# ACPCon2025

## 4TH NATIONAL CONFERENCE OF THE ASSOCIATION OF CLINICAL PHARMACOLOGISTS

*Conference Theme*

**REPOSITIONING CLINICAL PHARMACOLOGY IN INDIA**


**Organized By**
**MGMCRI Pondicherry**
**JIPMER Pondicherry**
**SRM MCH & RC Chennai**

**TNMC Credit Hours Applicable**

**12 - 13 Sep 2025**

**B.C.Roy Hall, MGMCRI, SBV, Pondicherry**

*All are invited*

# Invitation

Dear Delegates,

On behalf of the Association of Clinical Pharmacologists (ACP) and the organizing committee, it is our great pleasure to invite you to the 4th National Conference of ACP – ACPCon2025, hosted by Sri Balaji Vidyapeeth (SBV), Pondicherry, from September 11–13, 2025.

The conference will begin with Pre-Conference Workshops on September 11, conducted at three distinguished institutions:

- JIPMER, Pondicherry
- SRM Medical College Hospital & Research Centre, Chennai
- Institute of Salutogenesis and Complementary Medicine, SBV, Pondicherry

With the theme "Repositioning Clinical Pharmacology in India," ACPCon2025 aims to enhance the relevance and visibility of the discipline by integrating pharmacological expertise into clinical practice, innovative solutions for clinical research, gleaning real world evidence to better patient management, optimizing therapy using biomarkers and therapeutic drug monitoring. The conference will feature expert-led symposia, panel discussions, invited lectures, orations on the current trends in clinical pharmacology, and there will be a number of opportunities for youngsters to showcase their talents through the prize sessions for oral and poster presentations. This premier event provides an excellent platform for DM Clinical Pharmacology, MD Pharmacology, PhD students as well as clinical pharmacologists and other students, professionals from academia and industry, to exchange knowledge, share insights, and foster collaborations.

Nestled along India's southeastern coast, Pondicherry is a captivating blend of history, culture, and coastal beauty. Once a French colonial settlement, its cobbled streets, mustard-hued villas, and vibrant cafés offer a European charm. Explore the serene Auroville, the spiritual Sri Aurobindo Ashram, or unwind at Rock Beach and the Seaside Promenade. Nature lovers will adore Paradise and Serenity Beach, while architectural gems like the Basilica of the Sacred Heart of Jesus and Manakula Vinayagar Temple showcase its heritage.

From charming boutiques to Franco-Tamil cuisine, Pondicherry promises an unforgettable experience at ACPCon2025! We are confident that this conference will be intellectually stimulating, professionally rewarding, and personally memorable.

We look forward to your participation!

Warm Regards,

Prof. Nihar Ranjan Biswas
*Organizing Chairperson*

Prof. Melvin George & Prof. Manimekalai
*Organizing Secretaries, ACPCon2025*

# Organizing Committee

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**ACPCON 2025 – Conference program schedule**

**Track 1 – MGMCRI Pondicherry – BC Roy Hall**

**Day 1 – September 12, 2025**

| Time | Topic | Speakers | Chair Person |
|---|---|---|---|
| 8:00 – 9:00 AM | Registration | | |
| 9:00 – 9:20 AM | **Plenary lecture 1** – Lessons learnt from recent clinical trials | Dr. Sanish Davis Johnson & Johnson Mumbai | 1. Dr.Shoibal Mukherjee Medanta Hospitals New Delhi<br>2. Dr. Sandhiya Selvarajan JIPMER Puducherry |
| 9:20 – 9:40 AM | **Plenary lecture 2-** Looking beyond traditional designs in clinical research | Dr. Nilanjan Saha Jamia Hamdard & ICMR New Delhi | |
| 9:40 –10:00 AM | **Plenary lecture 3 -** A fairy tale of two game changers - the case of semaglutide & tirzepatide | Dr Gaurab Bhaduri Apollo, Kolkata | |
| 10:00–10:15 AM | **Special Lecture 1-** Promoting Patient Safety and Access: WHO support for strengthening Regulatory Systems and Safety of Medical Products in India. | Dr.Madhur Gupta WHO India | |
| 10:15 – 10:30 AM | **Coffee break** | | |
| 10:30 – 10:50 AM | **Plenary lecture 4** - Implementation research & its growing importance in clinical pharmacology | Dr.Subitha L JIPMER, Puducherry | **1.** Prof.Santanu Tripathi Jagannath Gupta Institute of Medical Sciences & Hospital, Kolkata<br>**2.** Prof. S.P. Dhaneria RD Gardi Medical College, Ujjain |
| **Symposium 1** – The Future of Patient-Centric Clinical Pharmacology: Beyond Molecules to Meaningful Care | | | **1.** Dr. N. R Biswas SBV, Puducherry<br>**2.** Prof. Santanu Munshi School of Tropical Medicine, Kolkata |
| 11:00 – 11:20 AM | Setting a clinical pharmacology OPD - lessons learnt | Dr. Sabnam Ara Begum RG Kar College, Kolkata | |
| 11:20 – 11:40 PM | Clinical pharmacologist – optimizing clinical therapeutics | Dr. Shambo Samrat Diabetes and Allergy-Asthma Therapeutics Specialty Clinic, Kolkata | |
| 11:40 – 12:00 PM | Role of clinical pharmacologists in hospital management | Dr. Sumalya Sen GIMSH, Durgapur West Bengal | |
| 12:00 – 12:15 PM | Discussion & wrap of session 2 | | |
| 12:15 – 12:45 PM | **Special Lecture 2-**Complexity and nuances of herbal products | Dr Rajesh Kumavat Himalaya Wellness Bengaluru | Prof.A.K.Das SBV, Puducherry |
| 12:45 – 1:00 PM | **Discussion & wrap of session 2** | | |
| 1:00 – 2:00 PM | **Lunch break** | | |

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|---|---|---|---|
| 2:00 – 2:45 PM | Inaugural function - Main Hall | | |
| 2:45 – 3:45 PM | Panel discussion1: Revisiting DM Curriculum – way forward | **Panelists**<br><br>1.Dr. Bhaskar Krishnamurthy KEM Mumbai<br><br>2.Dr. Balakrishnan AIIMS Bhopal<br><br>3.Dr. Sandhiya Selvarajan JIPMER, Puducherry | 1. Dr.Shoibal Mukherjee Medanta Hospitals New Delhi<br><br>2. Dr. Debasish Hota AIIMS Bhubaneswar<br><br>3. Dr. Melvin George. SRM MCH & RC Chennai |
| 3:45 – 4:00 PM | **Coffee break** | | |
| **Symposium 2** on Pharmacoeconomics | | | |
| 4:00– 5:00PM | Basics of Pharmacoeconomics | Dr. Bhaskar Krishnamurthy, KEM Mumbai | 1. Prof. Lalit Mohan IGIMS, Patna<br>2. Dr.Mehdi Ali Mirza ESIC Medical College and Hospital, Hyderabad |
| | How to write Pharmacoeconomics study protocol? | Dr Amol Patil, PGIMER, Chandigarh | |
| 5:00 – 5:15 PM | **Plenary Lecture – 5**<br><br>ADR signal Tools in Phase 4 studies | Dr Akila S MGMCRI, Pondicherry | Dr. Pajanivel Ranganadin MGMCRI, Puducherry |
| 5:15 – 6:30 PM | **GB Meeting - B C Roy Hall** | | |
| 6:30 – 7:10 PM | **Cultural program** | | |
| 7:10 – 8:00 PM | **Dinner** | | |

**Day 2 – September 13, 2025**

| **Time** | **Topic** | **Speakers** | **Chair Person** |
|---|---|---|---|
| 09.00 – 10.15 AM | **Symposium 3 –** Pharmacogenomics - Balancing Innovation and Access: Can Personalized Medicine Be Scaled in Public Health? | | 1.Dr. A Stanley AIIMS, Madurai<br><br>2. Dr. Amol Patil PGIMER, Chandigarh |
| | Optimizing therapeutic outcomes in oncology using pharmacogenomics | Dr.Chakradhar Rao, JIPMER, Puducherry | |
| | Realizing pharmacogenetics in low- and middle-income countries | **Dr. Nivedita Gowda** KMC, Manipal | |
| **Discussion & wrap up of session 3** | | | |
| 10:15- 10:55 AM | **Prof.R.R.Chaudhry Oration** | Dr. A. Sankaranarayanan<br><br>Vivo Bio Tech Ltd Hyderabad | 1. Dr.C Adithan Ex. Director Professor JIPMER, Puducherry<br>2. Prof. Santanu Tripathi Jagannath Gupta Institute of |

| | | | |
|---|---|---|---|
| | | | Medical Sciences & Hospital Kolkata |
| 10:55-11:00 AM | Indian Discovery –Injection for Kala – Azar by Dr.U.N.Brahmachary | Dr. Shambo Samrat, Kolkata | Dr. N. R Biswas SBV, Puducherry |
| 11:00 – 11:20 AM | **Coffee break** | | |
| 11.20 – 12.20 PM | **Symposium 4**– TDM – the need for expansion in Indian hospitals | | **1.** Dr. Reeta K H AIIMS, NewDelhi<br>**2.** Dr. Suganthi JIPMER, Puducherry<br>**3.** Dr. Smita Pattanaik PGIMER, Chandigarh |
| | 1. TDM in Immunology & Oncology | Dr Kumaravel J SRM Chennai | |
| | 2. Establishing TDM Unit | Dr Binu Ssusan Mathew CMC Vellore | |
| | 3. Challenges & opportunities in TDM | Dr Roopali Somani NIMS, Hyderabad | |
| 12:30 – 1:00 PM | Plenary lecture 6- Drug Resistant Tuberculosis and challenges ahead | Prof.S.P. Dhaneria RD Gardi Medical College, Ujjain | 1. Prof.K.S.Reddy, SBMS, Puducherry<br>2. Prof. Balanehru Subramaniyan, SBMS, Puducherry |
| 1:00 – 2:00 PM | **Lunch break** | | |
| | **Symposium 5** – Recent advances in clinical pharmacology | | 1. Dr. Melvin George SRM, Chennai<br>2. Dr. Ashok Dubey AIIMS Bilaspur, HP. |
| 2:00 – 2:20 PM | Dosage individualization using machine learning approach | Dr. Anand Srinivas, AIIMS Bhubaneshwar | |
| 2:20 – 2:40 PM | Role of AI in patient communication | Dr. Prafull Mohan, AFMC Pune | |
| 2:40 – 3:00 PM | Applying Real World data in drug discovery | Dr. Santosh Taur Pfizer Mumbai | |
| 3:00 – 3:30 PM | Optimizing Antimicrobial Therapy. Te Critical Role of C.P in Antimicrobial Stewardship | Dr Rachana AIIMS Bathinda | |
| 3:30 – 5:00 PM | Oral Prize sessions | | 1. Prof. Manimekalai MGMC, Puducherry<br>2. Dr. Pramod Manjhi AIIMS, Patna |
| 5:00 – 5:30 PM | Valedictory function and prize distribution | | |

**Track 2 – MGMCRI Pondicherry – Agasthya Hall**

**Day 1 – September 12, 2025**

| Time | Topic | Speakers | Chair Person |
|---|---|---|---|
| 10:00 – 1:00 PM | Prelims - Oral presentations /Poster presentations | **M.U.R. Naidu Award** (Oral)<br><br>**J.C.Shobha Award** (Poster) | **Judge**<br>1. Dr. Sandhiya Selvaraj JIPMER, Puducherry<br>2. Dr. Chayna Sarkar NEIGRIHMS, Shillong |
| 1:00 – 2:00 PM | Lunch | | |

**Day 2 – September 13, 2025**

| Time | Topic | Speakers | Chair Person |
|---|---|---|---|
| 10:00 – 1:00 PM | Quiz – finals | | |
| 1:00 – 2:00 PM | Lunch | | |
| 2:00 – 3:30PM | Prof. Santanu Kumar Tripathi Award" for Best Clinical Pharmacology Case Presentation | Moderator<br>Dr. Johan Pandian, SBV, Puducherry | 1. Prof A.R. Srinivasan, SBV, Puducherry<br>2. Prof. Avtar Canada<br>3. Dr. Debasis Bisoi AIIMS Hyderabad |
| 3:30 – 5:00 PM | Oral Prize sessions – Main hall | | |
| 5:00 – 5:30 PM | Valedictory function and prize distribution – Main hall | | |

**Message from the desk of the Chancellor**

It is heartening to note that the 4th National conference of the Association of clinical Pharmacologists is being held at MGMCRI, SBV on the 12th and 13th of September 2025, in commemoration of the silver Jubilee celebration of MGMCRI.

I heartily congratulate the organizing committee for having chosen the conference theme "Repositioning clinical Pharmacology in India", especially at a time when the scope of clinical pharmacology has vastly grown in the realms of public health, from bench to bedside, to marketing and quality of life thereafter.

*I wish the conference Great Success.*

***M. K. Rajagopalan***
***Chancellor, Sri Balaji Vidyapeeth***

**From the Desk of the Organising Chairman, ACPCON 2025**

Respected dignitaries, esteemed colleagues, distinguished guests, and dear participants,

It is with immense pride and heartfelt pleasure that I welcome you all to the Association of Clinical Pharmacologists Conference – ACPCON 2025. This annual gathering is more than just a meeting of professionals — it is a confluence of ideas, expertise, and aspirations, united by our shared mission to advance the field of clinical pharmacology for the betterment of healthcare in our country and beyond.

The theme for this year, "Repositioning Clinical Pharmacology in India", could not be more timely or more relevant. As healthcare systems evolve and the challenges of drug development, rational therapeutics, and personalised medicine grow ever more complex, there is a pressing need to redefine the role of our discipline. This conference is our opportunity to reaffirm the place of clinical pharmacology as a cornerstone of evidence-based medicine, patient safety, and innovative therapeutic strategies in India.

Over the next few days, we will engage in thought provoking keynote addresses, cutting-edge research presentations, and enriching panel discussions. These sessions are designed not only to expand our knowledge but also to inspire actionable change in our institutions, our policies, and our practice.

On behalf of the Organising Committee, I extend my deepest gratitude to our Scientific Team, our partners and sponsors, govt organisation, and the dedicated volunteers whose hard work and commitment have brought this vision to life.

I also thank each of you for making the time to be here, your participation and insights are what give ACPCON its true value.

I am thankful to our Honourable Chancellor and the entire management of Sri Balaji Vidyapeeth for allowing us to host this conference at our beautiful Pondicherry campus.

Once again, I warmly welcome you to ACPCON - 2025. May this conference be intellectually stimulating, professionally rewarding, and personally memorable for all of us.

Thank you.

**Prof.Nihar Ranjan Biswas**
**Organizing Chairperson – ACPCon – 2025 &**
**Vice Chancellor, Sri Balaji Vidyapeeth**

## Foreword

It is with immense pride that I present to you the souvenir of the **Fourth Annual Conference of the Association of Clinical Pharmacologists of India (ACPI)**.

The theme of this year's conference is **"Repositioning Clinical Pharmacology in India,"**. Clinical pharmacology plays a pivotal role in enhancing patient care, optimizing drug therapy, and ensuring the safe and effective use of medicines based on well designed, robust clinical trials. In an era where precision medicine, personalized therapy, and advancements in pharmacogenomics are reshaping healthcare, the need for clinical pharmacologists has never been more critical. This conference serves as an ideal platform to foster dialogue among clinical pharmacologists working as clinicians, researchers, policymakers, and students, providing an opportunity to discuss contemporary issues, share best practices, and explore the future of the discipline.

Our esteemed speakers, experts from various disciplines, and vibrant participants have contributed to the success of this event, making it a focal point for innovation and knowledge exchange. I also extend my deepest gratitude to the organizing committee from MGMCRI Puducherry, JIPMER Puducherry and SRM MCH &RC Chennai, funding agencies such as SERB and DHR, and other sponsor partners whose support and dedication have been invaluable in making this conference a reality.

Let us continue to work together in the pursuit of excellence in clinical pharmacology for the betterment of patient care across India. I welcome all delegates and participants to this exciting and inspiring conference and look forward to the fruitful discussions and connections that will emerge from this gathering.

**Warm regards,**
**Melvin George**
**Organizing Secretary**
**Association of Clinical Pharmacologists of India**

## Message from the Treasurer

I am privileged to be part of the ACPCon 2025, the 4th National Conference of the Association of Clinical Pharmacologists, organized jointly by MGMCRI, JIPMER, Puducherry, and SRM MCH & RC, Chennai. With the theme **"Repositioning Clinical Pharmacology in India"**, this conference highlights the vital role of Clinical Pharmacology in research, patient care, and healthcare.

I am equally delighted to host the academic endeavour, **Preconference Workshop on "Investigator-Initiated Clinical Trial & Good Clinical Practice"**, which will be held at JIPMER, an Institute of National Importance. This workshop will equip participants with the knowledge and skills to conduct ethical, high-quality clinical trials, while providing a valuable platform to learn from experts, gain practical insights, and build capacity for impactful research that will shape the future of healthcare.

Organizing such events requires meticulous financial planning, resource management, and committed teamwork. I sincerely thank the administration of MGMCRI, JIPMER, SRM MCH & RC, and the Association of Clinical Pharmacologists for their constant encouragement and support. I am deeply grateful to the Director, JIPMER and the Dean (Research), JIPMER, for allowing me to host this preconference workshop and promote the theme of clinical trials. I also extend heartfelt appreciation to all our organizing and executive committee members for their unconditional support and dedication in planning and executing these national workshops and conference. I am confident that the preconference workshops and the leading conference will offer an enriching academic experience, foster collaborations, and inspire meaningful advances in Clinical Pharmacology.

A special note of appreciation goes to all speakers and sponsors whose generous support has made this workshop and conference possible. Their commitment has laid the foundation for a meaningful gathering at the intersection of ethics, clinical research, and investigator-led innovation.

Finally, I welcome all delegates and wish you an enlightening experience and a fruitful participation in this event. I hope you will enjoy the academic feast and the warm hospitality of the organizers and create lasting memories in Puducherry, a city filled with rich heritage, warmth, and passionate culture.

**With best wishes**
**Dr. S. Sandhiya, MD, DNB, DM (Clin. Pharmacol.), MNAMS,**
**Treasurer ACP, Additional Professor and Head,**
**Department of Clinical Pharmacology, JIPMER, Puducherry**

## Foreword

It gives me immense pleasure to extend a warm welcome to all delegates, faculty members, researchers, and students to the **4th National Conference of the Association of Clinical Pharmacologists – ACPCon 2025**, hosted by Sri Balaji Vidyapeeth, Pondicherry. This landmark event, with the theme *"Repositioning Clinical Pharmacology in India"*, is both a celebration of our discipline's past achievements and a forward-looking step toward its expanding role in healthcare, research, and policy.

From being a largely academic specialty, Clinical pharmacology in India is now rapidly evolving into an indispensable component of patient care, therapeutic innovation, and regulatory science. The deliberations at ACPCon 2025 have been designed to reflect this transformation—highlighting the importance of therapeutic drug monitoring, pharmacogenomics, biomarkers, artificial intelligence, polypharmacy management, and patient-centric approaches.

Our pre-conference workshops, conducted across reputed institutions—JIPMER Pondicherry, SRM Medical College Chennai, and the Institute of Salutogenesis and Complementary Medicine at SBV—promise to enhance hands-on skills and offer practical insights into clinical research methodologies, medical device regulation, and integrative approaches to wellness. I am particularly delighted that the conference offers abundant opportunities for young pharmacologists and students to showcase their work through oral and poster sessions, case discussions, and quiz competitions.

Equally important, Pondicherry—the venue of our gathering—offers a serene backdrop where history, culture, and modernity converge. The coastal charm and spiritual ambience of this city will surely make your participation not only professionally rewarding but also personally memorable. On behalf of the organizing committee, I sincerely thank our patrons, advisors, and all colleagues whose tireless efforts have made ACPCon 2025 possible. I am confident that the discussions and collaborations that emerge from this conference will strengthen our collective vision to reposition clinical pharmacology as a vital force in India's healthcare system.

I warmly welcome you to ACPCon 2025 and wish you a stimulating and enriching experience.

**Dr. Johan Pandian J**
**Professor of Pharmacology, MGMCRI**
**Joint Organizing Secretary, ACPCon 2025**

## "Professor Ranjit Roy chaudhary and his contribution to Clinical Pharmacology in India"

Clinical Pharmacology in India has come a long way since its humble beginnings in the 60s. Among those who have played active role in its development, Dr. Ranjit Roychaudhary distinguishes himself in several ways. He was a graduate of the Prince of Wales Medical College in Patna, and as a Rhodes Scholar, went to Oxford for his D. Phil. Degree in Pharmacology. Soon afterwards, he became the youngest professor of Pharmacology at the PGI, Chandigarh. Recognizing that promotion of quality clinical research is the only way to make new medicines and therapies available promptly, he went on to establish the first-ever,
D.M. Clinical Pharmacology course in India at the PGI in 1978. As the Chairman of the Pharmacology and Toxicology Panel of the ICMR, he was involved in clinical evaluation of Indian Traditional Medicinal plants. His passion for traditional medicine resulted in his publication of the WHO monograph, "Herbal medicine for human health" (SEARO, No 20, 1991) discussing issues and challenges in exploiting the therapeutic potential on medicinal plants and herbs. In fact, in the 80s, he went on to carry out several assignments with the WHO in Geneva, Burma & Thailand. He had played significant role in drug regulation by chairing a National Committee in 2014 for the, "Policy and Guidelines for the Approval of New Drugs, Clinical Trials and Banning of Drugs in India". He was also instrumental in the formation of Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) that provided training and consultation to state governments. He has been honoured with many awards such as Shanti Swarup Bhatnagar Award, Dr. B.C. Roy award and the prestigious Padma Shri award in 1998. Dr Roy Chaudhary had been a visionary in medical education, drug regulation and clinical pharmacology research.

**Dr. A. Sankaranarayanan President,**
**Vivo Bio Tech Ltd, Hyderabad.**

## Looking Beyond Traditional Designs in Clinical Research

Clinical research has traditionally relied on rigid, one-size-fits-all randomized controlled trials (RCTs). While these have been foundational to drug development, they are often time-consuming, expensive, and poorly representative of real-world populations. In today's data-driven and patient-centered landscape, there is an urgent need to move beyond these static designs.

Innovative methodologies such as adaptive trials allow mid-course changes based on interim data, improving efficiency and ethics. Platform and basket trials offer flexible frameworks to test multiple therapies or diseases simultaneously, saving time and resources. Real-world data—from electronic health records to patient registries—is now informing trial design and regulatory decisions. Meanwhile, decentralized trials and digital biomarkers enhance patient participation and data richness, particularly post-COVID-19

Artificial intelligence is also transforming trial logistics, from recruitment to retention. However, innovation comes with challenges: regulatory alignment, data quality, and workforce training.

The future lies in hybrid trial designs that combine the scientific rigor of RCTs with the relevance of real-world evidence. By embracing technological and methodological advancements, we can design trials that are faster, smarter, more inclusive—and ultimately, more meaningful for patients.

**Prof. Nilanjan Saha MD, DM**
**Head, Dept of Translational & Clinical Research, Jamia Hamdard, New Delhi.**

**A Fairy Tale of Two Game Changers: Semaglutide & Tirzepatide**

**Introduction:**
Glucagon-like peptide-1 receptor agonists (GLP1-RA) and dual glucose-dependent insulinotropic polypeptide/GLP1 receptor agonists have transformed obesity and type 2 diabetes management. Semaglutide (pure GLP1-RA) and tirzepatide (dual GIP/GLP1) deliver substantial weight loss, glycemic control, and multi-organ benefits. Let us compare their efficacy and outcomes across metabolic, cardiovascular, renal, hepatic, and other functional endpoints.

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**Weight Loss – SURMOUNT-5:**
Head-to-head in obesity without diabetes, tirzepatide 15 mg weekly achieved –20.2% mean weight loss vs –13.7% with semaglutide 2.4 mg (–22.8 kg vs –15.0 kg; $p<0.001$). Greater proportions on tirzepatide achieved ≥10%, ≥15%, and ≥20% weight loss. Waist circumference change: –18.4 cm vs –13.0 cm. GI discontinuations: tirzepatide 2.7% vs semaglutide 5.6%.

**Glycemic Control – STEP 2 vs SURMOUNT-2:**
In obesity with type 2 diabetes, semaglutide 2.4 mg (STEP 2) reduced HbA1c by ~1.6–1.9%, while tirzepatide 10–15 mg (SURMOUNT-2) achieved an additional ~0.5% greater reduction. Normoglycemia (<5.7% HbA1c) achieved in 46–49% on tirzepatide, higher than semaglutide arms in STEP 2.

**Body Composition – STEP 1 vs SURMOUNT-1:**
DXA sub-study data show semaglutide-induced weight loss comprised ~60% fat mass and ~40% lean mass, while tirzepatide yielded ~75% fat mass and ~25% lean mass loss (fat: lean ratio ~3:1), indicating relatively greater lean mass preservation.

**Weight Regain on Withdrawal – STEP 4 vs SURMOUNT-4:**
STEP 4: after 20-week semaglutide run-in, withdrawal led to +6.9% regain vs –7.9% further loss on continued therapy.
SURMOUNT-4: after 36-week tirzepatide run-in, withdrawal led to +14% regain vs –5.5% further loss with continued therapy. Both drugs require ongoing therapy for maintenance.

**Cardiovascular Outcomes – SELECT, SUSTAIN-6 vs SURPASS-CVOT:**
SUSTAIN-6 (T2DM): semaglutide reduced MACE by 26% (HR 0.74).
SELECT (obesity, no diabetes): semaglutide 2.4 mg reduced MACE by 20% (HR 0.80, 6.5% vs 8.0%; $p<0.001$).
SURPASS-CVOT: tirzepatide noninferior to dulaglutide (HR 0.92; 95% CI 0.83–1.01), consistent with cardio-protection but without proven superiority.

**Peripheral Artery Disease – STRIDE:**
Semaglutide 1 mg in T2DM with symptomatic PAD increased maximum treadmill walking distance by 13% over placebo at 52 weeks; also improved pain-free walking distance and PAD-specific quality of life.

**Renal Outcomes – FLOW:**
In T2DM with CKD, semaglutide reduced composite kidney outcome by 24% (HR 0.76), cardiovascular death by 29% (HR 0.71), and all-cause mortality by 20% over 3.4 years.

**MASH – ESSENCE vs SYNERGY-NASH:**
**Semaglutide (ESSENCE):** Phase-3 evidence that **~63%** achieve MASH resolution and **~37%** achieve ≥1-stage fibrosis improvement at **72 weeks**, with **~10.5%** mean weight loss. Best current evidence base for fibrosis improvement among incretins.

**Tirzepatide (SYNERGY-NASH):** Phase-2b data show **dose-dependent** MASH resolution up to **~62% at 52 weeks** and meaningful fibrosis improvement; phase-3 confirmation is the key next step.

**Heart Failure with Preserved EF – STEP-HFpEF vs SUMMIT:**
STEP-HFpEF: semaglutide 2.4 mg improved KCCQ-CSS by +16.6 vs +8.7 placebo, 6MWD +21.5 m vs +1.2 m, NT-proBNP –21% vs –5%; numerically fewer HF admissions (1 vs 12).
SUMMIT (tirzepatide): reduced composite of CV death or worsening HF by 38% (HR 0.62), driven by fewer HF hospitalizations; functional gains similar to STEP-HFpEF.

**Obstructive Sleep Apnea – SURMOUNT-OSA:**
Tirzepatide reduced apnea–hypopnea index by –20 events/hour (–48–56% relative), hypoxic burden by ~60–70%, and weight by ~16–17% over 52 weeks; benefits seen with and without CPAP. No dedicated semaglutide OSA trial to date.

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**Conclusion:**
Tirzepatide achieves greater weight loss, glycemic lowering, lean mass preservation, less drug discontinuation due to GI disturbances with unique evidence in OSA and event reduction in HFpEF. Semaglutide has definitive cardiovascular (SELECT/SUSTAIN 6), renal (FLOW), and PAD (STRIDE) outcome benefits, with lesser weight regain upon discontinuation and more robust phase 3 data for MASH . Therapy choice should be guided by comorbidity profile: semaglutide favored for established CVD, CKD, PAD, MASH; tirzepatide for maximal weight loss, OSA, and HFpEF hospitalization reduction.

**Dr Gaurab Bhaduri**
**Endocrinologist**

**Apollo Clinic, Barrackpore,**

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**Promoting Patient Safety and Access: WHO India's Support for Strengthening Regulatory Systems and Medical Product Safety in India**

India, as a global leader in pharmaceutical production, plays a pivotal role in ensuring access to affordable, quality-assured medical products. Recognizing the importance of robust regulatory systems, World Health Organization (WHO) has partnered with the Government of India to enhance the safety, efficacy, and accessibility of medical products across the country and beyond. Through strategic initiatives such as the re-benchmarking of India's National Regulatory Authority (NRA) using the WHO Global Benchmarking Tool, India has achieved Maturity Level 3, affirming its compliance with international standards. Strengthening regulatory systems is a core and ongoing WHO priority to ensure the availability of safe, effective, quality medical products and to support equitable access globally

WHO India plays a pivotal role in strengthening health product regulation by robust pharmacovigilance systems to ensure the safe use of medicines, vaccines, and medical devices and IVDs. Through strategic support, WHO India provides expert advisory support to national committees, enhances safety monitoring, and builds regulatory capacity via risk-based GMP workshops, pharmacovigilance inspections, and the Regulators Conclave. It also promotes health technology assessment and fosters an enabling ecosystem for emerging technologies, ultimately contributing to improved patient safety and access.

To advance patient safety across the healthcare continuum, WHO India plays a critical role in advancing patient safety by partnering with the Government of India to implement strategic frameworks and initiatives aimed at reducing harm in healthcare. Through the National Patient Safety Action Plan, which outlines strategic actions to strengthen safety practices. These efforts engage national and sub-national healthcare institutions and stakeholders to promote patient safety principles and embed a culture of safety across the health sectors.

Furthering its support for local innovation, WHO India, in collaboration with the Government of India, has led a Local Production Initiative to strengthen the capacity of micro, small, and medium-scale pharmaceutical enterprises with the aim to enhance local production of quality, safe, and affordable medical products. Highlighted in the DG WHO's End of Biennium Results 2023 Report, India's impact story showcases how these initiatives contribute to global health goals by supporting regulatory approvals and WHO prequalification. This partnership also focuses on building a sustainable ecosystem for health technologies, reinforcing India's role in meeting global healthcare demands.

Together, these initiatives underscore WHO India's commitment to advancing regulatory governance, fostering innovation, and ensuring equitable access to safe and effective medical products. This collaborative model not only strengthens India’s health system but also contributes to global health security and the achievement of the Sustainable Development Goals (SDGs).

**Dr Madhur Gupta,**
**Technical Officer- Pharmaceuticals,**
**WHO India Country Office, New Delhi**

**Implementation research and its growing importance in Clinical Pharmacology**

Implementation Research (IR) is emerging as a vital discipline in clinical pharmacology, addressing the gap between research evidence and its application in real-world healthcare. Unlike conventional studies that focus only on efficacy and safety, IR employs context-sensitive methodologies- such as hybrid effectiveness-implementation studies, pragmatic trials, and participatory designs- to assess the adoption, scalability, and sustainability of interventions. It plays a key role in areas such as rational use of medicines, pharmacovigilance, patient adherence, antimicrobial stewardship, equitable access to essential drugs, and integration of digital health technologies. Frameworks like the Consolidated Framework for Implementation Research (CFIR) and RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) enable systematic evaluation of barriers, facilitators, and long-term outcomes. Despite challenges such as limited expertise, resource constraints, and methodological complexity, IR is gaining importance for guiding health systems and policies. Strengthening capacity, fostering interdisciplinary collaboration, and embedding IR into clinical practice will be essential to ensure pharmacological innovations translate into sustainable improvements in patient care and public health.

Keywords: Drug Utilization, Health Policy, Health System Strengthening, Implementation Science, Pharmacovigilance

Authors:

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**Clinical Pharmacology & Therapeutics OPD: A Pioneering Model for Rational Drug Use and Safer Prescribing in a Tertiary Teaching Hospital**

**Background:**

Polypharmacy, adverse drug reactions, and therapeutic complexity in multimorbid patients pose major clinical challenges. To address these issues, a Clinical Pharmacology & Therapeutics Outpatient Department (OPD) was conceived in 2020 at R.G. Kar Medical College, Kolkata, through collaboration with multiple specialties, and formally established in 2023 as an independent OPD with a dedicated prescription format and integration into the Swasthya Bhawan e-prescription portal.

**Scope and Services:**

The OPD focuses on optimizing drug therapy through comprehensive medication reconciliation, rationalization of drug regimens, prevention of prescribing cascades, individualized dose adjustment (especially in renal or hepatic impairment), and structured patient counseling to improve drug literacy and adherence. It also emphasizes reduction of cumulative anticholinergic burden in vulnerable patients. Referrals are prioritized for those on ≥5 medications, under the care of ≥3 specialists, experiencing adverse drug reactions, or struggling with medication confusion.

**Collaborations and Impact:**

Since 2023, referrals from Medicine, Neuromedicine, Psychiatry, Cardiology, Nephrology, Endocrinology, PMR, and other specialties have steadily grown. The service has improved therapeutic understanding, enabled early detection and prevention of drug-related problems, strengthened interdepartmental coordination, and enhanced patient adherence and satisfaction.

**Academic Relevance:**

The OPD serves as a unique platform for postgraduate and super-specialty training, supporting thesis work and providing real-world pharmacotherapy exposure.

**Conclusion:**

This pioneering OPD demonstrates how Clinical Pharmacology can directly strengthen patient safety and quality of care by integrating evidence-based prescribing with multidisciplinary collaboration.

**Dr. Sabnam Ara Begum**
**Associate Professor, Clinical Pharmacology Unit**
**Department of Pharmacology, R.G. Kar Medical College, Kolkata**

**Clinical Pharmacologist – Optimizing Clinical Therapeutics**

In an era of rapid medical advancements and increasingly complex patient needs, the role of the clinical pharmacologist has emerged as a critical interface between biomedical science and safe, effective therapeutic care. As medication regimens become more intricate—particularly among the elderly and patients with multi morbidity—the clinical pharmacologist is uniquely positioned to reconcile, review, and optimize pharmacotherapy in a manner that prioritizes efficacy, safety, and cost-effectiveness.

The concept of **Clinical Pharmacological Reconciliation, Review, and Feedback (CPRRF)** has transformed the clinical pharmacologist's role from a background advisor to a front-line clinical decision-maker. This structured methodology involves ten foundational pillars: medication necessity assessment, de-prescribing, transitional care coordination, personalized dosing, adverse drug reaction (ADR) management, medication adherence enhancement, affordability and access considerations, individualized treatment planning, polypharmacy rationalization, and overall quality-of-life improvement. These interventions are not only evidence-based but deeply patient-centric, aiming to bridge the gaps in care transitions and reduce the hazards of prescribing cascades and ADRs, especially in geriatric populations.

A compelling illustration of this role is the application of de-prescribing protocols in elderly patients—where clinical pharmacologists assess the cumulative burden of medications, including anticholinergic load and sedative toxicity. By leveraging validated tools such as the Beers and STOPP/START criteria and conducting comprehensive medication reviews (CMRs), clinical pharmacologists effectively identify and withdraw potentially inappropriate medications (PIMs), mitigating ADRs and enhancing therapeutic alignment with the patient's functional status and life goals.

Through CPRRF, clinical pharmacologists also serve as therapeutic stewards in high-risk domains such as diabetes, hypertension, asthma, toxicology, and addiction medicine. By integrating pharmacokinetic and pharmacodynamic principles with patient history and biomarkers, they guide appropriate dose adjustments, ensure optimal therapeutic drug monitoring (TDM), and anticipate inter-drug interactions. This is particularly vital in vulnerable populations such as those with renal or hepatic impairment, frail older adults, or patients on polypharmacy.

Furthermore, clinical pharmacologists play a crucial role in fostering **shared decision-making**—engaging patients and caregivers in understanding the purpose, benefit-risk tradeoffs, and financial implications of their medication regimens. The principle of "No Name, No Shame, No Blame" underpins their approach to de-prescribing: promoting a non-punitive, collaborative environment where therapeutic inertia can be safely challenged for better outcomes.

Recent real-world evidence and case series highlight the success of pharmacologist-led interventions. For instance, medication review and de-prescribing in an octogenarian with iatrogenic QT prolongation from overlapping prescriptions led to significant clinical stabilization and improved

adherence. Similarly, prompt recognition of a prescribing cascade in a diabetic patient post-stroke—with drug-induced seizures and fever—demonstrated how early pharmacological input could prevent morbidity and avoid unnecessary escalation of care.

Despite these successes, challenges remain—especially in resource-constrained health systems like India's, where out-of-pocket healthcare costs dominate, and ADR reporting remains suboptimal. In such contexts, the clinical pharmacologist must act not only as a therapeutic guide but also as an advocate for rational, equitable healthcare delivery. By championing cost-effective prescribing, encouraging generic substitution, and tailoring treatment strategies to socioeconomic realities, they help dismantle barriers to care.

The integration of technology—clinical decision support systems (CDSS), electronic health records (EHR)-embedded reconciliation tools, and mobile adherence trackers—further extends the reach and precision of clinical pharmacologists. These digital adjuncts empower real-time pharmacovigilance and patient education, ensuring continuity of care even beyond hospital settings.

In conclusion, the clinical pharmacologist is no longer confined to the laboratory or advisory desk. Instead, they are becoming an indispensable clinician at the bedside—navigating therapeutic complexities, reducing harm, and personalizing interventions. As health systems worldwide evolve toward value-based care, the clinical pharmacologist stands as a torchbearer for scientific precision, ethical prescribing, and patient-centred therapeutics.

**Dr. Shambo Samrat Samajdar**
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**Baguihati, Kolkata**

**Indian Discovery – Injection for Kala-Azar by Dr. U.N. Brahmachari**

Dr. Upendranath Brahmachari stands as a towering figure in the annals of Indian medical history for his groundbreaking contribution to tropical medicine—most notably, the discovery of urea stibamine, a life-saving treatment for kala-azar (visceral leishmaniasis). At a time when colonial India was grappling with widespread infectious diseases and limited healthcare infrastructure, Brahmachari's innovation emerged as a beacon of hope, born from indigenous research, deep scientific insight, and a relentless commitment to public welfare.

Kala-azar, caused by the protozoan parasite *Leishmania donovani*, had devastated rural communities across India in the early 20th century, especially in Bihar and Bengal. The disease was associated with high mortality rates ranging from 60% to 95% and manifested in prolonged fever, weight loss, splenomegaly, and anemia. At that time, treatment relied heavily on highly toxic and costly antimony-based compounds that were neither effective nor safe for the majority of patients.

Working under considerable constraints—minimal funding, inadequate lab facilities, and systemic neglect of tropical diseases—Dr. Brahmachari synthesized urea stibamine in 1920. This compound, created by integrating urea with para-aminophenyl stibnic acid, transformed kala-azar therapy by being less toxic, easier to administer, and highly effective. The therapeutic outcomes were revolutionary: within a few years, the mortality rate of the disease plummeted to 10%, and recovery rates soared to over 95%. Its impact was so widespread that by 1933, more than 328,000 patients in Assam alone had been successfully treated using this indigenous medicine.

Beyond its clinical efficacy, urea stibamine's affordability and ease of distribution enabled it to reach remote and impoverished populations. This democratization of treatment stood in contrast to Western pharmaceutical approaches of the time, which were often inaccessible in colonized regions. Notably, the drug's success was not limited to India; it played a significant role in managing leishmaniasis in countries such as China and Greece, exemplifying the global applicability of Brahmachari’s innovation.

While following up with patients treated for kala-azar, Dr. Brahmachari identified a new clinical entity—Post-Kala-Azar Dermal Leishmaniasis (PKDL), now often referred to as *Brahmachari’s Dermal Leishmaniasis*. First described in 1922, this condition involved nodular skin lesions that appeared after apparent recovery from visceral leishmaniasis. His research emphasized the importance of long-term monitoring and exposed the persistent nature of the parasite in the skin. This insight was critical for refining post-treatment care and advancing our understanding of leishmaniasis pathophysiology.

Dr. Brahmachari's contributions, however, extended well beyond his laboratory. As a passionate educator and institution-builder, he played a vital role in reforming India’s medical curriculum to

include tropical diseases and integrate scientific research into clinical education. He served as president of several prestigious Indian scientific bodies and mentored a generation of researchers and physicians. His advocacy helped establish a culture of medical inquiry that was rooted in the Indian context but resonated with global relevance.

Despite being nominated for the Nobel Prize in Physiology or Medicine in 1929, Brahmachari did not receive the award—likely due to geopolitical bias and limited international visibility of colonial scientists. Still, his contributions were acknowledged through honors like the Kaiser-i-Hind Medal, the Minto Medal, and a British knighthood in 1934.

Dr. Brahmachari's legacy serves as a testament to the power of innovation in resource-limited settings, the importance of public health-oriented research, and the unrecognized brilliance of colonized scientists. His work not only alleviated human suffering on a massive scale but also laid the foundation for tropical medicine as a critical discipline in India. The story of urea stibamine is not just one of scientific discovery—it is a powerful narrative of dedication, indigenous ingenuity, and a deep commitment to equitable healthcare.

**Dr. Shambo Samrat Samajdar**
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# Role of clinical pharmacologists in hospital management

The evolving landscape of modern healthcare demands a multidisciplinary approach to hospital management, where precision, safety, and rationality in pharmacotherapy take center stage. Among the key stakeholders, **clinical pharmacologists** are emerging as crucial players, uniquely positioned at the intersection of medicine, pharmacology, and patient safety. Their role is no longer confined to academic settings or drug development but has expanded significantly to include active participation in hospital-based clinical and administrative functions.

One of the most critical areas where clinical pharmacologists contribute is **medication reconciliation**. By systematically reviewing and verifying patients' medication histories during admission, intra-hospital transfer, and discharge, they help prevent inadvertent omissions, duplications, or harmful drug interactions—significantly reducing medication-related errors and readmission rates.

**Adverse drug reactions (ADRs)** remain a leading cause of iatrogenic morbidity. Clinical pharmacologists lead hospital pharmacovigilance initiatives by designing ADR monitoring protocols, analyzing trends, training clinical staff, and ensuring timely reporting to regulatory bodies. Their expertise enhances the early detection and mitigation of drug-induced harm, promoting a safer therapeutic environment.

In emergency and critical care settings, **clinical toxicology** becomes indispensable. Clinical pharmacologists assist in the diagnosis and management of poisoning and overdose cases, recommending evidence-based interventions, antidotes, and supportive strategies. Their ability to interpret toxicokinetics and assess cumulative exposures in complex cases adds life-saving value to critical care teams.

Another cornerstone of their contribution is **therapeutic drug monitoring (TDM)**. For drugs with narrow therapeutic indices—such as aminoglycosides, vancomycin, digoxin, phenytoin, and certain immunosuppressants—clinical pharmacologists optimize dosages based on serum drug levels, renal/hepatic function, and individual pharmacokinetic parameters. This patient-specific dosing ensures therapeutic efficacy while avoiding toxicity.

Beyond bedside applications, clinical pharmacologists are key contributors to **hospital policy and governance**. They provide scientific input in **Drug and Therapeutics Committees (DTCs)**, develop and update **hospital formularies**, and design **antimicrobial stewardship programs**—promoting rational antibiotic use and combating antimicrobial resistance.

Their role extends to **clinical research and ethics** as well. Clinical pharmacologists contribute to **trial design**, **protocol development**, and **regulatory compliance**, ensuring ethical conduct and scientific rigor in investigator-initiated and industry-sponsored studies.

Additionally, their involvement in **training and capacity building** enhances the knowledge and prescribing skills of junior doctors, nurses, and pharmacists—fostering a culture of rational medicine use across the institution.

In conclusion, clinical pharmacologists are indispensable to the structure and function of modern hospital systems. By integrating their expertise into patient care, quality assurance, policy-making, and clinical governance, they significantly elevate the standard of healthcare delivery. As healthcare systems grow increasingly complex, the inclusion of clinical pharmacologists in hospital management is not just beneficial—it is essential.

**Dr. Sumalya Sen**

**GIMSH, Durgapur,**

**West Bengal.**

## BASICS OF PHARMACOECONOMICS

Pharmacoeconomics is a branch of health economics that deals with the analysis of costs and consequences of therapeutic or other interventions. The basic tenet of pharmacoeconomics is to balance the competing priorities and the available economic resources. The costs can be calculated from various perspectives such as patient, healthcare provider, third-party insurance payer, or society. The costs can be classified as direct (medical and non-medical), indirect, and intangible. Opportunity costs represent the value of the alternative interventions foregone while selecting a particular intervention. The input in a pharmacoeconomic study is always cost. The output can be cost, clinical outcomes, or quality of life outcomes. Accordingly, pharmacoconomic studies can be classified as cost-benefit, cost-effectiveness, cost-utility, cost minimization, and cost of illness studies. The incremental cost-effectiveness ratio (ICER) in a cost-effectiveness study indicates the additional cost to be borne in order to achieve an additional desirable outcome. Sensitivity analysis and Markov modelling further refine the outputs obtained in a pharmacoeconomic study.

**Dr. Bhaskar Krishnamurthy**
**MD, DM Clinical Pharmacology,**
**Assistant Professor,**
**King Edward Memorial Hospital,**
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**The basics of Pharmacoeconomic analysis**

Markov models are widely employed in pharmacoeconomics to simulate the progression of diseases over time, incorporating health states, transition probabilities, and associated costs and outcomes. In this session, participants will learn the application of multi-matrix approaches in Microsoft Excel to efficiently handle complex Markov structures, such as multiple patient subgroups, varying cycle lengths, and scenario analyses. The workshop will demonstrate how to organize health state transition matrices, link them dynamically to cost and utility inputs, and apply Excel formulas for iterative calculations across multiple cycles. By the end of the exercise, learners will be able to construct and interpret a Markov model using Excel's formula-driven framework, enabling robust economic evaluation of healthcare interventions in real-world decision-making.

**Dr. Amol Patil,**
**Additional Professor Pharmacology,**
**PGIMER,**
**Chandigargh.**

**ADR Signal Tools in Phase 4 Studies**

**This conference talk will focus on:**

- World Health Organization's (WHO) definition of "Signal" in Pharmacovigilance
- Differences between the terms "Signal" and "Signal of Disproportionate Reporting" (SDR)
- Overview of Signal detection and management in Pharmacovigilance: Signal validation, signal prioritization and signal evaluation.
- Major Regulatory Databases for signal detection: Vigibase (World Health Organization), United States Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) and EudraVigilance Data Analysis System (EVDAS) maintained by European Medicines Agency (EMA).
- Qualitative and Quantitative methods of signal detection
- Disproportionality analysis- Frequentist methods like Reporting Odds Ratio (ROR) or Proportional Reporting Ratio (PRR) and Bayesian methods such as Bayesian Confidence Propagation Neural Network (BCPNN)
- Components of a Signal Assessment Report

**Keywords**: Pharmacovigilance, Signal Detection, Signal of Disproportionate Reporting, Disproportionality analysis

**Dr Akila Srinivasan, MD, DM (Clinical Pharmacology)**
**Associate professor,**
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**MGMCRI,**
**Pondicherry**

**Implementation of Pharmacogenomic Testing in oncology practice**

Past few decades, evidence has been generated for the utility of Pharmacogenomic (PGx)testing for pairs of many gene–one drug, or one gene-many drugs. However, practice is confined to a few domains such as oncology and cardiology that have shown a high impact. Pre-emptive PGx testing also demonstrated reductions in serious adverse events. Various studies across the globe have also demonstrated that each individual carries number of actionable PGx variants ranging from one to many depending upon their ethnicity. Though most of the drug labels do not require or recommend PGx testing, having this genetic information preemptively could be of help in their lifetime for guided dosing of drugs where there is clear demonstrated benefit in terms of treatment outcomes and costs. Evidence generation for other relevant medication in use, development and novel approaches, e.g. immunotherapy, remains a work in progress. Continued education, expanding the list of guidelines for PGx guided dosing and therapies, electronic health record system implementation systems with integration of PGx information is the key to successful implementation of PGx testing in clinics.

**Dr. Uppugunduri S Chakradhara Rao**
**Assistant Professor,**
**Department of Medical Oncology,**
**JIPMER, Puducherry**

**Realizing pharmacogenetics in low- and middle-income countries**

Pharmacogenetics, the study of genetic variations that influence individual responses to drugs, holds significant promise for advancing personalized medicine. However, its implementation in low- and middle-income countries (LMICs) faces considerable challenges, including clinical evidence gaps, technological limitations, regulatory hurdles, and a shortage of trained professionals. In particular, the scarcity of genome and drug response data specific to LMIC populations limits the development of effective pharmacogenetic applications.

To address these challenges, strategic approaches are required, including the enhancement of clinical evidence through collaborative research initiatives that generate region-specific pharmacogenetic data, the development of affordable and scalable genetic testing technologies to increase accessibility, the establishment of clear regulatory frameworks that ensure ethical and standardized implementation, and capacity building through education and training of healthcare professionals to interpret and apply pharmacogenetic information in clinical practice.

By adopting these strategies, LMICs can move closer to realizing the benefits of pharmacogenetics, enabling more personalized, effective, and safe healthcare delivery, while also contributing to global efforts in precision medicine.

**Dr. Niveditha K – Assistant Professor**
**Clinical Pharmacology Division, KMC, Manipal**

**Therapeutic Drug Monitoring/Management (TDM) - Immunology & Oncology**

Therapeutic drug monitoring (TDM) is a cornerstone of individualized medicine, using a data-driven approach to optimize drug exposure and clinical outcomes. This practice is especially critical in immunosuppressive therapy and oncology, where drugs have a narrow therapeutic window, inter patient variability, intrapatient variability and significant consequences from either sub-therapeutic or toxic drug levels.

In immunosuppression, TDM is vital for managing patients after solid organ transplantation. The main goal is to maintain drug concentrations within a tight range to prevent allograft rejection while avoiding systemic toxicities. Medications like tacrolimus, cyclosporine, mTOR inhibitors, mycophenolate mofetil show profound variability due to genetic factors, drug-drug interactions, and a patient's health status. By measuring trough drug concentrations, TDM allows clinicians to adjust doses, ensuring therapeutic efficacy and minimizing adverse events such as nephrotoxicity, neurotoxicity, and post-transplant diabetes mellitus.

Similarly, in oncology, TDM is a valuable tool for personalizing targeted therapies, including small-molecule inhibitors and monoclonal antibodies. These agents often have a steep exposure-response relationship, where a small change in concentration can drastically alter efficacy or toxicity. TDM for drugs like 5 fluorouracil, busulfan, methotrexate ensures patients achieve a minimum effective concentration to improve progression-free survival and response rates, while simultaneously preventing severe dose-limiting toxicities. The variability in drug metabolism, adherence, and tumor biology emphasizes the need for this tailored approach, helping to bridge the gap between standard dosing and the patient-specific exposure required for optimal outcomes.

In conclusion, TDM is an essential strategy for enhancing the safety and efficacy of high-risk medications in both immunosuppression and oncology. By shifting from a uniform dosing strategy to a personalized approach based on real-time drug level data, clinicians can significantly improve patient care, reduce the burden of adverse effects, and optimize the use of costly therapies. This proactive management is fundamental to the evolution of precision medicine.

**Keywords:** TDM, Oncology, Immunology, Dose Optimization, Precision Medicine

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**Establishing a TDM Unit**

This talk will focus on:

- Past and present experiences in initiating and advancing TDM services at CMC Vellore.
- Requirement in terms of manpower and their qualifications, clinical and administrative support, infrastructure, equipments, finance (for initiation and maintenance) of TDM Units , documentation and organizational management
- Patient care aspects in TDM
- Future of a TDM Unit.
- Requirements to maintain the quality of a TDM Unit, particularly the laboratory.

**Dr Binu Susan Mathew**
**Professor, Department of Pharmacology**
**Christian Medical College, Vellore**

**"Challenges & Opportunities in Therapeutic Drug Monitoring in India"**

**Background:**
Therapeutic Drug Monitoring (TDM) is an evidence-based tool that enhances medication safety, ensures compliance, and optimizes therapeutic outcomes, thereby improving the cost-effectiveness of medicines. Despite its proven benefits, TDM remains underutilized in India due to barriers such as limited access, high cost, delays in reporting, and challenges in accurate result interpretation.

**Challenges:**

**Limited Accessibility:** Predominantly available in tertiary care centers and select private laboratories.

**Economic Barriers:** Lack of cost-effectiveness and cost-utility data specific to the Indian population.

**Knowledge Gaps:** Limited clinician awareness about TDM guidelines and integration of results into clinical decision-making.

**Quality Deficits:** Absence of national accreditation, standardized operating procedures, and proficiency testing programs.

**Population-Specific Data Deficit:** Therapeutic ranges are often extrapolated from Western data, overlooking genetic, nutritional, and comorbidity differences in Indian patients.

**Opportunities:**

**Precision Medicine Expansion:** Integration of TDM and Model-Informed Precision Dosing (MIPD) into antimicrobial stewardship programs, tuberculosis and HIV management, antifungal therapy, and chemotherapy optimization.

**Generic Drug Evaluation:** Ensuring bioequivalence and safe transitions between brands.

**Research Potential:** Establishment of Indian-specific therapeutic ranges, Indian population specific Model informed precision dosing algorithms and studies on drug–drug and drug–herbal interactions.

**Conclusion:**
As global practice shifts from traditional TDM to Model Informed Precision Dosing softwares, India needs a clear, context-specific framework to embed TDM as an indispensable part of treatment planning. This will ensure judicious resource utilization while maximizing patient safety and therapeutic benefit.

**Dr. Roopali Somani**

**Tuberculosis : Challenges ahead**

India has significant burden of Tuberculosis disease. Drug susceptible TB is curable as well as preventable. Drug susceptible TB is managed by FDC of INH, Rifampicin, Ethambutol and Pyrazinamide administered daily for 2 months as intensive phase followed by FDC of INH, Rifampicin and Ethambutol administered daily for 4 months as continuation phase. These antitubercular drugs are highly effective with acceptable toxicity. These drugs are available free of cost under NTEP. Measures are taken to minimize the impact of adverse effects of these anti-TB drugs. TB being infectious and multisystem disease, the patient is motivated to complete 6 months treatment without any lapse. Irregular/incomplete/partial treatment may lead to development of Drug Resistant Tuberculosis (DR-TB), which is difficult to manage.

The Multidrug Resistant TB- MDR-TB is managed with 3 different regimes. The recently introduced is BPaLM regimen for patients over 14 years of age, In this Bedaquiline, Pretomanid, Linezolid and Moxifloxacin are administered for 26 weeks. Second regimen is 9-11 month shorter oral regimen which can be given also in patients under 14 years of age, In this 7 drugs are administered in intensive phase while 4 drugs in continuation phase. Third regimen is 18-20 months all oral longer MDR/XDR-TB regimen in which 4 drugs are given daily for 18-20 months with Bedaquiline for 6 months. Prompt and effective treatment of Drug Susceptible TB should be our priority so as to prevent the occurrence of DR-TB. Important to note that drugs used for treatment of DR-TB are toxic, poorly tolerated by patient, expensive, regimen is difficult to follow and some of the drugs are of uncertain efficacy. To make India TB-free by 2025 is a challenging task to accomplish. But certainly introspection, insight of ground reality, multidisciplinary team effort to improve patient adherence to therapy and trusting relationship between treatment provider and patient may bring us near goal.

**Dr. S.P. Dhaneria M.D., D.M., D.N.B., MNAMS**
**Professor & Head, Department of Pharmacology,**
**R.D. Gardi Medical College, Ujjain (M.P.)**

**Dosage individualization using machine learning approach**

"Machine learning (ML) is emerging as a powerful tool for dosage individualization, offering a promising alternative to traditional pharmacokinetic modeling. This is particularly crucial for drugs with high inter-individual variability, where personalized dosing can significantly optimize therapeutic outcomes. A systematic review of the literature reveals that ML models are increasingly being used for both a priori and a posteriori dose selection and optimization, and can also assist in therapeutic drug monitoring.

Studies in this area have predominantly focused on drugs with narrow therapeutic windows, such as immunosuppressants and anti-infectives. Various ML algorithms, including boosting-based, tree-based, instance-based, and regression-based models, have been employed. A significant portion of the research integrates ML with population pharmacokinetic models, while others develop standalone ML models. In terms of predictive accuracy, ML models have been shown to perform comparably to or even better than population pharmacokinetic models, especially for drugs with significant pharmacokinetic variability. Ensemble models, such as those combining XGBoost, random forest, and CatBoost, have demonstrated high predictive accuracy.

However, the field is not without its challenges. There is considerable heterogeneity in ML modeling approaches, feature selection, and model evaluation, which hinders the reproducibility and clinical applicability of these models. Many studies suffer from poor methodological quality, a high risk of bias, and a lack of external validation and clinical utility evaluation. To realize the full potential of ML in clinical practice, there is a pressing need for standardization in reporting and methodological practices. Future research should focus on improving the design, conduct, and reporting of these studies, as well as on the prospective validation of these models in a clinical setting. This will be essential to facilitate the translation of ML models from research to clinical practice and to enhance the efficacy and safety of drug treatment for a wide range of patient populations, including special populations like children, which are currently underrepresented in research."

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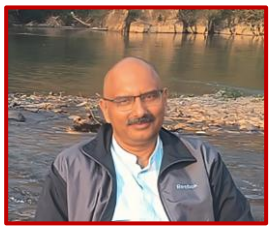

## ROLE OF AI IN PATIENT COMMUNICATION

AI-powered chatbots, virtual assistants, and interactive decision-support tools are now automating and standardizing history collection directly from patients, often via tablets or other digital interfaces. These systems gather symptoms and histories comprehensively, minimizing omission and bias, and streamline information flow to clinicians. By employing natural language processing, AI translates patients' narratives into structured, actionable data, making complex histories accessible and readily analyzable.

Studies show that AI can accurately synthesize medical information to propose differential diagnoses using only history data, with diagnostic concordance rates approaching those of experienced physicians. This not only supports clinicians in early risk stratification and triage but also facilitates continuous, patient-centered dialogue, even before in-person consultations. AI also ensures inclusivity by simplifying language, providing multilingual support, and personalizing content to individual backgrounds—helping bridge communication gaps for diverse and nonverbal populations.

Artificial Intelligence (AI) is redefining foundational aspects of clinical care, particularly in the domains of medical history taking and prescription communication. These traditionally time-intensive and error-prone processes are now being streamlined, personalized, and enhanced through AI-driven tools, resulting in more accurate diagnostics, safer prescribing, and improved patient outcomes.

In history taking, AI technologies such as intelligent chatbots, virtual assistants, and interactive digital platforms collect detailed patient narratives before clinical encounters. Through natural language processing (NLP) and decision-support algorithms, these systems translate patient-reported information into structured formats, aiding clinicians in identifying relevant symptoms, risk factors, and possible diagnoses—even in early stages. AI also offers multilingual and simplified communication interfaces, making history collection more inclusive for patients with varied literacy or language backgrounds. This not only reduces clinician burden but also enhances diagnostic accuracy by minimizing omissions and cognitive bias.

Simultaneously, AI is advancing prescription communication by ensuring clarity, compliance, and safety. Automated platforms interpret and transmit prescriptions accurately across electronic health records and pharmacy systems, minimizing transcription errors. AI-driven tools personalize medication instructions, provide reminders, and identify potential drug interactions based on a patient's medical history. These innovations support adherence, empower patients with real-time guidance, and enable early detection of complications or misuse.

Together, these AI applications represent a shift from reactive to proactive care. By capturing rich, patient-centered data and delivering precise, accessible communication throughout the prescribing process, AI strengthens continuity of care and trust between clinicians and patients.

However, challenges related to ethical oversight, data privacy, system interoperability, and maintaining human-centered empathy remain. Addressing these issues is critical to maximizing the benefits of AI-enabled healthcare.

In summary, AI is revolutionizing how clinicians gather patient histories and communicate prescriptions making care delivery smarter, safer, and more responsive.

**Col (Dr) Prafull Mohan**
**Professor & Head**
**Dept of Pharmacology, AFMC Pune**

**Optimizing Antimicrobial Therapy. The Critical role of Clinical Pharmacologist in Antimicrobial Stewardship**

"The Right dose of an antimicrobial in non-critically ill patients may not hold right in critically ill septic patients".

Antibiotic pharmacokinetics are highly variable in critically ill septic patients; therefore, inappropriate exposures are perhaps a critical confounder contributing to antibiotic resistance or improper clinical outcomes. Critically ill septic patients have various pathophysiological changes such as fluid shift causing third space collections, fluid accumulations due to aggressive fluid resuscitation, hyperdynamic state especially in early phase of sepsis, hypoalbuminemia and organ dysfunction (renal or hepatic impairment) affecting the pharmacokinetics of the antimicrobials, thus requiring dose optimization of antimicrobials so as to achieve target effective concentration at the target site.

In addition, there is a need to appreciate PK/PD principles of antimicrobials. For certain antibiotics, maximum bactericidal killing depends on the time the unbound concentration of antibiotic remains above the minimum inhibitory concentration (T>MIC) of the bacteria. Use of continuous or extended infusions as opposed to intermittent dosing has gained importance such antimicrobials especially for beta-lactams and carbapenems in patients with severe sepsis in the intensive care unit (ICU) setting. Conversely, for certain antibiotics which follow concentration dependent killing like aminoglycosides and fluoroquinolones; efficacy best correlates with the peak concentration to MIC ratio ($C_{max}$>MIC). For such antibiotics, once a day dosing has been shown to be more effective with better safety profile as compared to traditional twice a day dosing.

An appreciation of the PK/PD principles of the antimicrobial therapy with taking into consideration of patient factors, renal impairment, focus of infection, penetration of antibiotic at site of infection, and culture susceptibility profile can help the Clinical Pharmacologist foster more rational antimicrobial suggestion. In addition, integrating Therapeutic drug monitoring of antimicrobials such as vancomycin and aminoglycosides (amikacin, gentamicin) can help in dose optimization, improving patient outcomes.

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# SALUTOGENESIS, A NEW PARADIGM OF HEALING

## Introduction:

Institute of Salutogenesis and Complementary Medicine (ISCM) is the innovative brain child of Sri Balaji Vidyapeeth (SBV- A Deemed to-be-University in Pondicherry) that crosses boundaries of a regular healthcare university that introduced Yoga and Music Therapy in 2010 as a Centers of Yoga Therapy Education and Research (CYTER) and Music Therapy Education & Research (CMTER). Way before the concept termed "Salutogenesis" was incorporated into the realms of SBV; the practice of the underlying theory of transforming the focus from pathogenesis to salutogenesis through various activities in realms of patient care, health professionals' education and research has been entrusted to these centers. In the years that followed, ample infrastructure and facilities were provided, and eminent faculty members were recruited to fulfill the vision & mission of SBV.

It must be highlighted that SBV in the year 2018 brought forward an administrative policy statement and SBV Policy on Salutogenesis implementation and SBV Standard Operating Procedure for Salutogenesis that has also been copyrighted. Such a policy by the university reiterates its commitment towards the creation of a health promoting environment that is supportive of wellness. In technical terms, as suggested by Mittelmark et al (2022), this can be understood as a salutatory extra-person factor that promotes positive health.

The equivalent concept to Salutogenesis in Indian tradition is 'Swastha' that implies a sense of being at ease with oneself. Acharya Sushruta (~600 BC) defined this positive sense of wholesome wellness as a 'dynamic balance of the elements and humors, normal metabolic activity and efficient elimination coupled with a tranquil mind, senses and contented soul.' Yoga may be understood as one of the best means to achieve such a dynamic state of wholesome health and wellness at all levels of existence. The application of Yoga and Music towards this has been in regular practice in Indian tradition.

Healing in a holistic sense has faded from medical attention in recent times and is rarely discussed in modern medicine especially in therapeutics. To heal is to achieve or acquire wholeness as a person. The wholesomeness of personhood involves physical, emotional, intellectual, social, and spiritual aspects of human experience.

## Yoga Therapy in SBV

Modern medical advancements provide the rationale for integration of various traditional healing techniques like Yoga, Naturopathy, Ayurveda, Siddha and Music to promote health, healing and longevity. *"Government of India is currently promoting indigenous systems of health in an active manner through Ministry of AYUSH. The limitation of modern medicine in managing stress induced psychosomatic, chronic illnesses is the strength of these traditional healing systems and hence a*

*holistic integration of both systems enables best quality of patient care"*. In that context, this may be the first time around the globe that Yoga Therapy is incorporated as a regular training practice for healthcare students of medicine, dentistry and nursing colleges.

This pioneering innovation of integrating Yoga in the medical curriculum was initiated through **'Yogabhyasa'- a program especially organized and conducted for the benefit of medical students at SBV.** Since the integration has followed through with all students of Medical, Dental, Nursing, Allied Health Sciences and recently with students of pharmacy at SBV, who are provided with regular Yoga sessions, aimed at the holistic wellbeing of students in general. Salutogenesis, the term originally coined by the Austrian Sociologist Aaron Antonovsky, describes the focus on well-being and health instead of disease. This initiative would go a long way in stress management among students besides enhancing the well-being of the mind and body and improving the learning skills among the student community.

Yoga Therapy at SBV has taken up the opportunity to introduce Yoga in health care to foster a sense of wellness. It has also facilitated the incorporation of Yoga Therapy education in Nursing Curriculum, integrated Yoga in Health Professions Education and created Standard Operating Procedure for Application of Yoga in Primary Health Care Voyaging of Yoga Basics to Grass Roots — **VYBGR** with Department of Community Medicine. It has also contributed to **SBV Policy on Salutogenesis** implementation and SBV Standard Operating Procedure for salutogenesis.

**Prof KR Sethuraman**, the Former VC of SBV must be credited with introducing the concept of salutogenesis during his tenure and this has become the focus of our efforts towards Integrative Medicine. This step towards integrating Yoga as a curriculum enhanced the practice with related research not only on their physical health, but also included transformed personalities as well as a good sense of wellness, ability to express feelings of being capable, respected, contented, confident, composed, happy and peaceful. Following research, these regular practices have been converted into best practices and nally into copyrights.

**Music Therapy in SBV**

A small team of Medical Professionals came together with a spark of innovation to start a Music medicine unit along the lines of Yoga Therapy in 2010. The main focus of the team was to create a positive and holistic environment with Music for patients and healthcare workers. The **Music Medicine Unit** further evolved into **Center for Music Therapy, Education and Research** (CMTER), adding education & training for future Medical Music therapists.

CMTER focussed on building a team of credentialed, degree certified Medical Music Therapists, looking forward to creating a base for a unique curriculum connecting global Music Therapy concepts to traditional healing systems in India. The school of Music Therapy now proudly hosts a Post Graduate diploma in Music Therapy, M.Sc in Medical Music Therapy and a PhD program for Music Therapy under SBV. The practice of introducing Music Therapy and its therapeutic uses to the students of SBV has become a best practice and copyrighted as MEETS, started with the MBBS students in 2015 has been continuing till present times and has moved on to all other students of Nursing, Dental and AHS students. Similarly the needs to accommodate culturally different students into practice has created the clinical communication book and training is built around intercultural learning concepts within teaching and practice, regular clinical practice has evolved into a program for pregnant women called **"Garbh Sanskar"** and finally a protocol of references and procedural support has all been copyrighted.

This has propelled the increase in research papers and copyrights that showcase the uniqueness of Music Therapy and SBV. Evidence based practice and strong conviction towards ethical practice has paved the way in 2022, and we now have the first module for Music Therapy in nursing and the allied health science curriculum.

Music Therapy is still building its path to become stronger in terms of accreditation, acceptance into Professional vacancies and regular education programs through the central education portal of India. We are humbly indebted to SBV for having given us the platform to bring out a curriculum that has been accepted only through the channels of regular board of studies and rigorous and meticulous Academic council meetings to have a model that coincides with the UGC norms for Higher education in Music Therapy.

**Amalgamation of Yoga and Music Therapy at SBV into ISCM**

This well-equipped Yoga and Music Therapy centres have now been upgraded into the School of Yoga Therapy and School of Music Therapy respectively, under the purview of **Institute of Salutogenesis & Complementary Medicine since August 2022.** The support provided by the visionaries and the management of SBV have opened up avenues for faculty and student and increase in patient care in almost all areas including ICU and the operation theatres, apart from the plethora of other Medical departments of OG, Pediatrics, Psychiatry, Surgery, Cardiology, Palliative care, Orthopedics, ENT, Ophthalmology, Neurosurgery and Neurology, with the recent increase in interest shown from the Dental, Nursing and Allied Health science institutes within SBV.

The Fundamental concepts of salutogenesis such as Sense of Coherence (SOC) and **Generalised Resistance Resources (GRR)** have been inculcated in all students through various orientation programs and other student centric activities. A 'Salutogenic' approach is one that focuses on factors that support health and wellbeing, beyond a more traditional, 'pathogenic' focus on risk and problems. In this effort we have consistently acknowledged the contributions of **Professor Antonovsky.**

We at SBV have attempted to explore Yoga Therapy and Music Therapy as part of the GRR development through the **YOGABHYASA and MEETS** (Musically Express your Emotions Thoughts for Success) programs for our student community.

Furthermore both Yoga Therapy and Music Therapy have been utilised extensively in the clinical setting of our hospitals as a part of **Specific Resistance Resources (SRR)**. Best practices such as **PURNAM: CYTER Model of Salutogenic Communication of Wholesomeness in a Clinical Setting** and **Salutogenic Approach of Yoga for the Third Gender: The CYTER MODEL** that introduce a Salutogenic orientation in clinical practice have also been copyrighted.

Antonovsky proposed that the feeling of wellness is primarily governed by the **'sense of coherence'** that may be considered the heart of salutogenesis. This may be understood as a pervasive, long-lasting, and dynamic feeling of confidence that one's internal and external environments are predictable and that there is a high probability that things will work out as well as can be expected.' It has strong positive correlation to perceived health, mental health, and quality of life as it helps the 'diseased' to manage their condition and 'be well'.

The three components of SOC are based on a sense that

1. One's life is comprehensible,

2. It is manageable and

3. It is meaningful.

The sense of life being comprehensible is a cognitive process where the individual has the sense that **my world is understandable.** The coping skill in the second component enables the individual to feel, **my world is manageable** while the motivational aspect of life having a sense of meaningfulness manifests in the individual feeling, **my world has meaning.**

The comprehension, meaningfulness and manageability **(SOC approach)** in chronic diseases keeps them 'well' despite any limitations and is similar to 'physically disabled' becoming 'differently abled'. When an individual has these three aspects manifesting in their life, they have a sense of health, wellness, wellbeing and wholesomeness.

**Yogacharya Dr. ANANDA BALAYOGI BHAVANANI, DSc (Yoga)**

**Professor Yoga Therapy & Director**

**Institute of Salutogenesis and Complementary Medicine (ISCM)**

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**www.sbvu.ac.in/iscm**

# ORAL
# CASE PRESENTATION

**A case report of Stevens–Johnson Syndrome-Toxic Epidermal Necrolysis (SJS-TEN) Overlap in a patient on Phenytoin.**

**Presenter –** Dr Archana V, Postgraduate 1st year
**Co-authors -** Dr Padmavathi S, Professor,
Dr Meenakshi R, Assistant Professor,
**Affiliation** - Department of Pharmacology, MGMCRI, SBV, Puducherry

**Abstract**

**Background**

Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) are severe, life-threatening cutaneous adverse drug reactions characterized by extensive epidermal necrosis and sloughing. In addition, the mortality rates associated with SJS and TEN are estimated as 1–5% and 30% respectively. Medications are one of the most common causes for SJS/TEN.

**Case presentation**

A 23-year-old male was admitted with a 2-day history of itchy reddish raised lesions over the back and abdomen, chest, extremities, and face associated with oral and scrotal desquamation. He had history of traumatic brain injury two months ago, for which he was started on tablet phenytoin 100mg TID for about one month. Local examination revealed diffuse multiple purpuric maculopapular lesions and skin peeling over the trunk, extremities, face and also the mucosal surface of the oral and anogenital region. His SCORTEN (Severity-of-Illness Score for Toxic Epidermal Necrolysis) score was 2, indicating a moderate risk of mortality. Laboratory investigations showed elevated AST and ALT. The patient was diagnosed as a case of Phenytoin induced Steven Johnson Syndrome -Toxic Epidermal Necrolysis Overlap. Phenytoin was dechallenged and treated with oral Cyclosporine 300mg/day, intravenous Dexamethasone 8mg/day for eight days after which the patient improved symptomatically.

**Conclusion**

This case highlights the rapid progression and severe systemic involvement characteristic of phenytoin-induced SJS/TEN Overlap, emphasizing the critical need for prompt diagnosis and withdrawal of the offending agent. As Phenytoin is a frequently prescribed drug in neurology and neurosurgery, raising clinician awareness is crucial to prevent such severe outcomes. From a pharmacovigilance perspective, this case elicits the importance of ADR monitoring and reporting systems in recognizing drug safety signals.

**Keywords-** Phenytoin, SJS, SCORTEN, pharmacovigilance, drug safety.

**Periorbital Swelling as an Adverse Drug Reaction to Commonly Used Analgesics: A Case Series**

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**Abstract**

**Introduction**

Periorbital swelling as an adverse drug reaction (ADR) to commonly used analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol is rare but clinically significant. Early recognition of such hypersensitivity reactions is crucial for appropriate management and patient safety.

**Methods**

This case series describes six female patients (ages 24 to 55 years) who developed periorbital swelling following intramuscular (IM), intravenous (IV) as well as rectal suppository administration of NSAIDs (ketorolac, diclofenac, paracetamol) at a tertiary care centre. All patients were either postpartum or postoperative and received these drugs for pain management. The onset of swelling occurred shortly after drug administration, with no prior history of hypersensitivity reactions documented.

**Results**

All patients exhibited periorbital edema, and some had additional facial swelling. Symptoms resolved after discontinuation of the suspected drug and administration of antihistamines and corticosteroids. No severe systemic reactions were observed. Given the close temporal association, an immunological or idiosyncratic reaction is suspected.

**Conclusion**

This case series highlights the need for vigilance in recognizing hypersensitivity reactions to routine analgesics, especially in vulnerable patient groups. Clinicians should be aware of such presentations and initiate prompt management. Further studies are warranted to explore the underlying mechanisms and establish preventive strategies.

**Keywords**

Periorbital swelling, adverse drug reaction (ADR), NSAID induced, hypersensitivity, Pain management

**A case report of cutaneous adverse reaction following brand-to-brand switch of eplerenone in a tertiary care hospital**

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**Abstract**:

**Introduction:**
Drugs are substances composed of both active substance (API) and inert substances (Excipients). Although considered pharmacologically inert, excipients can initiate or propagate potential drug interactions.Adverse Drug Reactions (ADRs) not only arise due to Active Pharmaceutical Ingredient (API) but also due to differences in Excipients, Dissolution profiles or bioequivalence among brands.

**Case report:** Patient was on **Eplerenone 25mg** (Eplehef ®) oral dose – Once a day for Central Serous Retinopathy (CSR) of left eye since 7 days, On 8th day the brand was changed to **Eptus ® - Glenmark Pvt. Ltd.** due to local pharmacy stock exchange with the same generic composition of Eplerenone 25mg. Immedietly, within few hours patient developed severe itching and raised erythematous lesions all over the body including palms and soles. The patient thought it was due to food allergy, and took the tablet again the next day – **Rechallenge positive**. He developed severe itching and lesion all over the body and was presented with angioedema. The patient was diagnosed as Drug induced Exanthematous maculopapular rash and the patient stopped taking the medication (Eptus ®) - **Dechallenge positive** and was prescribed oral Cetrizine 10mg. The patient was advised to consult the ophthalmologist, following resolution of the rash, the patient was reinitiated on the previous brand of eplerenone 25mg (Eplehef ®) and patient did not develop any hypersensitivity reactions.

**Discussion:**
This case illustrates a **brand-specific hypersensitivity reaction** to eplerenone. Despite identical active ingredients, excipient or formulation differences likely triggered the reaction with *Eptus*® but not with *Eplehef*®. The positive rechallenge, resolution on dechallenge, and safe tolerance to the original brand support this conclusion. Such events emphasize the need to consider excipient-related intolerance when switching brands.

**Conclusion:**
Hypersensitivity may not always be due to the drug itself but to brand-specific excipients. Careful evaluation of rechallenge and dechallenge outcomes is essential for identifying the true cause and guiding safe therapeutic decisions.

**Toxic Epidermal Necrolysis: A Case Study of Drug-Induced Dermatological Emergency**

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**Abstract**:

**Introduction**:

Toxic Epidermal Necrolysis, or TEN, is a rare and serious skin reaction, most often caused by medications. It presents with widespread skin peeling, mucosal involvement, and can affect internal organs. Common triggers include painkillers, antiepileptic medicines, and antibiotics.

**Case Presentation:**

A 44-year-old man came to our hospital, with fever for four days, cough and breathing discomfort for three days, and painful skin rashes. Examination revealed raw skin over large areas, mucosal ulcers, and a positive Nikolsky sign. He had taken Inj. Diclofenac and T. Aceclofenac + paracetamol combination few days prior. Blood tests showed raised liver enzymes. Eye redness and discomfort were also noted. The SCORTEN score 3 elicits the severity.

**Management and Outcome:**

The Patient was admitted to the intensive care unit and managed with immunosuppressive treatment. Cyclosporine 300mg/day was started along with oral Prednisolone and Inj. Dexamethasone. Secondary infections were treated with parenteral antibiotics, and Moxifloxacin eye drops were used for ocular manifestations. Fluid balance, nutrition, and wound care were carefully monitored throughout. Liver enzyme levels remained elevated during recovery, adding complexity and extending treatment.

**Conclusion:**

This case reinforces the importance of pharmacovigilance in identifying serious adverse drug reactions like TEN. Early recognition, prompt drug withdrawal, and timely pharmacological intervention are critical to improving patient outcomes. NSAID-induced TEN with systemic involvement highlights the need for rational prescribing and close monitoring.

**Keywords:**

TEN, NSAID, Adverse Drug Reaction (ADR), SCORTEN Score, liver injury, eye involvement

**A Rare case of fexofenadine-induced supraventricular tachycardia**

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**Abstract**

**Background:**
Fexofenadine, a second-generation antihistamine, is widely prescribed for allergic conditions due to its favorable safety profile and minimal central nervous system effects. Unlike its predecessor terfenadine, which was withdrawn due to cardiotoxicity, fexofenadine is generally considered safe. However, rare cardiovascular adverse events have been sporadically reported.

**Case Presentation:**
We report the case of a 45-year-old female with no prior comorbidities, drug allergies, or regular medications who presented to the emergency department with sudden-onset palpitations and chest discomfort approximately six hours after taking tablet fexofenadine 120 mg (Allegra®) for an acute respiratory tract infection.

**Clinical Findings and Intervention:**
On admission, the patient was conscious and oriented with a blood pressure of 120/90 mmHg, heart rate of 200 bpm, and respiratory rate of 20/min. ECG revealed supraventricular tachycardia (SVT). Laboratory investigations including electrolytes, thyroid function, and cardiac biomarkers were unremarkable. She was managed conservatively with carotid massage and adenosine injection, resulting in spontaneous reversion to sinus rhythm.

**Outcome and Conclusion:**
No recurrence occurred during observation. WHO-UMC causality assessment suggested a *possible* adverse drug reaction. This case highlights a rare but clinically significant instance of fexofenadine-induced SVT, underscoring the importance of continued pharmacovigilance and clinician awareness regarding potential cardiac risks even with widely used antihistamines.

**Phenytoin induced Stevens-Johnson syndrome - a case report in tertiary care hospital,**

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## Abstract

**Introduction:**

Stevens-Johnson Syndrome (SJS) is a rare, severe mucocutaneous adverse drug reaction characterized by widespread skin lesions, mucosal involvement, and systemic manifestations. Antiepileptic drugs, particularly phenytoin, are well-documented triggers. Early recognition and prompt withdrawal of the offending agent are crucial to reduce morbidity and mortality.

**Case Report:**

We present the case of a 46-year-old male with newly diagnosed epilepsy who was initiated on phenytoin 300 mg twice daily. After three months of therapy, he developed ocular redness, diffuse hyperpigmented maculopapular rash, plaques, and both typical and atypical target lesions over the body. Clinical and dermatological evaluation confirmed phenytoin-induced SJS. Phenytoin was discontinued, and the patient was managed with intramuscular dexamethasone 4 mg, intravenous

ceftriaxone 1 g, and supportive care. According to the WHO-UMC causality assessment scale, the reaction was categorized as *probable*. The adverse event was reported to the Adverse Drug Reaction Monitoring Centre (AMC) through VigiFlow (report no: IN-IPC-301077182).

**Discussion & Conclusion:**

Phenytoin, despite its therapeutic role in epilepsy, carries a rare risk of life-threatening reactions such as SJS. Genetic predisposition (e.g., HLA-B*1502) has been implicated in susceptibility. With over 4,000 global reports of phenytoin-induced SJS in VigiAccess, clinicians must exercise caution, educate patients, and report adverse events to strengthen pharmacovigilance and improve drug safety.

**Immunosuppressants induced Graft versus host disease**

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**Abstract**

**Background**

Graft versus host disease (GVHD) is common clinical problem in patients taking immunosuppressants like cyclosporine, tacrolimus etc. after hematopoietic stem cell transplantation. Such patients usually present with clinical picture involving various organs like skin, liver and gastrointestinal tract. Treatment usually involves intravenous steroids like methylprednisolone tapered by oral steroids like prednisolone and prednisone. It is important to note that there is a potential drug interaction between immunosuppressants and steroids which can be life threatening occasionally.

**Case presentation**

A 6-year-old south-Indian girl was diagnosed with precursor B-cell acute lymphoblastic leukemia (B-ALL) in September 2019 and began standard-risk induction chemotherapy under the ICiCLe (Indian Collaborative Childhood Leukaemia) protocol, followed by maintenance therapy. In April 2021, she relapsed with CNS involvement and was treated with metronomic chemotherapy and cranial radiotherapy. Although her CSF cleared, minimal residual disease (MRD) persisted in the bone marrow despite salvage chemotherapy. She underwent a haploidentical stem cell transplant in December 2021, with her father as the donor. In the months following transplant, she developed pruritic vesiculobullous skin lesions, diagnosed as graft-versus-host disease (GVHD), which responded to steroids and rituximab. She later experienced a seizure-like episode with postictal confusion and elevated blood pressure, attributed to gliotic brain changes. A diagnosis of Posterior

Reversible Encephalopathy Syndrome (PRES) was suspected. She was managed with anticonvulsants and started on broad antimicrobial prophylaxis.

**Conclusion**

Posttransplant patient care poses a significant possibility of drug interactions and hence should be dealt with utmost caution making use of therapeutic drug monitoring wherever applicable.

**Injection Ceftriaxone-Induced Erythema Multiforme Major: A Rare Drug Reaction Case Report**

Presenter: Dr.R.Sivaramakrishnan, Second year postgraduate, MGMCRI.
Guide: Dr.Uma Narayanamurthy
Co-Guide: Dr.Akila

**Abstract**

**Introduction:**

Erythema multiforme major (EMM) is a rare, immune-mediated mucocutaneous hypersensitivity reaction, often triggered by infections or drugs. Cephalosporins, including ceftriaxone, are rarely mentioned as causes, but antibiotics are known to be responsible. Given the possibility of mucosal involvement and systemic consequences, early detection is crucial.

**Case Presentation**

A 48-year-old female, known case of diabetes for 5 years, on irregular treatment with Teneligliptin and known case of hypertension for 2 years, presented to dermatology department with complaints of swelling of the face, lips, and eyes for 2 weeks. It was followed by widespread itchy, erythematous raised lesions that started on the legs and progressed to the trunk, upper limbs, and face. She developed tense, fluid-filled bullae over both soles and crusting over the lips one day prior to admission. Examination revealed multiple atypical targetoid lesions with exfoliation on the face, trunk, gluteal region, palms, and soles; mucosal involvement included hyperpigmentation and crusting of the lips.Notably, she had been injected with ceftriaxone 2 weeks before for enteric fever. With the use of pertinent serology, the viral causes were ruled-out. Based on clinical presentation and drug history, a diagnosis of **ceftriaxone-induced erythema multiforme major** was made.

**Discussion:**

Although ceftriaxone is generally well-tolerated, in rare instances, trigger severe cutaneous adverse reactions such as EMM. In this instance, the diagnosis is supported by the correlation between drug exposure and the development of symptoms. Diabetes and other immune-compromised conditions may increase vulnerability.

**Conclusion:**This case emphasizes the need for vigilance regarding severe cutaneous adverse drug reactions. Clinicians should consider ceftriaxone as a potential cause of EMM, particularly when mucocutaneous symptoms follow its administration.

**A Case of "Acute Extrapyramidal Reaction following Antipsychotic Reinitiation Post Non-Compliance".**

Presenting Author: Dr. Shyamala V, First year postgraduate , MGMCRI, SBV, Pondicherry
Guide: Uma Narayanamurthy
Co-guide: Akila.S

**Abstract**

**Introduction**

Schizophrenia is a chronic psychiatric disorder characterized by disturbances in perception, thought, and behavior. Antipsychotic treatment, may lead to extrapyramidal side effects such as acute dystonia. This poster presents a case of a young female with schizophrenia who developed acute dystonia following abrupt medication noncompliance and re-initiation.

**Case presentation**

A 28-year-old unmarried female with a diagnosis of schizophrenia presented with muttering, suspicion, delusions of reference, for six months. She was earlier treated with antipsychotics and ECT. On 3rd May 2025, following 3–4 days of medication noncompliance and re-initiation of haloperidol, the patient developed sudden painful neck spasms, dysphonia, and respiratory difficulty. The patient had a prior history of good response to Haloperidol and ECT, but non-adherence to Haloperidol led to symptom relapse. On the day of admission, she developed acute dystonic reaction likely secondary to abrupt medication noncompliance and re-initiation of T.Haloperidol10mg for 3 to 4 days, which was improved by administration of promethazine 50 mg IM stat. Prompt intervention with airway support and symptomatic care stabilized the patient. She was stabilized in casualty and readmitted to psychiatry.

**Discussion**

This case underscores the importance of medication adherence in schizophrenia and the risk of extrapyramidal symptoms following abrupt changes in antipsychotic therapy. Acute dystonia, though reversible, can mimic life-threatening emergencies and requires high clinical suspicion and prompt management. Patient education and family support are critical in maintaining long-term treatment adherence.

**Conclusion**

Early recognition and management of antipsychotic-induced side effects are crucial in schizophrenia care. Structured psychoeducation, supervised therapy, and gradual dose adjustments can improve outcomes and prevent acute complications in vulnerable patients.

**A Rare Case of Acute Generalized Exanthematous Pustulosis (AGEP) Secondary to Terbinafine / Pustular Psoriasis**

**Presenting Author:** Dr. Syed Fazil S, First-Year Postgraduate, MGMCRI, SBV, Pondicherry**. Co-authors:** Dr. Johan Pandian, Professor, MGMCRI, SBV, Pondicherry
Dr. Hemamalini R, Assistant Professor, MGMCRI, SBV, Pondicherry

**Abstract**

**Introduction:**
Acute Generalized Exanthematous Pustulosis (AGEP) is a rare, self-limiting, drug-induced skin reaction characterized by the rapid onset of sterile, non-follicular pustules on erythematous and edematous skin, often accompanied by fever and neutrophilia. Terbinafine, a commonly used antifungal, is rarely implicated in AGEP or pustular psoriasis-like reactions.

**Case Presentation:**

A 24-year-old male presented with diffuse pustular eruptions, fever, and systemic symptoms of five days' duration. The lesions initially appeared on the forearms and progressively involved the trunk, groin, limbs, genitalia, scalp, and face. He had no history of psoriasis. The symptoms resolved after treatment for tinea incognito with oral terbinafine (250 mg for 9 days), itraconazole, amoxicillin-clavulanic acid, and topical luliconazole. Based on clinical history and presentation, AGEP was diagnosed, likely triggered by terbinafine.

**Discussion:**

AGEP typically resolves after discontinuing the offending drug. Differentiation from pustular psoriasis is crucial due to differences in management and prognosis. The EuroSCAR scoring system and histopathological evaluation aid in diagnosis. This case highlights the need for vigilance regarding rare cutaneous adverse drug reactions.

**Conclusion:**

Early identification and prompt drug withdrawal are key to effective management of AGEP. Clinicians and pharmacologists must maintain awareness of such rare reactions associated with commonly prescribed medications to improve pharmacovigilance and patient outcomes.

**Keywords:**
AGEP, Terbinafine, Adverse drug reaction, Pustular psoriasis, Pharmacovigilance

**Cyclosporine-Associated Ocular Surface Squamous Neoplasia in a Patient with Aplastic Anemia: A Case Report**

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**Abstract**

**Introduction:**

Ocular Surface Squamous Neoplasia (OSSN) encompasses a spectrum of epithelial neoplasms ranging from conjunctival intraepithelial neoplasia to invasive squamous cell carcinoma. Immunosuppressants such as cyclosporine may reduce tumor immune surveillance, contributing to OSSN in predisposed individuals.

**Case report:**

We report a case of a 59-year-old female with aplastic anemia, on long-term immunosuppression with oral cyclosporine (100 mg OD), eltrombopag, danazol, and supportive agents. She presented to the Ophthalmology OPD with redness, irritation, and foreign body sensation in the right eye for two months. Ocular examination revealed OSSN involving the bulbar conjunctiva. She was managed with topical 5-fluorouracil and lubricant drops and was referred to the Clinical Pharmacology & Therapeutics OPD for causality assessment.

**Discussion:**

A detailed medication history, temporal association, and absence of other definitive risk factors prompted a structured evaluation. Causality assessment was performed using both the WHO-UMC criteria, which suggested a 'Possible' link, and the Naranjo Adverse Drug Reaction Probability Scale, which scored +3, indicating a 'Possible' association between cyclosporine and OSSN.

**Conclusion:**

This case highlights the need for regular ophthalmic monitoring in immunosuppressed patients, especially those on chronic cyclosporine therapy. Further pharmacovigilance is essential to understand the oncogenic risks of long-term immunosuppression.

**Key words:** Cyclosporine, Ocular Surface Squamous Neoplasia, Causality Assessment

**"Febrile Seizures Following Pentavalent Vaccination: A Case Report with Causality Assessment"**

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**Abstract**

**Objective:**

To report a case of acute febrile seizures temporally associated with administration of the pentavalent vaccine, and to assess causality and severity of the adverse reaction.

**Methodology:**

A 1½-year-old female child presented with fever and one episode of tonic-clonic seizures within four hours of receiving the pentavalent vaccine. Detailed clinical history, physical examination, and relevant investigations were conducted. Previous similar episodes were reviewed, and a causality assessment was performed. A thorough differential diagnosis was considered to rule out other causes, including central nervous system infection, birth trauma, metabolic derangements, or familial epilepsy, using clinical evaluation and history-based exclusion—consistent with the approach presented in the case documentation.

**Results:**

The child developed high-grade fever at 2:45 PM and subsequently experienced convulsions at 3:00 PM, characterized by tonic-clonic movements and up-rolling of the eyeballs. Past history revealed a similar febrile seizure episode unrelated to vaccination. No signs of CNS infection or familial epilepsy were noted. The patient was managed symptomatically and stabilized. The causality was assessed as “intermediate” with a consistent temporal association but insufficient evidence to confirm direct causation. The reaction was categorized as Type B (idiosyncratic), moderate severity (Level 4).

**Conclusion:**

Though febrile seizures are known rare adverse events following immunization, particularly due to the pyrogenic response of vaccine components, genetic predisposition and reactogenicity may play a role. This case highlights the importance of post-vaccination monitoring, timely management, and reporting to strengthen vaccine safety surveillance systems.

**Keywords:** Pentavalent vaccine, febrile seizures, adverse drug reaction, causality assessment, vaccine safety

# ORAL POSTER PRESENTATION

**A Community-Based Study on Drug Use Patterns for Chronic Pain in Elderly Patients**

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**Abstract**

**Objective:** To study the drug profile used for management of chronic pain in the elderly in the community.

**Methodology:**. This descriptive cross-sectional study was conducted in a semi-urban area, covering five randomly selected Urban Health Centres (UHCs). A convenient sampling method was used, and 371 elderly participants with chronic pain were enrolled after cognitive screening and informed consent. Pain was assessed using the Visual Analogue Scale (VAS) and the Short Form McGill Pain Questionnaire (SF-MPQ). Participants were also evaluated for comorbidities and medication use, which was categorized as doctor-prescribed, over-the-counter/self-medicated, or extended prescription . Data were collected through house-to-house surveys with ASHA workers' assistance.

**Results:** Out of 835 elderly individuals screened, 404 had chronic pain, and after excluding 33 with cognitive impairment, 371 participants (51.75% males, 48.25% females) were included. Among them, 39.36% used only pharmacotherapy, 22.10% used both pharmacotherapy and alternative therapies, 16.44% used only alternative therapies, and 22.10% did not use any therapy. NSAIDs were the most commonly used drug class (72.81%), with diclofenac (46.06%) being the most preferred,

followed by ibuprofen (16.29%). Tablets were the dominant formulation (86.52%), and self-medication was prevalent (81.46%). Among non-NSAID drugs, steroids (48.64%) and immunosuppressants (16.22%) were common. Massage was the most used alternative therapy, both alone (41.96%) and in combination (39.86%), while other therapies like Ayurveda, Unani, Yoga, and Homeopathy were used by fewer than 2.8% of participants.

**Conclusion:** This study highlights that chronic pain is a significant issue among the elderly, with a considerable number not receiving any form of treatment. NSAIDs, especially diclofenac, remain the most commonly used pharmacological agents, often accessed through self-medication. A notable proportion of elderly individuals rely on alternative therapies, particularly massage, either alone or alongside pharmacotherapy. The widespread use of over-the-counter drugs and extended prescriptions raises concerns about unsupervised medication practices. These findings underscore the need for better awareness, monitoring, and accessible pain management services tailored to the elderly population

**Keywords: :** Chronic pain, elderly, NSAIDs, pain management, India, self-medication,

**Efficacy and safety of saroglitazar as add-on therapy on glycemic status in patients with type 2 diabetes mellitus: A randomized, double blind, placebo-controlled trial**

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**Background:**

Peroxisome Proliferator Activated Receptor (PPAR) γ agonist pioglitazone and dual α/γ agonist saroglitazar are approved by DCGI for type 2 diabetes mellitus and diabetic dyslipidemia respectively. Saroglitazar has multiple add-on metabolic benefits in addition to reducing the glycemic burden whose data regarding the effects is ongoing. **Objective**: This study was done to evaluate the add-on effect of saroglitazar on HbA1c in patients with type 2 diabetes mellitus (T2DM) as compared to placebo at the end of 12 weeks.

**Methodology:**

Thirty-three patients (more than 30 years), having type 2 diabetes mellitus were randomized (1:1) to receive either saroglitazar 4 mg tablet once daily (Group A) or oral placebo (Group B) once daily for 12 weeks along with standard background treatment of metformin and sulfonylureas. They were followed at week 4, week 8 and week 12 for measurement of fasting blood glucose, post-prandial glucose levels, liver profile, urea and creatinine. Parameters of vascular function and exercise capacity were measured at baseline and 12 weeks.

**Results:**

There was a significant mean reduction in HbA1c (0.573%) noted in add-on saroglitazar group ($p = 0.043$) as compared to that of placebo. There was no significant change in fasting blood glucose and post-prandial glucose levels. There was significant change in aortic systolic blood pressure in

Group A (p=0.042). There was no difference in parameters assessing exercise capacity and the drug was tolerated with comparable adverse events between the two groups.

**Conclusion:**

Saroglitazar improved HbA1c over 12 weeks in patients of T2DM receiving standard background therapy and has a promising potential to reduce the cardiovascular risk in T2DM patients. However, the study findings have to be confirmed in a larger sample size.

**Key words**: Saroglitazar, Type 2 diabetes mellitus, Peroxisome proliferator-activated receptors (PPAR α/γ) agonist, aortic systolic blood pressure

## Effectiveness of two doses (500 mcg and 1000 mcg) of vitamin B12 supplementation on glycaemic control in poorly controlled type 2 diabetic patients with hyperhomocysteinemia- A randomized, open-label, parallel group clinical trial

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**Abstract**

**Introduction:**

Vitamin B12 supplementation in patients with metabolic syndrome decreases homocysteine and insulin levels, improve insulin resistance. This study was designed to investigate effectiveness of oral vitamin B12 supplementation at 500 mcg Vs 1000 mcg dose in poorly controlled type 2 diabetic(T2DM) patients with hyperhomocysteinemia and to determine optimal dosage for vitamin B12 in T2DM patients.

**Methodology:**

This study was a randomized, active comparator controlled, open label, parallel group Clinical trial. Poorly controlled, 76 T2DM patients, with vitamin B12 level Vitamin B 12 levels < 300 pg/ml, Homocysteine levels ≥ 15µmol/L were enrolled in this study. In group A, 33 patients and in group B, 32 patients were administered (500 mcg and 1000 mcg of Vitamin B12 respectively with standard antidiabetic drug therapy. Levels of homocysteine, Vitamin B12, plasma insulin, Lipids were assessed at baseline and 12 weeks and glycaemic parameters (FBS, PPBS, HbA1c) were assessed at baseline and 12 weeks and 6 months

**Results:**

HbA1c was significantly reduced from 65 (56- 88) to 56 (51- 66) mmol/mol in group A and from 72 (66-79) to 49 (45- 58) mmol/mol in group B. HOMA-IR was significantly reduced from 4.70 (3.21-7.95) to 2.89 (1.90-3.51) in group A and from 5.46 (3- 7.49) to 2.12 (1.16-3.31) in group B. Improvement of HbA1c was correlated with significant reduction in serum Insulin and HOMA-IR. Increase in Vitamin B12 and decline in homocysteine were significant in both the arms. The fall of

HbA1c and homocysteine and increase in vitamin B12 was significantly more in group B as compared to group A.

**Conclusion**:

Vitamin B12 1000 mcg is more effective in causing reduction in the levels of HbA1c and homocysteine in T2DM. Hence, add- on supplementation with vitamin B12 can help in better glycaemic control as well as reduce the risk factors associated with elevated homocysteine levels in T2DM.

**Association of UGT2B7 Gene Polymorphisms with Clinical Response and Serum Concentration of Sodium Valproate in Pediatric Epilepsy: A Prospective Observational Study from Eastern India**

Authors: Karmakar A[1], Munshi S[1], Datta K[2], Mukherjee M[1]

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**Abstract**:

**Background**:
Sodium valproate (VPA) is a widely used antiepileptic drug (AED), yet its clinical efficacy and serum levels show considerable interindividual variability, potentially influenced by genetic factors. The UDP-glucuronosyltransferase 2B7 (UGT2B7) enzyme plays a crucial role in VPA metabolism. This study investigates the impact of two UGT2B7 gene polymorphisms (802C>T and 161C>T) on the therapeutic response and serum VPA levels in pediatric epilepsy patients.

**Methods**:
A prospective, 18-month study was conducted at a tertiary care hospital in Kolkata, involving 50 pediatric patients (2-12 years) diagnosed with generalized or partially generalized epilepsy. All participants received VPA monotherapy and were monitored for clinical response, adverse drug reactions (ADRs), and serum VPA concentrations. Responders were defined as those with no seizures or one seizure episode within six months; non-responders experienced ≥2 seizures or ADRs. Genotyping for UGT2B7 802C>T and 161C>T polymorphisms was performed using PCR-based methods. Quality of life (QoL) was assessed at baseline and at 12 months using a validated pediatric QoL instrument.

**Results**:
Out of the 50 patients, 14 (28%) were classified as non-responders. The average serum VPA concentration among non-responders was 78.5 ± 21.8 mcg/ml. Statistical analysis revealed no significant association between UGT2B7 802C>T and 161C>T polymorphisms and serum VPA levels. Although 66.7% of patients with ADRs carried the heterozygous CT genotype for 802C>T, and 33.3% of these carried the CC genotype for 161C>T, no statistically significant genotype-phenotype correlations were observed. Notably, QoL scores improved significantly over the 12-month treatment period, rising from 52.4 to 65.66 ($p < 0.001$), reflecting overall treatment benefit.

**Conclusion**:
This study found no significant correlation between UGT2B7 802C>T and 161C>T polymorphisms with serum VPA levels or clinical outcomes in pediatric epilepsy. However, genotype-related ADR

trends suggest genetic markers may influence VPA tolerance, warranting larger multicentric studies in Indian children.

**Effect of dapagliflozin therapy on arterial stiffness measured by PeriScope device, in adults with type 2 diabetes mellitus: a 6-month prospective observational study**

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**Objectives:**
Type 2 diabetes mellitus (T2DM) is associated with increased arterial stiffness, a key contributor to cardiovascular morbidity and mortality. Dapagliflozin, a sodium–glucose cotransporter-2 inhibitor (SGLT2i), has demonstrated benefits in glycaemic control, blood pressure, and cardiovascular outcomes, but its effect on arterial stiffness in T2DM patients remains underexplored. This study aimed to evaluate the effect of dapagliflozin on arterial stiffness as an add-on therapy in T2DM patients with inadequate glycaemic control (HbA1c 7–9%), and to assess its safety, tolerability, and impact on metabolic parameters.

**Methodology:**
A prospective, observational study was conducted at the School of Tropical Medicine, Kolkata, after getting ethical approval. Adult T2DM patients (≥18 years) with inadequate glycaemic control, attending the outpatient department, were enrolled after obtaining informed consent. Dapagliflozin was added to their existing oral antidiabetic regimen. Arterial stiffness was assessed using carotid–femoral pulse wave velocity (cfPWV) measured by the PeriScope™ device at baseline, 3 months, and 6 months. Secondary outcomes included changes in body weight, glycaemic, hepatic, and renal parameters, as well as safety and adherence. Data were statistically analysed using paired t tests and repeated ANOVA with significance set at $p<0.05$.

**Results:**
A total of 66 patients were enrolled, with 65 completing the 6-month follow-up. Dapagliflozin therapy resulted in a significant reduction in mean cfPWV from baseline to 6 months (mean difference: 321.36 m/s, $p<0.05$). Significant improvements were also observed in HbA1c, fasting plasma glucose, and body weight. No serious adverse events were reported; dapagliflozin was well-tolerated. Treatment adherence remained high throughout the study period.

**Conclusion:**
Dapagliflozin as add-on therapy significantly reduced arterial stiffness and improved metabolic parameters in T2DM patients over 6 months, with a favourable safety profile. These findings suggest a potential role for dapagliflozin in mitigating macrovascular risk in T2DM.

**Key Words:** Arterial stiffness, pulse wave velocity, PeriScope™ device, Dapagliflozin, Type 2 Diabetes Mellitus

**Association of scn1a [c>t] (rs3812718) chr:166053034 polymorphism with adverse drug reactions of phenytoin monotherapy in south indian population**

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**[2] Assistant Professor, Department of Pharmacology, JIPMER, Puducherry, India**

**Introduction**

Epilepsy represents a significant public health concern that affects around 50 million people worldwide. The SNP *SCN1A* [C>T] (rs3812718) encode for sodium channels, like Phenytoin's therapeutic action. Due to this, the polymorphisms might cause cortical hypometabolism and causes cognitive impairment, exaggerating the ADRs in the patient resulting from Phenytoin monotherapy. If there is an association found, then genetic testing before the start of ASMs will reduce the ADRs help in improving the quality of life. To evaluate the association between SCN1A [C>T] (rs3812718) polymorphism and the occurrence of adverse drug reactions of Phenytoin monotherapy.

**Methods:**

All patients attending the epilepsy clinic in JIPMER Pondicherry who met the inclusion criteria and were willing to give written informed consent were interviewed. At baseline visit, the demographic data, details about the anti-seizure medication, and ADRs related to Phenytoin and will be collected. 4 ml blood collected for estimating plasma drug levels and genotyping of SCN1A. Then the patients are followed up for a period of 6 months, monthly once for identifying ADRs. Data were analysed with SPSS 29.0

**Results:**

In our study, majority were males **(63.1%),** followed by females **(36.9%)**. Among the participants, **81.5%** have mutant genotypes (CT/TT) and **18.5%** had wild type genotype (CC). The Chi-square test and Pearson association between SCN1A and ADRs, OR (CI) of 0.347 (0.043-2.775) for overall ADRs, OR (CI) of 1.74 (0.775-3.906) for GI ADRs, OR (CI) of 0.867 (0.274-2.743) for CNS ADRs, OR (CI) of 1.007 (0.993-1.022) for misc. ADRs.

**Conclusion:**

Our study suggested that there is no significant association between SCN1A and ADRs of Phenytoin monotherapy. Hence genetic testing need not be included as a part of routine testing in epilepsy management.

**Evaluation of medication adherence and its factors to antidiabetic therapy among patients with type 2 diabetes mellitus**

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**Abstract:**

**Background:**

Type 2 Diabetes Mellitus (T2DM) has become a significant health issue that requires a multifaceted management. Failure to adhere to anti-diabetic medication led to inadequate glycemic control, which in turn raise the risk of developing chronic complications, as well as results in higher rates of hospitalization and mortality. The aim of the study was to evaluate the level of Adherence to anti–diabetic therapy and to determine the factors associated with adherence to anti diabetic therapy among Type 2 Diabetes Mellitus patients.

**Materials and methods:**

After obtaining IEC approval, this cross-sectional questionnaire study was carried out among T2DM patients in the Department of Pharmacology in collaboration with the Department of General Medicine for three months. Medication Adherence were accessed with Morisky 8 item Medication Adherence scale(MMAS-8) whose responses were recorded as yes -0, No – 1. Results were categorized as 0- High Adherence, 1 or 2-Moderate Adherence, ≥3-Low Adherence. Data was analyzed using SPSS Software version 29. Continuous data was expressed in mean and standard deviation. categorical data was expressed in proportions. Difference between groups was analyzed using"t" test.

**Results:**

118 Participants were enrolled in this study whose, mean age was 40 ±20 years with 65% female preponderance. only 10% of study participants had high adherence. Moderate adherence was reported by 19% of the participants. 64% of the participants had low adherence. 35% of low-adherence was caused by forgetfulness, while 20% was caused by a lack of funds.Poor family support - 40% was an added cause to non-adherence.

**Conclusion:**

According to the study, forgetfulness and a lack of funds were the main causes of T2DM patients' low-adherence. Therefore, family counseling should be a vital part of T2DM management in addition to individual counseling.

**Keywords:** T2DM, Mortality, MMAS -8, Adherence

**Comparing effectiveness of Ivabradine versus Beta-Blockers in Heart Failure: Insights from a Real-World Retrospective Study in India**

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**Background:**

Heart failure with reduced ejection fraction (HFrEF) is associated with high morbidity and mortality, with elevated resting heart rate (HR) predicting adverse outcomes. Beta-blockers remain standard

therapy, but ivabradine is an option when beta-blockers are contraindicated or insufficient. This study compared the real-world effectiveness and safety of ivabradine versus beta-blockers.

**Methods:**

A retrospective analysis was performed on 211 adult HFrEF patients (LVEF ≤40%) treated at a tertiary hospital between June 2022 and April 2024. Patients received either ivabradine (n=67) or a beta-blocker (n=144). Outcomes included HR control (≤70 bpm or ≥30% reduction), NT-proBNP change, and hospital readmissions. Data were analyzed using Wilcoxon tests and multivariable regression in R.

**Results:**

Both groups achieved significant HR reduction. Ivabradine produced a greater mean HR drop at 24 weeks (−13.59 vs. −7.79 bpm), while beta-blockers were associated with lower NT-proBNP levels (median 883 vs. 4685 pg/mL; p=0.026) and fewer readmissions. Adequate HR control rates were comparable.

**Conclusion:**

Ivabradine and beta-blockers both effectively reduce HR in HFrEF. However, beta-blockers confer superior biomarker improvement and prognostic benefit. Ivabradine remains a useful alternative in patients intolerant to beta-blockers.

## Effect Of Probiotic Supplementation On Hormonal Profile, Levels of Inflammatory Biomarkers and Oxidative Stress in Women with Polycystic Ovarian Syndrome – A Randomized Double-blind Placebo-controlled Trial

**Authors**
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**Abstract**

**Introduction:**
Polycystic ovarian syndrome (PCOS) is a prevalent endocrine disorder affecting reproductive-age women, characterised by hormonal imbalances, chronic low-grade inflammation, and oxidative stress. Growing evidence suggests that gut microbiota plays a role in PCOS pathogenesis, and probiotic supplementation may help regulate hormonal and metabolic disturbances. This study evaluates the effect of probiotics on serum testosterone, inflammatory biomarkers, and oxidative stress in women with PCOS.

**Methods:**
A randomized, double-blind, placebo-controlled trial was conducted at JIPMER, Puducherry, involving newly diagnosed PCOS women aged 18–45 years. Participants were randomized to receive either a multistrain probiotic supplement or a placebo for three months. Serum testosterone, high-

sensitivity C-reactive protein (hs-CRP), total antioxidant capacity (TAC), and malondialdehyde (MDA) were measured at baseline and post-intervention. Statistical analysis was performed using IBM SPSS software version 19.0, with a significance level $p<0.05$.

**Results:**
Probiotic supplementation significantly reduced serum testosterone levels with a median decrease of **11.3 ng/dL** (from 60.1 to 48.2 ng/dL; $p < 0.001$) compared to the placebo group (median change: −0.8 ng/dL (from 55.6 to 59.3; $p = 0.155$) by the Mann-Whitney test. However, no statistically significant differences were observed in inflammatory biomarkers (hs-CRP) or oxidative stress markers (TAC and MDA) between the groups.

**Conclusion:**
Probiotic supplementation significantly reduces serum testosterone levels in women with PCOS, indicating a potential role in managing hyperandrogenism. However, its effects on inflammation and oxidative stress remain inconclusive, warranting further long-term studies.

## Assessment of satisfaction and usage pattern of a hospital formulary mobile application among trainee doctors

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**Abstract**

**Objectives:**

To determine the overall satisfaction with the hospital formulary mobile application in providing prescribing drug information to the trainee doctors using a questionnaire. The secondary were to determine the frequency of application usage, categories of information searched, obtain feedback and determine the factors the promote the reuse of the application.

**Methodology:**

The junior residents and interns not satisfied with their current consulted sources were the participants. The overall satisfaction with the sources consulted was measured as a composite of five factors including usefulness, user-friendliness, reliability, ease of searching information, and improving confidence while prescribing. The prescribing information such as the indications, dosages, available dosage forms, adverse effects, drug interactions, instructions for patients, and precautions for use in special populations was compiled for hospital medications. The content was reviewed by subject experts followed by quality control and beta testing of the developed application. A questionnaire to assess the overall satisfaction was developed, validated and provided to participants at baseline and after two months of application usage.

**Results:**

Evaluation of the mobile application after two months of use revealed a statistically significant improvement in the overall satisfaction (P=0.003), usefulness (P<0.001), user-friendliness (P<0.001) and ease of finding drug information (P<0.001). Mobile application usage steadily increased over a period of two months (P<0.001). Accessibility (99.5%), provision of comprehensive information (65.6%) and search functionality (29.8%) were the top three factors that promoted the repeated use of this application.

**Conclusion:**

In providing ready drug information for prescribing, the hospital formulary mobile application improved the overall satisfaction of the users compared to their previous sources.

## Appropriateness of fixed-dose pegfilgrastim in breast cancer patients receiving doxorubicin–cyclophosphamide chemotherapy

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**Abstract**

**Introduction**

Pegfilgrastim (Peg-GCSF), given as a fixed 6 mg subcutaneous dose, is widely used to prevent chemotherapy-induced neutropenia. Doxorubicin–cyclophosphamide regimens in breast cancer often require G-CSF support due to myelosuppression. In a prior study (CTRI/2024/02/079274), nearly half of patients showed neutrophil decline despite Pegfilgrastim. This study compared BSA-normalized Peg-GCSF exposure (PGCSF/m²) between patients with rising and falling neutrophil counts post-chemotherapy.

**Methodology**

Absolute neutrophil counts from 30 breast cancer patients receiving doxorubicin (60 mg/m²) and cyclophosphamide (600 mg/m²) per cycle were analyzed. Patients were classified as Group 1 (fall in neutrophil count) or Group 2 (rise in neutrophil count) between cycles 2–4. Mean Peg-GCSF/m² values were compared using an independent samples t-test.

**Results**

The mean value of Peg-GCSF/$m^2$ value in group 1 (fall in neutrophil count) was 4.01 mg/$m^2$, and the mean value in group 2 (rise in neutrophil count) was 3.96 mg/$m^2$. Student's t-test revealed p-value = 0.764, signifying that the difference between the means of the groups was not statistically significant.

**Conclusion**

No significant difference in mean Peg-GCSF/m² values was observed between patients with rising versus falling neutrophil counts, supporting the appropriateness of fixed-dose Pegfilgrastim for neutropenia prophylaxis in breast cancer patients on AC chemotherapy. Variability in response may reflect multiple biological factors influencing neutrophil recovery. Findings should be interpreted cautiously due to the small sample size.

## "Beyond the Bones: A Protocol summary of a Systematic review of published Clinical trials of Vitamin D3 evaluating Its Extra-Skeletal Effectiveness and Optimal Dosage"

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**Abstract**

**Objective:**

To evaluate the comparative effectiveness of different doses of vitamin $D_3$ on diverse clinical outcomes in randomized controlled trials (RCTs).

**Methods:**

This prospectively registered systematic review (PROSPERO and CTRI) will include adult RCTs comparing any dose or frequency of vitamin $D_3$ with placebo or active comparators. Eligible outcomes include mortality, cardiovascular events, cancer biomarkers, and inflammatory and respiratory markers. A comprehensive database and trial registry search using MeSH terms and keywords was completed (latest search: 24 March 2025). Two independent reviewers with one verifier will extract study, participant, intervention, comparator, and outcome data using a standardized form. Risk of bias will be assessed using the Cochrane RoB 2 tool, and certainty of evidence rated using the GRADE framework. Meta-analysis will be conducted if feasible, with subgroup and sensitivity analyses to explore heterogeneity. RevMan software will be used for statistical analyses.

**Results:**

The study has applied for ethics-cum-scientific committee approval (exemption requested) and prospective CTRI registration; data extraction will commence thereafter.

**Conclusion:**

This systematic review once completed will help to bridge the evidence gaps by evaluating the comparative effectiveness of various vitamin D doses on diverse clinical outcomes, ultimately providing evidence-based guidance for clinicians and policymakers.

**Keywords:** Autoimmune diseases, Cardiovascular, Diabetes mellitus, Inflammatory Bowel Diseases, Vitamin D3

**Adverse Drug Reaction Profile: An Observational Study**

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**Abstract**

**Introduction:**
Adverse drug reactions (ADRs) are a significant concern for patient safety and healthcare systems. This study is aimed to describe the epidemiology, severity, and causality of ADRs reported at Hamdard Institute of Medical Sciences over a period of six months, with special focus on demographic and drug-related factors by retrospective cross-sectional studies.

**Methods:**
In this retrospective cross-sectional study, 90 ADR forms submitted during the period between November 2024 and April 2025 to the Institutional Pharmacovigilance Unit were analysed. Data on demographics, Anatomical Therapeutic Chemical (ATC), system organ classification, and causality (WHO-UMC criteria) were evaluated.

**Results:**
Among 90 ADRs, 58% occurred in females and 42% in males. Adults (14–60 years) accounted for 70% of cases. Serious reactions requiring hospitalization were seen in 13%. Dermatological events were most frequent (61%), followed by gastrointestinal (22%) and renal (17%). NSAIDs were the leading causative class (36%), with ibuprofen (22%) and diclofenac (13%) as key agents. Other common drugs included amoxicillin–clavulanic acid (17%) and metformin (11%).

ADRs were most commonly associated with drugs prescribed for pain/inflammation (28%), hypertension (22%), infection (20%), and diabetes (17%). Causality assessment classified 51% of reactions as “possible,” 28% “probable,” 16% “certain,” and 5% “unclassified.”

**Conclusion:**
Findings reflect the known predominance of dermatological ADRs and NSAID-related events. The moderate proportion of serious ADRs underscores the importance of robust pharmacovigilance. Limitations include retrospective design, single-center data, and dependence on voluntary reporting. Prospective multicenter studies are needed for broader insights and improved ADR detection.

**Keywords:**
Adverse Drug Reaction (ADR), Pharmacovigilance, Health care professionals, WHO-UMC

# POSTER PRESENTATION

**Development and Validation of Self-Administration Medication Error (SAME) tool**

**Anusha Natarajan, Bhargavi Kumar, Priyadharsini R**

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**Abstract**

**Introduction:**

Medication errors, especially self-administration, pose significant risks to patient safety and lead to adverse drug events (ADEs). Existing tools for medication error assessment primarily focus on provider-administered medications, not those administered by patients themselves. Hence this tool was developed. To develop & validate the SAME tool in patients of a tertiary care hospital

**Method:**

This cross-sectional, quantitative study was conducted at Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry, from May 2023 to April 2024. The tool was developed through a literature review and patient interviews, resulting in ten items evaluating various aspects of self-administration. Content validity was assessed by four experts using a 4-point Likert scale, and the Content Validity Index (CVI) was calculated. The tool was then tested on 100 adult patients with chronic diseases (e.g., diabetes, hypertension, cardiovascular diseases, epilepsy) attending the JIPMER pharmacy. Internal consistency was measured with Cronbach's alpha, and Pearson Product Moment Correlation analysis was used to assess validity.

**Results:**

The SAME tool demonstrated strong content validity, with all items achieving a CVI of ≥0.88 and an overall Scale-Level CVI (S-CVI) of 1.0. Cronbach's alpha was 0.815, indicating good internal consistency. Pearson correlation coefficients for individual items ranged from 0.492 to 0.740, all statistically significant ($p < 0.05$), confirming the tool's validity. The estimated prevalence of self-administration errors among participants was 17%, underscoring the need for effective assessment tools.

**Conclusion:**

The SAME tool is a reliable and valid instrument for identifying self-administration errors, highlighting its potential to enhance patient safety and improve medication management. Future research should explore its application across diverse healthcare settings.

**A cross-sectional observational study on knowledge, attitude, and practice towards hemovigilance among medical interns at a tertiary care hospital.**

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**Background:**

Blood transfusion is a lifesaving procedure that leads to serious adverse events. Hemovigilance program of India ensures safety Blood transfusion by monitoring every step of the process from donor to recipient. The Aim of the study was to access the knowledge, attitude and practice of Hemovigilance among CRMIs and to Evaluate the various causes of under reporting in a Tertiary care hospital.

**Materials and methods:**

After obtaining IEC approval, the nature and purpose of the study was explained to the study participants. This cross-sectional questionnaire study was conducted among MBBS interns (CRMIs) in Department of Pharmacology - Melmaruvathur Adhiparasakthi institute of medical sciences and research. The Duration of the study was 3 Months.117 CRMIs was provided with a sheet containing 20 –Pre validated questionnaire (Knowledge -10, Attitude -5, Practice -5) pertaining to Hemovigilance and 30 minutes was provided to them for answering. Data was analyzed using SPSS Software version 29. Continuous data was expressed as mean and standard deviation while, categorical data was expressed as Proportions. Difference between groups was accessed in “t” Test.

**Results:**

Knowledge regarding adverse events reporting was 75% whereas, 82 were aware that Reporting is Essential.63% of the study participants believed that blood transfusion is risk to the patient. 70% of the participants did not know where to report reaction leading to Underreporting.

**Conclusion:**

Although the health care Professionals had Good Knowledge and Attitude but the practice of reporting was only 50% leading to underreporting. Incorporation of Hemovigilance education in CRMIs Duty curriculum would enhance reporting of adverse effects due to Hemovigilance.

**Keywords:** Hemovigilance, Blood Transfusion, Knowledge, Attitude, Transfusion Reactions

## From Rash to Recovery: A Retrospective Study on Clinical Profile, Drug Associations and Outcomes of DRESS Syndrome

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**Abstract**

**Background:**

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) is a severe, delayed hypersensitivity reaction with diverse clinical features and potentially life-threatening systemic involvement. This study aimed to evaluate the clinical profile, causative drugs, systemic involvement, treatment outcomes, and prognostic factors in patients with DRESS.

**Methods:**

A retrospective observational study was conducted at a tertiary care teaching hospital in South India from January 2023 to May 2025. Twenty-eight patients diagnosed with DRESS based on RegiSCAR criteria were included. Clinical, laboratory, drug-related, and outcome data were analysed.

**Results:**

The mean age was 33.6 ± 20.8 years; 53.6% were male. Antibiotics (57.1%) were the most common culprits, followed by anticonvulsants (25%). Cutaneous manifestations were universal, and the liver was the most commonly affected organ (71%). Eosinophilia was present in 64.3%. Statistically significant associations were found between drug class and liver involvement, phenytoin use and multi-organ involvement, and RegiSCAR score and hospital stay. All patients recovered completely with corticosteroids.

**Conclusion:**

DRESS syndrome presents with varied clinical features and is most commonly induced by antibiotics in this cohort. Early diagnosis and corticosteroid therapy ensure favourable outcomes.

**Keywords**

*Drug Hypersensitivity Syndrome*, *Antibiotics*, *Phenytoin*, *Eosinophilia*, *Corticosteroids*.

**Comparative Evaluation of Netarsudil and Latanoprost Ophthalmic Solutions to Assess Their Efficacy and Safety in Newly – Diagnosed Primary Open Angle Glaucoma Patients – A Randomized Controlled Trial**

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**Abstract**

**Background:**

Primary open-angle glaucoma (POAG) is a leading cause of irreversible blindness. Effective

intraocular pressure (IOP) control is essential for managing POAG. This randomized, active-controlled, open-label study compared the efficacy and safety of Netarsudil, a rho-kinase inhibitor, with Latanoprost, a prostaglandin analogue, in newly diagnosed POAG patients.

**Objectives:**
To compare the mean change in IOP over 6 months of treatment between Netarsudil 0.02% and Latanoprost 0.005% ophthalmic solutions. Safety was assessed based on adverse events, and changes in visual fields were also evaluated at 6 months.

**Methods:**
Sixty-five patients were randomized to receive either Latanoprost (n=33) or Netarsudil (n=32). IOP was measured at baseline, 2 weeks, 4 weeks, 4 months, and 6 months. Visual field progression was monitored at 6 months.

**Results:**
Both drugs significantly reduced IOP ($p<0.0001$ in both groups). Netarsudil exhibited a quicker IOP reduction at 2 weeks ($p=0.0002$), while Latanoprost provided more sustained IOP control over 6 months ($p=0.0027$). Visual field changes were minimal and comparable between the two groups ($p=0.064$ and 0.26 for Latanoprost and Netarsudil, respectively). Netarsudil was associated with more adverse drug reactions (6 vs 2 in Latanoprost group), mainly conjunctival hyperaemia, but no serious systemic ADRs were observed.

**Conclusion:**
Both Netarsudil and Latanoprost effectively reduced IOP in newly diagnosed POAG patients. Netarsudil demonstrated a quicker onset, while Latanoprost provided superior long-term IOP control. These findings support individualized treatment strategies based on the urgency of IOP reduction and patient tolerance. Further studies are needed to assess long-term outcomes in diverse populations to optimize POAG management.

## Unveiling the Recent Trends: Therapeutic Drugs Monitoring of Antiepileptic drugs in Western India's Tertiary Care Hospital

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**Abstract**

**Introduction:** The primary goal of epilepsy management is to completely eradicate the disease without causing much adverse effects. However, physicians are not achieving this despite availability of anti-seizure medicines and therapeutic drug monitoring services. Objective was to evaluate three years' time-trend of ASMs use and primarily comparing TDM requisitions for older versus newer ASMs.

**Methods:** This is an analytical, observational time-trend analysis of TDM services. The author retrospectively assessed TDM records of 122 statistically computed patients receiving a total of 448

ASMs over a years from January 2019 to December 2021 stored in the department. Z-test, Chi-square test for trend, and trendline were plotted to establish the trend.

**Results:** A Significant portion of the sample comprised older ASMs (252 out of 448, 56.25% (95% C.I. 14 46-65%)). Comparison between monotherapy and polytherapy showed a statistically significant difference ($p<0.05$) with a trend for polytherapy. The minimum number of ASMs used in polytherapy was two, prescribed to 43.24% of PWEs. Of the two ASMs combined, the commonest combination was of phenytoin and levetiracetam, prescribed to 31.25% of patients receiving two ASMs. The maximum number of ASMs prescribed to patients was five, and seen in 2/74 of patients receiving polytherapy. Eighteen % of referrals cited therapeutic failures, with four ADRs documented at the therapeutic level.

**Conclusion:**

Time-trend analyses of ASMs showed that in between 2019 and 2021 there was rising trend for use of newer ASMs. Overall, TDM requisitions for older drugs were more in number than newer drugs. Majority were treated with more than one ASMs and seizure control was satisfactory with few ADRs documented.

**Keywords:** Carbamazepine, Epilepsy, Phenobarbital, Phenytoin, Time trend analysis

## Effectiveness of offline tools in identifying inappropriate prescriptions for the elderly in a tertiary care teaching hospital in Central India: A retrospective study

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**Abstract**

**Background:**
Inappropriate prescribing among the elderly remains a pressing concern due to age-related pharmacokinetic and pharmacodynamic changes, polypharmacy, and a high burden of comorbidities - leading to increased risks of adverse drug reactions, hospitalizations, and healthcare costs.

**Objectives:**
To evaluate the effectiveness of established offline screening tools - Beers Criteria, STOPP (Screening Tool of Older Persons' Prescriptions), and START (Screening Tool to Alert to Right Treatment) - in identifying potentially inappropriate prescriptions (PIPs) and potential prescribing omissions (PPOs) among elderly inpatients at a tertiary care teaching hospital in Central India.

**Methodology:**

A retrospective review of 295 elderly inpatients (≥60 years) from Medicine, Cardiology, and Nephrology (2018–2020) was conducted. Prescriptions with >5 drugs were assessed using STOPP, START, and 2019 Beers Criteria.

**Results:**
The cohort (n=100) had a mean age of 66.1±5.99 years, with 63% males. Patients received an average of 12.17±4.88 medications per prescription (total 291 drugs). Across 1051 potentially inappropriate prescribing (PIP) encounters, Beers Criteria detected the highest proportion (29%), followed by STOPP (18%) and START (5%). The most frequent potentially inappropriate medication (PIM) was pantoprazole (73%), followed by benzodiazepines and diuretics. STOPP Criteria flagged prolonged PPI use, benzodiazepines (fall risk), and first-generation antihistamines (anticholinergic burden). START Criteria revealed prescribing omissions, most commonly beta-blockers in ischemic heart disease (12%) and statins in cardiovascular disease (6%).

**Conclusion:**
Offline tools effectively identify prescribing issues in the elderly. Beers Criteria was particularly sensitive in detecting PIMs. Incorporating such tools into routine practice may enhance geriatric pharmacotherapy and inform the development of India-specific prescribing guidelines.

**Keywords:**
Inappropriate prescribing, elderly, polypharmacy, STOPP/START criteria, Beers Criteria, retrospective analysis, Indian geriatric care