic and Chemical (ATC) classification, with drug consumption expressed as Defined Daily Dose (DDD) per 100 bed days based on the 2020 ATC/DDD index. Statistical analyses, including Student's t-test and One- and Two-way ANOVA, assessed significance, with results presented as Mean ± SD, Median (IQR), and percentages. **Results**: 1521 prescriptions reviewed, 810 met inclusion criteria. Prolonged hospital stay was the leading risk factor (83 positive culture tests), followed by corticosteroid use (43 tests). Fluconazole was the most prescribed antifungal (59.3%), predominantly in the Medicine department (41.48%), while Ophthalmology (0.1%) and Dialysis (0.2%) had minimal usage. Conclusion: This study highlights antifungal drug utilization trends, identifies prolonged hospital stay and corticosteroid use as key risk factors, and recommends candida scoring to optimize therapy and improve fungal infection outcomes.

Fixed Drug Eruption: Paracetamol as the Unseen Trigger

Medha Mishra[1], Afroz Abidi[1], Afzal Noor[1], Babra Shafi[1]

[1]Department of Pharmacology, Era's Lucknow Medical College & Hospital, Lucknow

Introduction (Background & Objective): Adverse Drug Reaction (ADR) is defined as any response to a drug that is noxious and unintended and that occurs at dose used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function. Fixed drug eruption (FDE) is a recurrent, immune-mediated hypersensitivity reaction to specific drugs, characterized by erythematous or hyperpigmented lesions that recur at the same site upon re-exposure. A common painkiller and antipyretic, paracetamol, is an uncommon cause of FDE. In this case series, three patients' clinical characteristics, diagnosis, and treatment of paracetamol-induced FDE are highlighted. **Methodology:** Three patients who used paracetamol and developed

cutaneous lesions were assessed. Comprehensive physical examination sand clinical histories were conducted. Based on the distinctive lesion appearance, and causal relationship to drug exposure, all patients were classified as FDE. **Results: Case 1: A 70-year-old patient who developed erythematous to hyperpigmented violaceous macules with erosions on the bilateral upper and lower limbs and trunk two days after taking paracetamol for fever and loose stools. Case2:A45-year-old patient who used paracetamol during feverish episodes developed recurring violaceous macules on the trunk and limbs.**

Case3: One day after taking paracetamol for a headache, a 50-year-oldpatientdeveloped purpuric, well-defined macules on the face and neck. Topical corticosteroids and antihistamines caused the lesion store solve in all individuals, although some hyperpigmentation persisted. To prevent using paracetamol in the future, counselling was offered. **Conclusion:** The significance of identifying FDE caused by paracetamol is shown in this case series. Patient education, medication cessation, and early diagnosis are essential in managing FDE and preventing recurrence.

Evaluation of QTc in Multidrug-Resistant Tuberculosis Patients Treated with Delamanid: A Prospective Study

Pratik V. Ganvir[1], Farida Ahmad[1], Jameel Ahmad[1], Mohammad Shameem[2],
[1]Department of Pharmacology, Jawaharlal Nehru Medical College, AMU, Aligarh
[2]Department of TB and Chest Diseases, Jawaharlal Nehru Medical College, AMU, Aligarh

Introduction Multidrug-resistant tuberculosis (MDR-TB) represents a major global health challenge, highlighting the urgent need for innovative treatments to enhance patient outcomes. Delamanid, a novel anti-tubercular medication, has demonstrated encouraging results in managing MDR-TB cases. Along with the most common side effects of nausea and vomiting, many studies have found the QTcF prolongation associated with Delamanid during multidrug-resistant tuberculosis (MDR-TB) treatment. **Objective**: The study aimed to evaluate the QTc in patients of MDR-TB receiving Delamanid. **Methodology** This prospective, open-labeled, interventional study was conducted at JNMCH, AMU, and included 70 MDR-TB patients who were resistant to either Group A or B drugs of the All-Oral Longer regimen. Patients were treated with Delamanid (100 mg twice daily) for six months. QTcF intervals were assessed before and after treatment using a standard electrocardiogram. The age and sex distribution among the enrolled MDR-TB patients are also noted. **Results**: Out of 70 patients, 69 completed the six-month treatment. QTcF prolongation was observed in 71.01% of patients (Grade 1) and one patient (Grade 2), with a statistically significant increase in QTcF values post-treatment ($p < 0.0001$). Most of the patients with prolonged QTcF were above 60 years, followed by those aged 31–40 years. None of the patient's QTcF exceeded 500 ms, and no severe cardiac events were reported during the study. **Conclusion** Delamanid-based regimens are associated with mild-to-moderate QTcF prolongation, particularly in older patients. While no severe cardiac outcomes were observed, regular monitoring of QTcF is essential to ensure the safety of patients undergoing MDR-TB treatment.

A Case Report on Craniopharyngioma

Aatmi Kapasi
Anand Pharmacy College

Introduction: This case study presents the clinical management and outcomes of a patient

diagnosed with craniopharyngioma, a rare benign tumor of the seller and suprasellar region. Craniopharyngiomas, although typically slow-growing, can present a range of challenges due to their proximity to critical brain structures, including the hypothalamus and optic nerves. This uncommon benign tumour of the central nervous system primarily affects the pituitary and/or hypothalamus. In the seller or parasailer areas, it is a cystic embryonic abnormality. Craniopharyngioma symptoms may include headache, nausea, vomiting, vision abnormalities, and hormonal imbalances. **Case Summary:** We report an unusual case of craniopharyngioma induced multiple complications of visual disturbances, amenorrhoea, headache, and extreme dizziness in a 20 years old female patient. Pre-operative imaging examinations such as MRI and CT scan reveals the presence of suprasellar lesion which is significantly compressing the optic chiasm and confirms the diagnosis of craniopharyngioma. In this case, there are involvement of several specialists including- neurosurgeons, endocrinologists, and ophthalmologists. The initial signs and symptoms that the patient faced were severe headache, amenorrhea, visual disturbances, and extreme dizziness. Upon the confirmation of the diagnosis, the patient was operated for the same under the process of Craniotomy. Upon discharge, the patient follows up with a yearly MRI and every month with the Endocrinologist.

Assessment of surgical antimicrobial prophylaxis (SAP)and impact of implementation of an antimicrobial stewardship intervention in patients undergoing clean and clean contaminated surgery at a tertiary care hospital

Rishika A.[1], Shilpa N Kaore[1], Swagata Brahmachari[1], Ajay Shukla[1], Shubham Atal[1]
[1]AIIMS Bhopal

Background: Surgical antimicrobial prophylaxis (SAP) plays a crucial role in preventing surgical site infections and spread of resistance. The appropriateness of SAP is determined by correct choice of drug, timing of administration, dose and duration of antimicrobials. Despite guidelines for SAP, compliance is often suboptimal, necessitating interventions like antimicrobial stewardship programs (AMSP) to optimize prophylactic antimicrobial use. **Objective**: 1. To assess appropriateness of surgical antimicrobial prophylaxis (SAP) in patients undergoing clean and clean-contaminated surgeries. 2.To plan and develop AMSP intervention for optimization of surgical antimicrobial prophylaxis. 3.To compare the surgical antimicrobial prophylaxis before and after AMSP intervention. **Secondary Objectives:** 1.To identify SSI in post-operative period. 2.To identify barriers for implementation of good surgical prophylaxis practices. **Method**: A prospective longitudinal study was conducted at a tertiary care hospital. During the phase-1 study period,126 patients were recruited, and data on their SAP prescribed was collected. We further evaluated the appropriateness of antimicrobial use based on ICMR Treatment Guidelines for Antimicrobial Use in Common Syndromes 2022 and WHO AWaRe (Access, Watch, Reserve) Antibiotic Book, 2022.Intervention was given to the residents of surgery department and the phase 3 data collection was done as such in phase-1. **Result**: An analysis of 126 patients revealed that as per ICMR guidelines,100% of patients(n=126) received pre-incisional antimicrobials within the recommended time. Only 14% of the surgeries(n=18) involved the appropriate choice and dose of antimicrobials that aligned with ICMR guidelines, and 100% of cases extended antimicrobial use beyond the recommended 24-hour duration. After the intervention was given, there was improvement seen. **Conclusion**: In phase 1 study, collectively only few cases were partially compliant to ICMR guidelines. These deviations from choice, dose and duration of antimicrobials highlight significant areas for improvement in AMSP

practices within the hospital setting. And once the intervention was done, there were improvements in adherence to the guidelines.

Polypharmacy and Drug-Drug Interactions: A Comparative Study of Three Drug Interaction Checkers in Tertiary Care Centre

Swastik Verma[1], Shubham Atal[2], Sadasivam Balakrishnan[2]
[1]All India Institute of Medical Sciences Bhopal
[2]Department of Pharmacology, All India Institute of Medical Sciences, Bhopal

Introduction: Polypharmacy, defined as use of five or more medications, is prevalent in tertiary care centers, especially among elderly patients and those with chronic illnesses(1). While it can improve therapeutic outcomes, it increases risk of drug-drug interactions (DDIs), leading to adverse drug reactions (ADRs)(2,3). This study aims to compare effectiveness of three widely used drug interaction checkers—Lexicomp®, Medscape, and Drugs.com—in identifying and categorizing major DDIs in a tertiary healthcare setting. **Methodology:** Data from 4,523 prescriptions were reviewed, with 500 randomly selected for analysis. A total of 1,133 unique drug combinations were generated and analyzed using Lexicomp®, Medscape, and Drugs.com. Each tool categorized DDIs by severity, and agreement among the checkers was assessed using Cohen's kappa statistic. **Results:** Drugs.com identified highest proportion of DDIs (11.78%), followed by Lexicomp® (11%) and Medscape (9.06%). Among the analyzed drug combinations, several pairs were found to exhibit significant interactions. These included tramadol and carbamazepine (reduced analgesic efficacy due to enhanced metabolism), spironolactone and ramipril (risk of hyperkalemia), aspirin and apixaban (increased bleeding risk), and escitalopram and domperidone (risk of QT prolongation and arrhythmias). The drug combination pairs that showed major DDIs are mentioned in table. Cohen's kappa values ranged from 0.47 to 0.5, indicating moderate agreement among the checker. **Conclusion:** This study emphasizes need for standardized drug interaction checkers to enhance accuracy of drug-drug interaction detection. By highlighting high-risk combinations, it underscores importance of clinical judgment in prescribing practices, ultimately aiming to improve medication safety, minimize adverse reactions, and enhance therapeutic outcomes in polypharmacy settings.

PIM analysis in outpatient prescriptions of elderly patients in a tertiary health care centre using Beers' Criteria 2023

Harshit Vishwakarma[1], Ajay Shukla[1], Ratinder Jhaj[1], Balakrishnan S.[1]
[1]Department of Pharmacology, AIIMS Bhopal

Introduction: Polypharmacy is common in elderly. Curbing the use of PIMs is urgent in older adults. We aimed to audit PIM usage in the outpatient service of a tertiary health care facility-AIIMS Bhopal. **Methods:** A cross-sectional study, which was done in the department of Pharmacology, AIIMS Bhopal after the collection of OPD prescriptions from Amrit Pharmacy, AIIMS Bhopal. OPD prescriptions with patients aged 60 and above were included & inpatient prescriptions were excluded. Outpatient prescriptions were reviewed during the period October 2023 to November 2024. The 2023 American Geriatrics Society (AGS) Beers Criteria was used to assess PIMs in this study. **Results:** During the 13-month study period, 619 prescriptions were

taken from Outpatient department, including 248 women and 371 men, with a mean age of 75.4 ± 9.6 years (range: 60-95). The mean number of medications prescribed per patient was 4.6. Of the 619 prescriptions 51 prescriptions had one or more PIMs. Out of the total 1925 drugs analysed the number of Potentially Inappropriate Medications was found to be 140, of which 118 were to be avoided and 22 were to be used with caution. **Conclusion:** Older adults are frequently prescribed PIMs. However, clinical decision-making for this vulnerable population needs to take into account safety as reflected by the Beers Criteria. **Keywords:** PIMs, Beers Criteria

Low Serum Vitamin B12 Levels Elevate the Risk of Eating Disorders in Patients with Type 1 Diabetes Mellitus

Kanwarpreet Sadhu[1], Shivani Sidana[2], Abhinav Kanwal[1]

[1]Department of Pharmacology, All India Institute of Medical Sciences, Bathinda, Punjab
[2]Department of Endocrinology, All India Institute of Medical Sciences, Bathinda, Punjab

Introduction: Type 1 diabetes mellitus, an autoimmune disorder, is globally on the rise. Managing it poses challenges, including consistent insulin adherence, eating disorders, comorbidities, and heightened risk of mental health problems. Autoimmunity against gastric parietal cells in Type 1 diabetes increases vulnerability to Vitamin B12 deficiency. Limited data exists on B12 deficiency prevalence in North Indian Type 1 diabetes patients. This study reveals low serum Vitamin B12 levels in these patients, highlighting an elevated risk of eating disorders. **Aim and Objectives:** The Aim of this study is to analyze the **effect of Vitamin B12 Supplementation on Eating disorders** and **Glycemic control in Type1 Diabetes Mellitus patients**, which will be fulfilled by meeting the following objective: Study the prevalence of abnormal eating patterns among Type 1 Diabetes Mellitus patients and explore the effect of Vitamin B12 supplementation on glycemic control (Hb1AC) in Type 1 Diabetes Mellitus. **Methodology:** In this pilot study, 52 Type 1 Diabetic patients (28 males, 28 females) were recruited based on inclusion/exclusion criteria. All participants were interviewed using the EAT-26 questionnaire, Serum Vitamin B12 levels and HbA1c levels measured. Statistical analysis was conducted using SPSS version 25. **Results:** Our study shows significant prevalence of Vitamin B12 deficiency in Type 1 diabetic patients, coexisting with abnormal eating attitudes. It showed that 34.6% of the Type 1 Diabetic patients had low Vitamin B12 using the manufacturer's cut–off of 187 pg/mL and also are at **high risk for eating disorders. Conclusion:** The study examines potential associations between Vitamin B12 deficiency and abnormal eating attitudes in this population. The findings indicate **low serum Vitamin B12 levels** and **increased risk of eating disorders in individuals with Type 1 diabetes mellitus. Keywords:** Diabetes Mellitus, Vitamin B12, HbA1c, Eating disorder

Investigating the Impacts of Product Quality and Need of Robust Vigilance: Lessons from A Cluster of Gemcitabine Induced ADR Cases at A Regional Radiation Oncology Centre

Gupta N[1], Mittal N[1]

[1]Department of Pharmacology, PGIMS, Rohtak

Background: Gemcitabine is a commonly used chemotherapy agent with a known safety profile. This case series documents an unusual cluster of seven cases of gemcitabine-induced hypersensitivity reactions within a single week, linked to a questionable quality of batch of 1000 mg Gemcitabine vials in the hospital drug supply. **Aim**: To document and analyze gemcitabine-induced adverse drug reactions (ADRs), emphasizing the role of pharmacovigilance in identifying product quality issues and ensure patient safety. **Material and Methods**: This case series analyzed the patients who developed adverse drug reactions during treatment with gemcitabine. Clinical data, including patient details, type of cancer, treatment given, dosage, duration of therapy, mode of drug administration, healthcare personnels involved and the nature of ADRs were collected from medical records and retrospective investigation. Each ADR was assessed for causality WHO-UMC causality assessment criteria. The drug samples were sent for testing at a regional testing laboratory and the results followed up. **Results**: All the seven patients, experienced similar adverse reaction. Causality assessment classified all cases ADRs as "probable". Results of the drug testing reported sample to be of Standard Quality. Prompt intervention, including use of a different batch of vials and supportive care, led to resolution in all cases in the daycare ward. The findings align with known toxicity profiles but highlight the need for close monitoring to manage quality related and dose related reactions. **Conclusion**: This case series highlights the critical role of pharmacovigilance in identifying and managing clusters of adverse drug reactions (ADRs) caused by product quality defects. The findings emphasize the need for stringent quality control in drug manufacturing, storage, timely reporting of ADRs to prevent future occurrences. **Keywords**: Gemcitabine adverse drug reactions, Signal Detection in Pharmacovigilance, Excipients, CDSCO, WHO-UMC causality assessment, drug quality control

Pharmacovigilance Study of Schizophrenia patients attending a Tertiary Care Teaching Hospital in Central India

Dr. Mehul Soni,
LN Medical College and Research Centre, Bhopal

Background: Adverse drug reactions (ADRs) in schizophrenia patients are a significant concern due to polypharmacy and the prolonged use of antipsychotics. This study evaluates the prescribing patterns, ADR profiles, causality assessments, and associated costs in schizophrenia patients in a tertiary care teaching hospital. **Aim:** To study the profile of adverse drug reactions in hospitalized and ambulatory schizophrenia patients in a tertiary care teaching hospital in Central India. **Methods:** This prospective observational study included schizophrenia patients receiving antipsychotic therapy. Data on demographic details, prescribing patterns, ADRs, and associated costs were collected using structured forms. ADRs were classified and assessed using Naranjo's Algorithm for causality. **Results:** The study included 100 schizophrenia patients, with 44% males and 56% females. The majority (46%) were in the 31-40 years age group, and only 2% were in the 10-20 years range. The illness duration was less than 5 years in 74% of cases. Haloperidol was the most commonly prescribed typical antipsychotic (60%), followed by penfluridol (30%) and chlorpromazine (10%). Among atypical antipsychotics, aripiprazole (24.44%) was the most frequently prescribed, followed by risperidone (22.22%), quetiapine (20%), and olanzapine (15.55%). Common ADRs included weight gain (20.96%), drowsiness (17.74%), sedation (16.12%), hyperglycemia (14.51%), constipation and extrapyramidal symptoms (11.29% each), hypotension (4.83%), and dry mouth (3.22%). **Conclusion:** The study demonstrates distinct prescribing trends and ADR profiles in schizophrenia patients. Haloperidol

and aripiprazole were the most commonly prescribed antipsychotics, while weight gain and sedation were the predominant ADRs. These findings highlight the need for enhanced pharmacovigilance practices to minimize ADR-related risks and improve the management of schizophrenia. **Keywords:** Adverse Drug Reactions, Pharmacovigilance, Schizophrenia, Antipsychotics, Naranjo's Algorithm, Weight Gain, Sedation, Polypharmacy.

Why and How Pharmacovigilance came? Tragedies, establishment, detection, reporting and causality assessment to the adverse drug reaction

Chanda Malviya
VNS Group of Institution, Faculty of Pharmacy, Bhopal MP

Background and objective: A drug is a chemically synthesized molecule that exerts its therapeutic action on numerous diseases and disorders. The drug molecule has to cross multiple preclinical and clinical evaluation stages to defend and emphasize its therapeutic action on human ailments. The clinical studies have limitations due to fewer participants in the trial period raises the question on novel drug action when approved globally to treat population. Anciently, drug therapies are reported with severe and detrimental tragedies. Then, the World Health Organization (WHO) introduced the definition of adverse reaction due to drugs and collaborated with the Uppsala Monitoring Center (UMS) to supervise and monitor unintended reactions of drugs globally. In India, government regulatory authorities established the National Coordinating Center (NCC) in different states to collect adverse reports of post-marketed drugs. UMS accepted all the reports and, then work has to find the causal relationship between the drug and adverse reaction using different methods. This review aims to explain and reveal the importance of Pharmacovigilance in Adverse Drug Reaction (ADR) monitoring to protect the population's health. **Methodology:** This review collected information from valid sources, Science Direct, PubMed, and Google Scholar. These sources helped obtain data on previous drug tragedies and the initiation of Pharmacovigilance against post-marketed drugs. The signal detection of ADR, various sources of reporting, and causality assessment methods are explained according to the WHO scale. **Conclusion:** This review provided an awareness and understanding of ADR whereas, Pharmacovigilance is the system that is vigilant for ADR collection to ensure the safer use of drugs. The ADR minimization is only dependent on volunteer reporting of undesirable reactions that help UMC to generate ADR signals.

A review on vaccine safety surveillance and causality assessment using adverse event following immunization

Tina Malviya
Department of Pharmaceutics, VNS Group of Institution, Faculty of Pharmacy, Bhopal MP

Background and objective: A vaccine is a biological product or formulation that triggers the human immune system to develop specific antibodies against specific viral antigens. The principle of vaccine production comprised the use of inactivated or modified viral protein including some excipients that disable the virus to utilize the body's nutrients to multiply themselves. The administration of novel vaccines is associated with the risk of adverse reactions

due to genetic variability. Past studies also have evidence that shows vaccine-related adverse episodes occurred after administration. Vaccine Pharmacovigilance is a global networking system that seeks and trap the unpredicted adverse reaction developed after vaccine immunization in a population. The objective of the presenting review is the collection of data on vaccine failure after an immunization program and the role of vaccine pharmacovigilance to minimizing it. **Methodology:** The source for data was the Adverse Reaction Following Immunization (AEFI) WHO platform. The information was also collected by using an online MOOC course on the AEFI program for vaccines. Vaccine failure may be associated with a causal relationship between vaccines and adverse reactions. These reactions may have a direct pharmacological relation with adverse reactions and sometimes alternative options work (eg; anxiety and product quality) that fail the therapy. AEFI forms help in signal detection and find the casual relationship between vaccine and adverse reaction due to multiple etiological factors. **Conclusion:** This review summarized the causes of vaccine failure after an immunization program. However, to generate the actual signal of unpredictable adverse reactions causality assessment is important.

Pharmacovigilance Understanding, Attitude, And Participation Among Community Pharmacists: A Cross-sectional Study in Central India

Shweta Kumar, Sanjay Gupta[1], Suraj Mewada[1], Sandeep Kumar Gupta[1]
[1]Department of Pharmacy, S. V. Polytechnic Govt. college, Bhopal

Background: Adverse drug reactions, or ADRs, place a heavy clinical and financial strain on the nation's healthcare system around the world. India's reporting rate is below 1%, compared to the global average of 5%. Strengthening pharmacovigilance is critical to improving patient safety. An active pharmacovigilance program depends on the community pharmacist promptly reporting adverse drug reactions. (Shareef et al., 2024) **Objective:** The purpose of this study is to evaluate the understanding, attitude, and participation (UAP) of community pharmacists regarding pharmacovigilance concept and practice. **Methods:** A prospective, questionnaire-based study was conducted to assess pharmacists' profiles, knowledge, opinions, and participation in ADR reporting. (Prakasam et al., 2012) **Results:** To look at the overall UAP results and background data on the study participants, we employed statistical tests. Of the 500 distributed questionnaires, 280 (56.0%) were returned fully completed. According to the study, participants reported side effects with poor behaviors but good understanding and attitude scores. Since pharmacovigilance topic was only recently added to the diploma curriculum, community pharmacists generally know less about it than current diploma graduates. **Conclusion:** Pharmacists, as frontline healthcare providers, play a vital role in identifying, counselling, and reporting ADRs. Pharmacy authorities should mandate that all community pharmacists attend periodic trainings to update their understanding on reporting ADRs. Leveraging their role is essential for a safer healthcare system and effective drug safety practices.

Oral Semaglutide-a significant milestone in the management of Type 2 Diabetes Mellitus

Manu Arya
Teerthanker Mahaveer Medical College & Research Centre, Bagadpur, UP

Background and Objective:
Glucagon-like peptide-1 receptor agonists (GLP-1RAs) are integral to the management of type 2 diabetes mellitus (T2DM), offering glycemic control, weight reduction, and cardiovascular safety. Despite these benefits, traditional GLP-1RAs have poor oral bioavailability and require injectable formulations. Oral semaglutide, the first oral GLP-1RA, overcomes these limitations. This study aims to review the clinical efficacy, safety, and unique pharmacological properties of oral semaglutide, highlighting its role in improving diabetes management. **Methodology:** Data from the PIONEER trials (PIONEER 1–8) were analyzed to evaluate the efficacy and safety of oral semaglutide across different T2DM patient populations. The mechanism of oral bioavailability enhancement was reviewed, focusing on the role of sodium N-(8-[2-hydroxybenzoyl] amino) caprylate (SNAC) in facilitating gastric absorption. Comparative data on HbA1c reduction, weight loss, and cardiovascular outcomes were assessed against placebo and other antidiabetic agents. **Results:** Oral semaglutide demonstrated significant reductions in HbA1c and body weight across all stages of T2DM. In the PIONEER trials, it showed superior glycemic control compared to placebo and other GLP-1RAs. Cardiovascular safety was established in PIONEER 6, with tolerable gastrointestinal side effects. SNAC enhanced bioavailability by 100 times, allowing consistent absorption through the gastric epithelium. **Conclusion:** Oral semaglutide is a groundbreaking advancement in T2DM management, combining the proven benefits of GLP-1RAs with the convenience of oral administration. It is effective in glycemic control, weight management, and cardiovascular risk reduction, marking a new era in peptide-based therapeutics.

Adverse Drug Reactions induced by Etoricoxib: A Retrospective Analysis from the ADR Monitoring Centre at a Tertiary Care Hospital

Bushra Siddiqui[1], Ratinder Jhaj[1], Deepa Choudhary[2]
[1]Department of Pharmacology, AIIMS Bhopal
Pharmacovigilance Associate, AIIMS Bhopal

Introduction: Cyclooxygenase inhibitors were developed in the quest of enhanced analgesic efficacy devoid of gastric side effects. Etoricoxib is a second-generation COX-2 inhibitor and as its use increases so do the reports of side effects. Etoricoxib is currently approved in a number of countries for various indications such as treatment of Low back pain, Asthma, Bursitis of knee etc. **Objective**: To analyze the pattern and nature Adverse Drug Reactions (ADRs) from Etoricoxib and evaluation of ADRs in patients at a tertiary care teaching hospital. **Methodology**: This study is a retrospective study of tertiary care hospital, AIIMS Bhopal. Each case was reported to ADR monitoring centre and assessed using WHO causality assessment tool. These ADRs were analyzed for the pattern, System Organ Class involved, suspected drug/drugs and causality assessment. **Results**: A total of 154 ADRs were reported. The age of the patients was between 21-88 years with female preponderance. The General disorders and administration site conditions (43.5%) were most occurred, followed by the skin & subcutaneous tissue (37.01%), Gastrointestinal disorders (15.58 %), Nervous system disorders (6.5 %), Eye disorders (2.59%) and Renal and urinary disorders (1.29%) Ear and labyrinth disorders, Musculoskeletal and connective tissue disorders, Psychiatric disorders, Respiratory, thoracic and mediastinal disorders, Vascular disorders were (0.64%). Clinical improvement was noted in all patients after stopping the drug. **Conclusion**: The majority of ADRs were moderate in nature but mostly were recovered. Our goal in this report is to increase awareness of the possible ADR of Etoricoxib.

The medical community should be aware of the adverse effects of Etoricoxib, recognize them in time, recommend drug-use cessation, and warn patients against repeated use.

Comparative evaluation of innovative teaching learning methods to teach pharmacovigilance to undergraduate medical students

Anuradha Deshkar[1], Shubhada Gade[1]
[1]Datta Meghe Medical College, Nagpur

Introduction: It is a need of time to empower undergraduate medical students in pharmacovigilance and ADR reporting for better patient safety. New teaching learning (TL) methods like cinema education, case-based learning, exercises, peer learning, role play should be implemented for better understating and to make topic interesting.

Objectives: 1) To evaluate the effectiveness of innovative TL methods for pharmacovigilance
2) To assess the perception and satisfaction level of students

Methodology: 148 Phase II MBBS students were included. Participants were divided in two groups. Group A (n= 74) was exposed to didactic lecture and practical while Group B (n= 74) was exposed to innovative TL methods to teach the pharmacovigilance and ADR reporting. Pretest and Post test was administered to evaluate effectiveness of innovative TL methods. Feedback from the students was taken to assess the perception and satisfaction level.

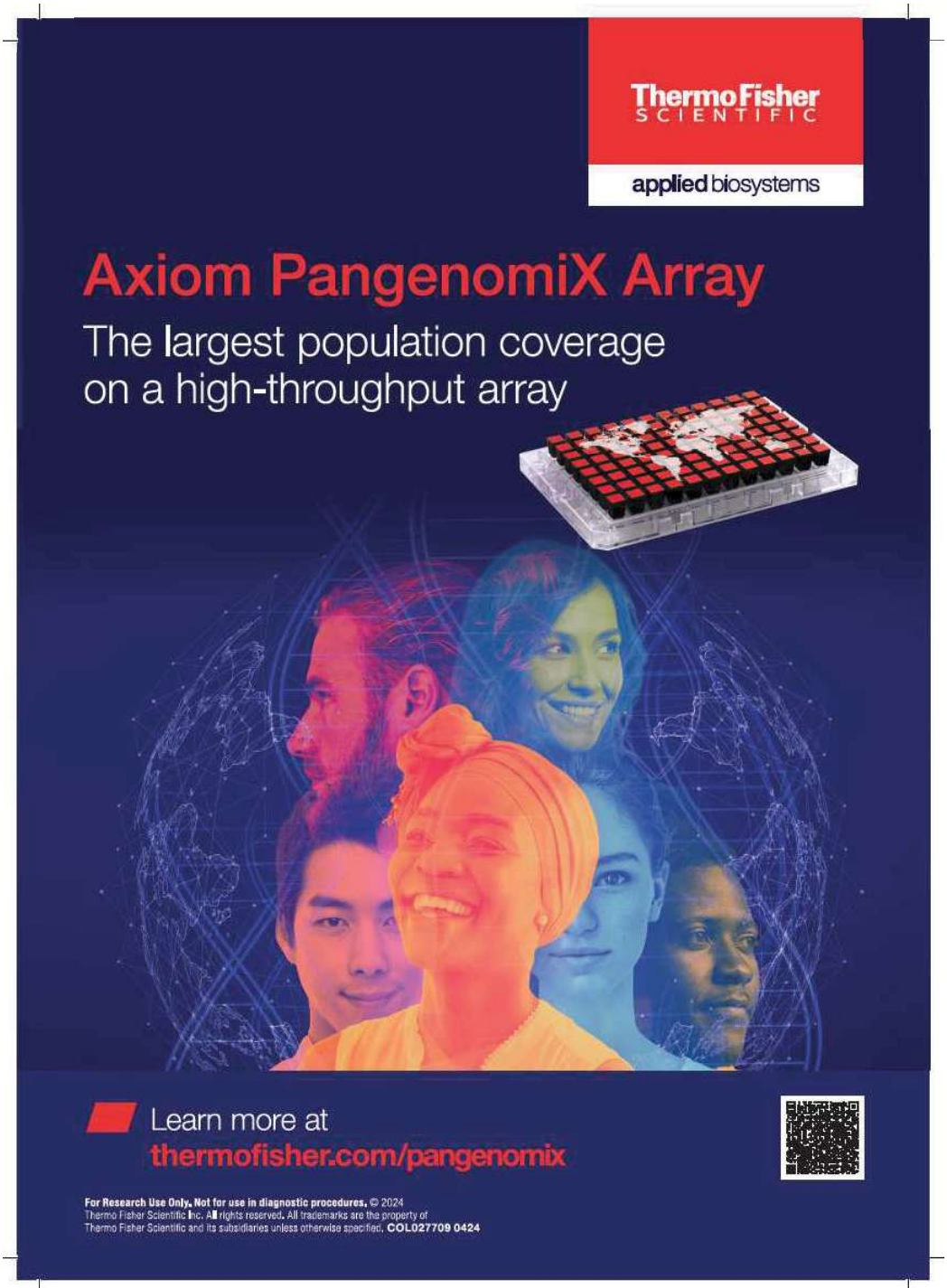
Results: The mean percentage increase in post test score is more in Group B compared to Group A. There was statistically significant ($p < 0.05$) difference between two groups in mean percentage increase in post test score. The feedback analysis reported of high satisfaction levels among the Group B students as compared to Group A. 88% students in Group B strongly agreed about understanding, improved factual recall and knowledge gain while it is 58% in Group A.

Conclusion: Improved performance and positive feedback with innovative TL methods outweighed its benefits to teach the pharmacovigilance and ADR reporting.

Anaphylactic reaction to Ferric Carboxymaltose: A Case Report

Chanchal Priyadarshni[1], Chaudhary Deepa[2], S Balakrishnan[2], Jhaj Ratinder[2]
[1]VNS Institute of Pharmacy Bhopal
[2]Department of Pharmacology, AIIMS Bhopal

Introduction: Iron-deficiency anaemia is most frequently related with insufficient nutrition. However, it is also encountered in chronic diseases including chronic renal failure (CRF) and congestive heart failure (CHF). Oral or intravenous (IV) iron replacement is recommended for its treatment Ferric carboxymaltose (FCM) is a nondextran third-generation IV-iron preparation which has the advantage of normalizing haemoglobin and replenishing iron stores over a short period of time**.** Acute hypersensitivity reactions during iron infusions are very rare but can be life-threatening. **Case Summary:** A 30 years old, female patient admitted in Obstetrics and Gynaecology department with the chief complain of severe anaemia. Inj. Ferric Carboxymaltose was administered to her for the treatment of anaemia, after 5 minutes of starting the infusion of injection Ferric Carboxymaltose patient developed Anaphylactic Reaction. **Management and Treatment:** Anti-histamine, Steroid, O2 support through face mask, IV Adrenaline, Intravenous fluids and were given to patient for the treatment of adverse drug event. **Outcome:** Patient was recovered from the Anaphylactic reaction after 3-4 hours along with treatment. **Discussion and Conclusion:** Anaphylactic reactions, particularly fatal ones, associated with intravenous iron therapies are rare. A public health initiative aimed at reducing the number of severe adverse reactions to parenteral iron would require a rational use of this drug.



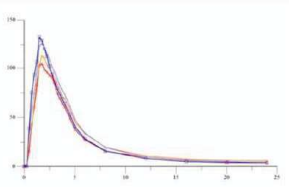
Thermo Fisher Scientific Inc. is the world leader in serving science, with annual revenue of more than S40 billion. Our Mission is to enable our customers to make the world healthier, cleaner and safer. Whether our customers are accelerating life sciences research, solving complex analytical challenges, increasing productivity in their laboratories, improving patient health through diagnostics or the development and manufacture of life-changing therapies, we are here to support them. Our global team delivers an unrivaled combination of innovative technologies, purchasing convenience and pharmaceutical services through our industry-leading brands, including Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services, Patheon and PPD.

CRO Specialising in Bioavailability & Bioequivalence Studies

AZIDUS
Laboratories Ltd.
The Trusted CRO

Azidus Laboratories Ltd. is a physician owned, contract research organisation (CRO) with facilities in India, USA & Ghana.
Azidus specializes in

- Bioavailability & Bioequivalence studies
- Clinical research involving various endpoints
- Global regulatory filing services



Science driven approach in research, design & study conduct is the key focus of Azidus; enabling a lasting & successful relationship with our clients globally.

AZIDUS Performs world class testing of generic medicines via bioequivalence clinical research to test and validate the safety and quality of drug products.

Advantage - AZIDUS Global

- Clinical, Bioanalytical & Diagnostic laboratory - all under single roof.
- Conducted over 3000 Bioequivalence studies till date.
- Our facilities have been Inspected multiple times by **US-FDA, EMA, ANVISA, DCGI, WHO, ISP and other global agencies.**

Clinical Infrastructure

Bionalaytical Infrastructure

- **32 LCMS/MS** & **3 ICPMS** machines
- Over 600 Bioanalytical methods developed. Validation done as per ICH M10.
- Expertise in developing & validating BA methods for complex molecules including,
  - Liposomal products (Doxorubicin/Amphotericin)
  - Locally acting drugs (Mesalazine, Pinaverium bromide)
  - Hormonal products (Dydrogesterone, ethinyl estradiol)

Over 600 beds across the globe (480 beds under single roof in India).

Fully equipped Advanced Care Unit with 18 beds

Specializing in complex products BA/BE studies

Controlled substances, Narcotics & Restricted drug Products BE studies

In-House Diagnostic Lab (CAP & NABL accredited)

Tailored designs for highly variable drug products

Azidus Laboratories Ltd., India
23, School Road,Rathnamangalam, Vandalur, Chennai – 600127, India
Contact: be@azidus.com / www.azidus.com

COSMO
CLINICAL RESEARCH
ACCESS TO QUALITY RESEARCH

Cosmo Clinical Research LLP is a spin-off of Azidus Laboratories ltd.

Cosmo enables ethical compliant and affordable research for emerging markets with no compromise to science.

About COSMO

- 1st Clinical Research Organization in the Union Territory of Puducherry.
- Provides end-to-end solutions for BA/BE studies for all dosage forms at an affordable cost.
- Focused on disrupting the space of affordable research with no compromises on quality.
- CDSCO - GCP approved clinical site.

COSMO Services

- **Bioavailability & Bioequivalence**
- **Bioanalysis services**
- **Auditing & Monitoring of clinical research studies**
- **Evaluation and consultancy for clinical research data.**

Clinical & Bioanalytical Infrastructure

- **3 Clinics with 60 beds capacity**
- **Fully equipped advanced care units with 3 beds.**
- **6 LCMS/MS Machines**

COSMO CLINICAL RESEARCH LLP
89/2 & 89/3, Thavalakuppam,
Cuddalore Road, Puducherry - 605 007

Contact: bd@cosmocr.com
www.cosmoclinicalresearch.com

Astragile Consultancy Services Pvt. Ltd.

ASTRAGILE
CONSULTANCY SERVICES

Software solutions for Clinical Research, Pharmacovigilance and GxP Services

Contact email ID : Senthil@astragile.com

Arun Jain
Director

Mob.: 8839238522
9406522189

Chirag Scientific Sales

Deals in : Chemicals Reagents Glass Wares & Equipments

H.O.: Near Indane Gas Agency Samer Wall Gali Mill Road,
Ganj Basoda, Distt. Vidisha (M.P.) 464221
B.O.: H.No. 162, Rajat Nagar, Piplani, Bhopal (M.P.) 462022
E-mail : chiragscientific2018@gmail.com