JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
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# CLINICAL PHARMACY NEWSLETTER

*A Newsletter of Drug and Prescribing Information*

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**INSIDE THIS ISSUE**


| CONTENTS | Pg. No |
|---|---|
| Model Infoemed Precision Dosing MIPD | 1 - 2 |
| Inhalable Oxytocin - A Potential Treatment Option for Postpartum Haemorrhage | 2 |
| DRUG PROFILE TIRZEPATIDE | 3 |
| Tirzepatide once weekly reported to cause exceptional weight loss | 4 |
| Event Corner | 4 - 5 |
| Publications from the Department of Pharmacy Practice | 6 |
| Alumni Interaction Series | 6 |
| Academic Expert Interaction Series | 7 |


## *Model Informed Precision Dosing (M I P D)*

It is the documented fact that the success rate of the different treatment options across various diseases ranges as high as 62 % and as low as 25 %. Thus, when the patients are treated with empirical dosing, three types of outcomes are generally possible viz. responders, non-responders, and toxic responders, but the proportion varies from one disease to the others. This is because 'One Size Does Not Fit All'. i.e., one dose does not fit all patients since the so called 'therapeutic window' and 'therapeutic index' are only the probability or generalization derived from the clinical trials in which a very few numbers and less diversified patient cohort is studied compared to the real time patient cohort. There are several factors such as biological, environmental, and cultural which significantly influence or alter the pharmacokinetic / pharmacodynamic profiles of the drugs.

This understanding paved the way to 'Precision Medicine', which was also synonymously referred as 'Personalized Medicine' and 'Individualized Medicine'. The term precision medicine became more popular only after the Precision Medicine Initiative announced in USA in 2015 which fueled new research programs that have been embraced by global regulatory agencies, major research centers and the pharmaceutical industries. NIH defined Precision Medicine (PM) as "an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person". There are two major segments in PM viz. identifying a population subgroup who are responders and non-responders and defining better dosage regimen for those two subgroups. The number of drugs approved number of molecules in the drug development & the global market associated with PM are steadily increasing year on year.

The process of PM has three stages such as setting the specific target range for a specific population / individual, hitting the target as precisely as possible using a precision dose (PD) and optimize the treatment outcome with minimal risk. PD utilizes the information pertaining to drug attributes (e.g., narrow therapeutic index (NTI), PK-PD variability); disease state characteristics (e.g., extent of morbidity) and patient-specific factors (e.g., organ function, genetic polymorphism) to optimize the drug therapy. Thus, PD is applying the PM concepts at the bed side / clinic to individual patients' treatment outcomes and there are many overlapping characteristics between both.

Model informed precision dosing (MIPD) is all about using the information technology for precision dosing. MIPD is defined as the use of computer based mathematical modeling and simulation (M&S) to predict a drug dosage regimen that is most likely to yield a better benefit-to-harm balance than traditional dosing in patients, based on their individual characteristics. In case of empirical dosing, the prescribers are guided by their in-cerebro bio simulation whereas in MIPD they are guided by in-silico simulations. Hence, it is important for the prescribing team the skill sets in newer technology and their applications for implementing MIPD.

One of the simple frameworks proposed for MIPD is to feed the patients' clinical characteristics, drug dosing history and disease status through lab data & biomarkers as input for modelling and simulation using Bayesian technique along with the understanding of individual PK/PD to determine the optimal dosing regimen. The Bayesian technique use the priori and current data to predict the posterior data. MIPD generally requires custom-made software tools since conventional modeling software are too cumbersome for most practicing healthcare providers to learn and apply. Few of such software tools available for MIPD meet the needs of both research and clinical.

The key strengths of MIPD include decrease in frequency of hospital admissions, length of hospital stay, frequency of speciality visits, incidence of ADRs and health expenditure. The weaknesses of MIPD are lack of understanding that it is only a guide or tool not the end point, interdisciplinary collaboration, evidence-based efficacy, cost-benefit analysis in healthcare. Such weaknesses of the process give the opportunities for the widespread application of MIPD by increased engagement between the modelers and clinicians, harmonization of PK data collection, analysis, reporting and effective communication on the value of MIPD by modelers to key healthcare stakeholders. However, the following challenges have to be addressed for the successful implementation of MIPD, viz., selecting a model that matches the intended population, published models did not perform well for individual patients, challenged by patients with more "extreme" PK/PD characteristics than expected and handling of the inter-occasion variability arising from the time -varying nature of individual patient physiology and PK-PD.

There is a wide recognition for MIPD from all the stakeholders viz. pharmaceutical companies, regulators, clinicians, and patients, but at the same time it is not necessary to apply to every drug and or patient. A clear guideline about MIPD based on the need assessment should be made by the healthcare community. It is accepted that MIPD will result in improved health outcomes and reduced economic burden.

Since there is an amalgamation of science and technology, MIPD requires a multidisciplinary team to succeed. Such success is already demonstrated in the field of oncotherapy and will be applicable to the other specialities as well. The continued evolution of computer technology, regulatory policy, and clinician adoption may allow precision drug dosing to transform the standard of care for other diseases

Some of the important future perspectives about MIPD are: Patient characterization will go beyond genetics and address proteomics and other elements defining the biology and physiology at each stage of health and disease for each patient. Artificial intelligence and machine learning are entering the arena of precision dosing that could be a potential game changer for utilization of real-world patient and health-care data. The integration of Clinical Decision Support System (CDSS) with MIPD and electronic health records is important for enabling widespread use. Evidence generation & implementation of MIPD in health care require multidisciplinary collaboration between health care, academia, regulators, patients, and other key stakeholders.

To conclude, the empirical dosing had an approach of administering a fixed dose resulting in significantly variable plasma concentration & PK profiles and extremely variable clinical outcomes. When the TDM was introduced in clinical decision-making process, the pharmacokinetic dosing had a fixed concentration range with significant variability in dosing and reduced variability in the clinical outcomes. But, now in MIPD, it is advocated to fix the desired clinical outcome and accordingly the plasma concentration & PK parameters shall significantly vary and thus there will be an extreme variation in the dosing among individuals based on their characteristics.

**Further Readings:**


1. Darwich AS, Ogungbenro K, Vinks AA, Powell JR, Reny JL, Marsousi N, Daali Y, Fairman D, Cook J, Lesko LJ, McCune JS, Knibbe C, de Wildt SN, Leeder JS, Neely M, Zuppa AF, Vicini P, Aarons L, Johnson TN, Boiani J, Rostami-Hodjegan A. Why has model-informed precision dosing not yet become common clinical reality? lessons from the past and a roadmap for the future. Clin Pharmacol Ther. 2017;101(5):646-656.

2. Darwich AS, Polasek TM, Aronson JK, Ogungbenro K, Wright DFB, Achour B, Reny JL, Daali Y, Eiermann B, Cook J, Lesko L, McLachlan AJ, Rostami-Hodjegan A. Model-Informed Precision Dosing: Background, Requirements, Validation, Implementation, and Forward Trajectory of Individualizing Drug Therapy. Annu Rev Pharmacol Toxicol. 2021;61:225-245.

3. Franziska Kluwe, Robin Michelet, Anna Mueller-Schoell, Corinna Maier, Lena Klopp-Schulze, Madelé van Dyk, Gerd Mikus, Wilhelm Huisinga and Charlotte Kloft. Perspectives on ModelInformed Precision Dosing in the Digital Health Era: Challenges, Opportunities, and Recommendations. Clinic.Pharm.Therap. 2020.

4. Kantasiripitak W, Van Daele R, Gijsen M, Ferrante M, Spriet I, Dreesen E. Software Tools for Model-Informed Precision Dosing: How Well Do They Satisfy the Needs? Front Pharmacol. 2020 May 7;11:620. doi: 10.3389/fphar.2020.00620. PMID: 32457619; PMCID: PMC7224248.

5. Kluwe, Franziska, et al. "Perspectives on model-informed precision dosing in the digital health era: challenges, opportunities, and recommendations." Clinical Pharmacology & Therapeutics 109 (2021): 29-36.

6. Maier C, de Wiljes J, Hartung N, Kloft C, Huisinga W. A continued learning approach for model-informed precision dosing: Updating models in clinical practice. CPT Pharmacometrics Syst Pharmacol. 2022;11(2):185-198.


## *Inhalable Oxytocin - A Potential Treatment Option for Postpartum Haemorrhage*

Postpartum haemorrhage (PPH), defined as blood loss of 500 ml or more within 24 h of childbirth, is responsible for one fift all maternal deaths and is the leading cause of maternal mortality globally. According to the World Health Organization (WHO), around 60,000 women die from Postpartum Haemorrhage (PPH) each year, 99 % of whom are in the developing world. PPH incidence in India is 2%-4% following vaginal delivery and 6% following caesarean section. PPH as the important cause of 19.9% of maternal mortality in India. About 75 to 90% of PPH cases are caused by uterine atony. Almost 60-70% of atonic.

The WHO recommends provision of prophylactic uterotonics for every woman during the third stage of labour. Five drugs are available for PPH prevention: oxytocin, carbetocin, ergometrine, misoprostol, and prostaglandin. These lives could be saved by administering oxytocin to mothers immediately after they have given birth. The WHO endorses oxytocin (10 IU) delivered intravenously or intramuscularly to prevent PPH. Injectable form of oxytocin is available and currently in use. Recently, an innovative, heat-stable powder formulation of oxytocin was developed that, when inhaled, aims to provide the same protection against PPH as an intramuscular (IM) injection, the current global standard.

Injectable oxytocin requires supply and storage under refrigerated conditions, and trained personnel need to administer the product to ensure safety. This restricts its accessibility in resource-limited countries.

An inhalable oxytocin in dry powder form is expected to eliminate the need for refrigeration, as well as expand its reach and ease-of-administration by frontline health workers, birth attendants and potentially mothers themselves.

Responses to an inhaled oxytocin product were predominantly positive, and expressions of praise or willingness to accept this type of product were voiced in almost all FGDs and IDIs conducted across all regions and amongst all participant groups in this study. Most healthcare providers and policy makers described the heat stability as a the most significant benefit of an oxytocin inhaler. Amongst community members, an inhaler may be accepted as more advantageous than the current injection, as inhaled medications were generally viewed as fast-acting and easy to use. In contrast, injections were often described as less favoured due to pain and infection-related side effects. Ease of product use and heat-stability were the most significant anticipated advantages of an oxytocin inhaler cited by all stakeholders, who largely expressed a willingness to accept and use this type of product as long it had equivalent efficacy to the injection.

The majority of PPH-related morbidity and mortality are preventable through the effective implementation of evidence-based guidelines. These new WHO recommendations guide skilled health personnel and other stakeholders on how best to use uterotonics to prevent PPH in women giving birth in facility or community settings in high-income, middle-income or low-income countries. To implement these recommendations, personnel need effective, quality-certified uterotonics, and the necessary training, equipment and support to ensure that all women have access to good-quality PPH prevention and management care at birth.

**Further Reading:**


• Carvalho N, Hoque ME, Oliver VL, Byrne A, Kermode M, Lambert P, McIntosh MP, Morgan A. Cost-effectiveness of inhaled oxytocin for prevention of postpartum haemorrhage: a modelling study applied to two high burden settings. BMC medicine. 2020;18(1):1-8.

# DRUG PROFILE

## TIRZEPATIDE

**Class:**
Glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist

**Indication:**
An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

**Mechanism of Action:**
Tirzepatide is a GIP receptor and GLP-1 receptor agonist. It is a 39-amino-acid modified peptide with a C20 fatty diacid moiety that enables albumin binding and prolongs the half-life. Tirzepatide selectively binds to and activates both the GIP and GLP-1 receptors. Tirzepatide enhances first- and second-phase insulin secretion, and reduces glucagon levels, both in a glucose dependent manner. GIP is an incretin hormone that induces insulin secretion in response to a meal (primarily by hyperosmolarity of glucose in the duodenum) to facilitate the metabolism of carbohydrates, fats, and proteins. GLP-1 receptor agonists increase insulin secretion in the presence of elevated blood glucose, suppress glucagon postprandially, delay gastric emptying to decrease postprandial glucose, and decrease glucagon secretion. Pharmacodynamic effects observed include lower fasting and postprandial glucose concentration, decreased food intake, and reduced body weight.

**Dosage form and Administration:**
Tirzepatide is available as injection which is clear, colorless to slightly yellow solution available in pre-filled single-dose pens available in the following strengths:

- 2.5 mg/0.5 mL
- 5 mg/0.5 mL
- 7.5 mg/0.5 mL
- 10 mg/0.5 mL
- 12.5 mg/0.5 mL
- 15 mg/0.5 mL

Tirzepatide should be stored in a refrigerator at 2°C to 8°C (36°F to 46°F). If needed, each single-dose pen can be stored unrefrigerated at temperatures not to exceed 30°C (86°F) for up to 21 days. Drug should not be used if stored in freezer.

Tirzepatide can be administered once weekly, any time of the day with or without meals. It should be injected subcutaneously in the abdomen, thigh, or upper arm. It is suggested to rotate injection sites with each dose. When Tirzepatide is used along with insulin, it should be administered as separate injections and never mixed. It is acceptable to inject Tirzepatide and insulin in the same body region, but the injections should not be adjacent to each other

The recommended starting dosage of Tirzepatide is 2.5 mg injected subcutaneously once weekly. The 2.5 mg dosage is for treatment initiation and is not intended for glycemic control. After 4 weeks, Tirzepatide can be increased to 5 mg injected subcutaneously once weekly. If additional glycemic control is needed, dose can be increased in 2.5 mg increments after at least 4 weeks on the current dose. The maximum dosage is 15 mg injected subcutaneously once weekly.

If a dose is missed, patients should be instructed to administer injection as soon as possible within 4 days (96 hours) after the missed dose. If more than 4 days have passed, patients should be instructed to skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

**Pharmacokinetics:**
The pharmacokinetics of Tirzepatide is similar between healthy subjects and patients with type 2 diabetes mellitus. Steady state plasma Tirzepatide concentrations were achieved following 4 weeks of once weekly administration. Following subcutaneous administration, time to maximum plasma concentration of Tirzepatide ranges from 8 to 72 hours. The mean absolute bioavailability of Tirzepatide following subcutaneous administration is 80%. Similar exposure was achieved with subcutaneous administration in the abdomen, thigh, or upper arm.

The mean apparent steady-state volume of distribution of Tirzepatide following subcutaneous administration in patients with type 2 diabetes mellitus is approximately 10.3 L. Tirzepatide is highly bound to plasma albumin (99%). Apparent population mean clearance of Tirzepatide is 0.061 L/h with an elimination half-life of approximately 5 days.

Tirzepatide is metabolized by proteolytic cleavage of the peptide backbone, beta-oxidation of the C20 fatty diacid moiety and amide hydrolysis. The primary excretion routes of Tirzepatide metabolites are via urine and feces. Intact tirzepatide is not observed in urine or feces.

**Contraindications:**
Tirzepatide is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome. Tirzepatide is contraindicated in patients with known serious hypersensitivity to Tirzepatide or any of the excipients in dosage form.

**Precautions:**

- Pancreatitis: Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists. Health care professionals should monitor the patients for any symptoms of pancreatitis.
- Hypoglycemia with concomitant use of Insulin Secretagogues or Insulin: Patients receiving Tirzepatide in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia.
- Hypersensitivity reactions: Hypersensitivity reactions have been reported with Tirzepatide in clinical trials (e.g., urticaria and eczema) and were sometimes severe. If hypersensitivity reactions occur, patients should be discontinued with drug and treated promptly as per standard of care, and monitor until signs and symptoms resolve
- Acute Kidney Injury: Tirzepatide has been associated with gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhea. These events may lead to dehydration, which if severe could cause acute kidney injury.
- Diabetic Retinopathy Complications in Patients with a history of Diabetic Retinopathy: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Tirzepatide has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.
- Acute Gallbladder disease: Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and post marketing.

**Drug Interactions:**

- Concomitant use with an Insulin secretagogue (Eg: sulfonylurea) or with Insulin: When initiating Tirzepatide, physicians should consider reducing the dose of concomitantly administered insulin secretagogues or insulin to reduce the risk of hypoglycemia.
- Tirzepatide delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Tirzepatide.
- Health care professionals should monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Tirzepatide.

**REFERENCES:**


o Highlights of Prescribing information, from USFDA website: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf

o Lilly Pharmaceuticals maintained separate website for Tizepatide (Brand name: Mounjaro): https://www.mounjaro.com/

## Tirzepatide once weekly reported to cause exceptional weight loss

Tirzepatide, developed by Lilly, has recently been approved in the United States for the treatment of type 2 diabetes under the brand name Mounjaro. Tirzepatide is the first agent on the US market from a novel class of dual-incretin agonists, with a molecular structure engineered to activate both the glucagon-like protein-1 (GLP-1) receptor and glucose-dependent insulinotropic polypeptide (GIP), the two predominant incretins in the human gut. This combined activity has led to the "twincretin" nickname for Tirzepatide.

Not only for the diabetes, Tirzepatide was found to be effective in reducing body weight in obese participants as well. Obesity which is a chronic disease that results in substantial global morbidity and mortality. The efficacy and safety of Tirzepatide, a novel glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 receptor agonist, in people with obesity are not known. In a phase 3 double-blind, randomized, controlled trial. Investigators assigned 2539 adults with a body-mass index (BMI; the weight in kilograms divided by the square of the height in meters) of 30 or more, or 27 or more and at least one weight-related complication, excluding diabetes, in a 1:1:1:1 ratio to receive once-weekly, subcutaneous Tirzepatide (5 mg, 10 mg, or 15 mg) or placebo for 72 weeks, including a 20-week dose-escalation period. Coprimary end points were the percentage change in weight from baseline and a weight reduction of 5% or more. The treatment-regimen estimand assessed effects regardless of treatment discontinuation in the intention-to-treat population.

The study reported that at baseline, the mean body weight was 104.8 kg, the mean BMI was 38.0, and 94.5% of participants had a BMI of 30 or higher. The mean percentage change in weight at week 72 was −15.0% (95% confidence interval [CI], −15.9 to −14.2) with 5-mg weekly doses of Tirzepatide, −19.5% (95% CI, −20.4 to −18.5) with 10-mg doses, and −20.9% (95% CI, −21.8 to −19.9) with 15-mg doses and −3.1% (95% CI, −4.3 to −1.9) with placebo (P<0.001 for all comparisons with placebo). The percentage of participants who had weight reduction of 5% or more was 85% (95% CI, 82 to 89), 89% (95% CI, 86 to 92), and 91% (95% CI, 88 to 94) with 5 mg, 10 mg, and 15 mg of Tirzepatide, respectively, and 35% (95% CI, 30 to 39) with placebo; 50% (95% CI, 46 to 54) and 57% (95% CI, 53 to 61) of participants in the 10-mg and 15-mg groups had a reduction in body weight of 20% or more, as compared with 3% (95% CI, 1 to 5) in the placebo group (P<0.001 for all comparisons with placebo). Improvements in all prespecified cardiometabolic measures were observed with Tirzepatide. The most common adverse events with Tirzepatide were gastrointestinal, and most were mild to moderate in severity, occurring primarily during dose escalation. Adverse events caused treatment discontinuation in 4.3%, 7.1%, 6.2%, and 2.6% of participants receiving 5-mg, 10-mg, and 15-mg Tirzepatide doses and placebo, respectively.
Study finally concluded that withIn the 72-week trial in participants with obesity, 5 mg, 10 mg, or 15 mg of Tirzepatide once weekly provided substantial and sustained reductions in body weight.

**References:**


• Jastreboff AM, Aronne LJ, Ahmad NN, Wharton S, Connery L, Alves B, Kiyosue A, Zhang S, Liu B, Bunck MC, Stefanski A. Tirzepatide Once Weekly for the Treatment of Obesity. New England Journal of Medicine. 2022.

• Mitchel L Zoler. Tirzepatide Powers 'Unprecedented' Weight Loss in Obesity Trial. Medscape Pharmacist. Available from : https://www.medscape.com/viewarticle/975061#vp_3


## EVENT CORNER

• Dr K P Arun, Associate Professor, Department of Pharmacy Practice acted as resource person and delivered talk on 'Education empowerment for first generation Students' during the 'Symposium on Impactful Education and Sustainable Development Goals' organized by Howard University College of Pharmacy & JSS academy of Higher Education & Research on 6th April 2022.

• Dr G K Sadagoban, Asst. Professor, Department of Pharmacy Practice acted as resource person and delivered a talk on 'Pharmacist's Role in Disease Prevention and Health Maintenance' during the 'Symposium on Impactful Education and Sustainable Development Goals' organized by Howard University College of Pharmacy & JSS academy of Higher Education & Research on 6th April 2022.

• Mr Vishwas H N, Lecturer, Department of Pharmacy Practice participated in the event, 'Impactful Education and Sustainable Development Goals' organized by Howard University, USA & JSS Academy of Higher Education & Research, Mysuru on 6th & 7th April, 2022.

• Dr Swathi Swaroopa Borra, Asst. Professor, Department of Pharmacy Practice participated '4-day virtual Workshop at WCOP-Pharmacometric Modeling & Simulation with PUMAS -2022' sponsored by University of Maryland, Baltimore on 7th to 10th April 2022.

• Dr. Keerthana C, Mr Vishwas H N, Dr J Jeyaram Bharathi, Faculty, Department of Pharmacy Practice participated in virtual Guest Lecture on "Mindful Eating : A Satisfying Strategy in Healthy Living and Diabetes Management - Eat Right Not Less" organized by JSS Academy of Higher Education and Research, Mauritius on 8th April 2022.

• Dr J Jeyaram Bharathi, Resident, Department of Pharmacy Practice participated in the event 'Marketing Yourself: Resume Writing & Interview Tips' organized by IPGA, Kerala Branch on 10th April, 2022.

• Dr S Ponnusankar, Dr K P Arun, Dr Deepalakshmi M, Mr Vishwas H N, Faculty, Department of Pharmacy Practice participated in "Faculty development program cum workshop on 'Psychological skills for Effective Teaching & Learning'" organized by JSS Dental College & Hospital, JSS Academy of Higher Education & Research, Mysuru on 12th April 2022.

• Dr Swathi Swaroopa Borra, Asst. Professor, Department of Pharmacy Practice participated in the introductory session 'Finding the Leader in You (FLY) Program' organized by Project Dontabhaktuni on 12th April 2022.

• Dr J Jeyaram Bharathi, Resident, Department of Pharmacy Practice participated in "9th International Congress of Society for Ethnopharmacology, India – SFEC 2022" organized by JSS College of Pharmacy, Mysuru between 22nd to 24th April 2022.

• Dr G K Sadagoban, Asst. Professor, Department of Pharmacy Practice participated in the event, 'BLAZE - JSS AHER Innovation Pitching and Takeoff Platform' organized by SPARKLE CINE Foundation of JSS Academy of Higher Education & Research, Mysuru during April 2022.

• Dr G K Sadagoban, Asst. Professor, Department of Pharmacy Practice participated in the event, 'Role of Simulation in Improving Quality of Patient Care' organized by Special Interest Group Patient Management Care – JSS Medical College, Mysuru during April 2022.

• Dr M Deepalakshmi, Asst Professor, Department of Pharmacy Practice received financial assistance of Rs. 0.40 Lakhs from CSIR and JSS Academy of Higher Education & Research, Mysuru for organizing two-day Seminar On ''Capacity Building For Menstrual Hygiene Management among Adolescent School Girls including Tribes at Nilgiris District'' and successfully conducted on 25th & 26th April, 2022.

• Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice acted as resource person and delivered a talk on 'The Impact of Menopausal Symptoms on Quality of Life' during the three days Health Awareness Workshop on "Community -centered approaches for the management of maternal health & urinary tract infections among the rural women of Nilgiris" organized by Department of Pharmaceutical Chemistry, JSS College of Pharmacy, Ooty. Event was sponsored by DST-SERB, Govt. of India, New Delhi along with CSIR-HRDG, Govt. of India, New Delhi & JSS Academy of Higher Education & Research, Mysuru on 7th to 9th April 2022. The event was conducted at Masinagudi Village, The Nilgiris, Tamil Nadu.

## EVENT CORNER

• Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice acted as resource person and delivered a talk on 'Educating the Girls and women about what is menstruation and how the menstruation cycle works' during Two days Seminar on 'Capacity Building for Menstrual Hygiene Management among Adolescent School Girls including Tribes at Nilgiris District' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty. The event was sponsored by CSIR-HRDG, Govt. of India, New Delhi & JSS Academy of Higher Education& Research, Mysuru on 25th & 26th April, 2022.Event was conducted at Manjakombai Hatty & Nedungalkombai Hatty, The Nilgiris, Tamil Nadu.

• Dr. Keerthana C, Resident, Department of Pharmacy Practice participated as resource person and delivered a talk on 'Drugs, Lifestyle Modifications and Non-pharmacological approach on Maternal health' during the three days Health Awareness Workshop on "Community -centered approaches for the management of maternal health & urinary tract infections among the rural women of Nilgiris" organized by Department of Pharmaceutical Chemistry, JSS College of Pharmacy, Ooty. Event was sponsored by DST-SERB, Govt. of India, New Delhi along with CSIR-HRDG, Govt. of India, New Delhi & JSS Academy of Higher Education & Research, Mysuru on 7th to 9th April 2022. The event was conducted at Masinagudi Village, The Nilgiris, Tamil Nadu.

• Dr. Keerthana C, Resident, Department of Pharmacy Practice participated as resource person and delivered a talk on 'Providing Adolescent Girls with Menstrual Hygiene Management Choices' during the Two days Seminar on 'Capacity Building for Menstrual Hygiene Management among Adolescent School Girls including Tribes at Nilgiris District' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty. The event was sponsored by CSIR-HRDG, Govt. of India, New Delhi & JSS Academy of Higher Education& Research, Mysuru on 25th & 26th April, 2022. Event was conducted at Manjakombai Hatty & Nedungalkombai Hatty, The Nilgiris, Tamil Nadu.

• Dr. Aneena Suresh, Asst. Professor, Department of Pharmacy Practice participated as resource person and delivered a talk on ' Importance of safe menstrual hygiene practices and disposal of menstrual waste' during the Two days Seminar on 'Capacity Building for Menstrual Hygiene Management among Adolescent School Girls including Tribes at Nilgiris District' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty. The event was sponsored by CSIR-HRDG, Govt. of India, New Delhi & JSS Academy of Higher Education& Research, Mysuru on 25th & 26th April, 2022.Event was conducted at Manjakombai Hatty & Nedungalkombai Hatty, The Nilgiris, Tamil Nadu.

• Dr J Jeyaram Bharathi, Resident, Department of Pharmacy Practice participated and delivered a talk on 'An overview on Government policies to promote Reproductive and Child Health' during two days health awareness workshop on "Community-centered approaches for the management of maternal health & urinary tract infections among the rural women of Nilgiris" organized by JSS College of Pharmacy, Ooty at Masinagudi village on 07th April 2022.

• Dr M Deepalakshmi, Dr B S Roopa, Asst. Professor, Department of Pharmacy Practice acted as a 'Reviewer of Manuscript' for three manuscripts in 'Journal of Pharmacy Practice'

• Dr G K Sadagoban, Asst. Professor, Department of Pharmacy Practice acted as a 'Reviewer of Manuscript' for a manuscript in 'Journal of Clinical Pharmacy and Therapeutics'

• Mr. Vishwas H N, Lecturer, Department of Pharmacy Practice acted as a 'Reviewer of Manuscript' for 'Journal of Applied Pharmaceutical Sciences'

• Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in the event 'I- DECON 2022' organized by Endocrine Society of India and Sri Ramakrishna Hospital, Coimbatore between 11th & 12th June 2022.

• Dr. M. Deepalakshmi, Asst. Professor, Department of Pharmacy Practice participated in CPE Programme On "Effective Presentation Skills" organized by Department of Pharmaceutical Chemistry, PSG College of Pharmacy, Coimbatore between 20th to 24th June 2022.

• Dr. Mohsina Hyder, Lecturer, Department of Pharmacy Practice participated in the webinar on 'Sample size Made Easy- Diagnostic Accuracy Studies' organized by Department of community and family medicine, AIIMS, Patna on 14th June 2022.

• Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated as Resource person and delivered a talk on 'Effect of interventional strategies on insulin resistance in prediabetes-An open label prospective multicentre study' during the 'I-DECON 2022' organized by Endocrine Society of India and Sri Ramakrishna Hospital, Coimbatore between 11th & 12th June 2022.

• Dr KP Arun, Associate Professor, Department of Pharmacy Practice acted as resource person and delivered a talk on 'Model Informed Precision Dosing- An Overview' at National College of Pharmacy, Kozhicode, Kerala on 8th June 2022.

• Dr KP Arun, Associate Professor, Department of Pharmacy Practice acted as resource person and delivered a talk on 'Model Informed Precision Dosing- An Overview' at Al Shifa College of Pharmacy, Malapuram, Kerala during June 2022.

• Dr.M.Deepalakshmi, Asst. Professor, Department of Pharmacy Practice acted as resource person and delivered a talk on 'IPE: Need in Health Sciences' during the CPE Programme On "Effective Presentation Skills" organized by Department of Pharmaceutical Chemistry, PSG College of Pharmacy, Coimbatore between 20th to 24th June 2022.

• Dr Keerthana C, Resident, Department of Pharmacy Practice acted as a resource person and delivered a talk on 'Guide and help others to overcome' during the event 'Gender Sensitization & Prevention of Sexual Harassment Awareness for Rural and Tribal People in the Nilgiris District'organized by Department of Pharmaceutical Chemistry, JSS College of Pharmacy, Ooty. Event was sponsored by Council of Scientific & Industrial Research, New Delhi on 28th & 29th June 2022 at Manjakombai.

• Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice received grant of Rs.1 Lakh from JSS Academy of Higher Education & Research, Mysuru for the project entitled 'Dosage regimen optimization using pharmacogenomics and pharmacometrics approach' during the month of June 2022.

• Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice received grant of Rs.1 Lakh from JSS Academy of Higher Education & Research, Mysuru for the two days Seminar On "Capacity Building For Menstrual Hygiene Management among Adolescent School Girls including Tribes at Nilgiris District" organized in 25th & 26th April 2022.

• Mr.Vishwas H N , Lecturer, Department of Pharmacy Practice acted as 'Reviewer for Manuscript' in 'Journal of Applied Pharmaceutical Sciences'. Review completed on 28/06/2022.

# WORLD NO TOBACCO DAY
# MAY 31ST 2022

## Publications from Department of Pharmacy Practice


• Dharini B, Akshatha JS, Uma B, Hema S, Arun KP, Deepalakshmi M. Analysis of Adverse Drug Reactions associated with Anti-tubercular drugs– A Retrospective study. Research Journal of Pharmacy and Technology. 2022;15(4): 1483-1486.

• Sadagoban GK, Sanjeev S, Baiju A, Manomohan A, Swathi SB. Comprehending healthcare professionals' perspectives and expectations on drug information services at point-of-care: an online survey. Drugs Ther Perspect. 2022; (38):243–250.

• Borra SS, Diya C, Gopika N, Hema CC, Jegathis KM, Sadagoban GK, Arun KP. Development and validation of methodology to study the genetic polymorphism of organic cation transporter 1 (OCT1) - rs622342 A Prospective open-label study. Journal of medical pharmaceutical and allied sciences. 2022;11(12): 4607-4613.

• Patnool RB, Wadhwani A, Balasubramaniam V, Ponnusankar S. Antimicrobial Resistance and Implications: Impact on Pregnant Women with Urinary Tract Infections. J Pure Appl Microbiol. 2022;16(2):769-781.

• Rajavardhana T, Geethavani M, Vanitha Rani N, Ponnusankar S, Sreedhar V, Rajanandh MG. Are diabetic patients with metabolic syndrome and tuberculosis are most vulnerable to COVID-19 infection? Jundishapur Journal of Microbiology. 2022; 15(1): 952-958.

• Govind RK, Deepu VB, Tenzin T, Shahban AA, Arun KP, Deepalakshmi M. Assessment of Potentially Inappropriate Prescriptions among Geriatric population using START/STOPP criteria in Indian geriatric patients. Journal of Positive School Psychology. 2022; 6(3): 6608–6613.

• Aneena S, Ashna M, Reji K, Joel D. Awareness of Immunisation Health Care Providers on Adverse Events Following Immunisation: A Multicentre Study. Journal of Communicable Diseases. 2022; 54(1):1-9.

• Ponnusankar S, Vishwas HN, Anjali K, Kumar SM, Balasubramaniam V. Medication adherence and patient satisfaction among low socioeconomic hypertensive older people visiting a secondary care public hospital in south India. Journal of Applied Pharmaceutical Science. 2022;12(06):186-93.

• Bhavatharini PA, Shri SG, Grace T, Arun KP. Dosage Optimization of Lamotrigine in Pregnancy: A Pharmacometric Approach using Modeling and Simulation. The Journal of Clinical Pharmacology.2022;1-2.

• Swathi SB, Narendiran K, Dinesh K, Ayilya M, Sadagoban GK. A Comprehensive Review on Efficacy and Adverse Events Associated With Different Covid-19 Vaccines. Jordan Journal of Pharmaceutical Sciences. 2022;15(02): 289-304.


## Alumni Interaction Series

### *Bridging the gap: Connecting to the world*

**Speaker:**
*Mr. Sivarajan Velmurugan*
*Director – Marketing*
*Servier India Pvt Ltd*
*Mumbai*

**Title of the presentation:**
*Patient Centricity in Pharma!*

**Date of Presentation:** *09.04.2022*

*Alumni Interaction Series (AIS) is a new initiative of Dept. of Pharmacy Practice and Pharmacy Education Unit of JSS College of Pharmacy, Ooty to connect the Pharm D students with the alumnus of our department with the quote "Bridging the Gap-Connecting to the World". This interaction series will provide an opportunity to the Pharm D and M Pharm (Pharmacy Practice) students to establish their professional connection with the alumnus of the institution and also understand the various topics dealt by the invitee. Further, this interaction will help the students to better appreciate the various requirement for the academic learning including the pharmacotherapy knowledge, clinical case, etc. understanding to serve as clinical pharmacists in diverse patient care settings. As patient care expert / specialist; our students have the responsibility to learn more from the working professionals which will help them to function as a member of a multidisciplinary health care team member and provide their services to the needy population.*

Mr Velmurugan started his presentation with the classic introduction of patient centricity as "Being patient-centric for the pharma industry means ensuring that patients are front and centre in all that we do — that today means boldly ushering in a new age of automation and digitisation to ensure controls like we never had before on our products, processes, and quality systems".

***What is the best definition of patient centricity?***

Patient centricity should be defined as 'Putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family'.

A patient-centric approach is a way healthcare systems can establish a partnership among practitioners, patients, and their families to align decisions with patients' wants, needs, and preferences.

How do you achieve patient centricity? OR How to improve patient centricity; • Make information accessible • Involve patient associations • Ensure patients feel valued • Reduce inconvenience wherever possible • Empower patients through technology

***What is Person-Centred Care?***

• Person-centred care is one of the 13 fundamental standards of care that the Care Quality Commission (the independent regulator of health and social care in England) requires healthcare providers to meet.

• Delivering person-centred care involves caring for patients beyond their condition and tailoring the service to suit their individual wants and needs. It's about respecting that they have their own views on what's best for them, and have their own values and priorities in life.

• To do this, need to get to know patients as a person and actively involve them in care-related decisions. No one appreciates having decisions made for them without their input. It makes them feel like an object or task, rather than a human being with thoughts and feelings.

As its name suggests, person-centred care puts the person at the heart of their care. You adapt your service to their expectations and preferences, not the other way around. Doing so enables patients to retain their dignity and autonomy during an already challenging time. Rather than leaving them feeling hindered by their ailment or disability, or debilitated during their time as an inpatient, you help them live a fulfilling life.

After the presentation, question and answer session was organized. Further, he added his experience of establishing his team in marketing at Servier Indian Ltd, he shared. A total of 89 participants were present in the session.

## Academic Expert Interaction series

**Speaker:**
*Dr. Jimmy Jose*
*Associate Professor, Dept. of Pharmacy Practice / Clinical Pharmacy*
*School of Pharmacy*
*University of Nizwa, Oman*
*& Adjunct Faculty, JSSAHER, Mysuru*

**Title of the presentation:**
*Predisposing factors of Adverse Drug Reactions: Clinical Implications*
**Date of Presentation:** *07.04.2022*

Dr Jimmy started his presentation with the importance of understanding and considering predisposing factors for ADRs. Many factors play a crucial role in the occurrence of ADRs, some of these are patient related, drug related or socially related factors. Age for instance has a very critical impact on the occurrence of ADRs, both very young and very old patients are more vulnerable to these reactions than other age groups. Alcohol intake also has a crucial impact on ADRs. Other factors are gender, race, pregnancy, breast feeding, kidney problems, liver function, drug dose and frequency and many other factors. The effect of these factors on ADRs is well documented in the medical literature. Taking these factors into consideration during medical evaluation enables medical practitioners to choose the best drug regimen.

***Types of predisposing factors:***
Pharmacological, immunological, and genetic factors are involved in the pathogenesis of ADRs. Factors that predispose to pharmacological ADRs include dose, drug formulation, pharmacokinetic or pharmacodynamic abnormalities, and drug interactions. The metabolic conversion of drugs to metabolite is now established as a requirement for many idiosyncratic drug reactions. Increased levels of reactive drug metabolites, their impaired detoxification, or decreased cellular defence against reactive drug products appears to be an important initiating factor. Immunological and genetic factors may play a role in the reaction of the body toward the drugs given. Ethnic variations also play an important role in the development of ADRs. It is understood that some risk factors are consistent for all ADRs and across multiple therapeutic classes of drugs, while others are class specific. High-risk agents should be closely monitored based on patient characteristics (gender, age, weight, creatinine clearance, and number of comorbidities) and drug administration (dosage, administration route, number of concomitant drugs).

Factors affecting the occurrence of ADRs are subdivided into five groups; Patient related factors, Social factors, Drug related factors, Disease related factors and ADR related factors. The above affecting factors were discussed in detail by the presenter with specific examples.

There was a question-and-answer session where staff and students clarified their doubts related to pharmacovigilance. A total of 96 participants were present in the session.

*"GIVE THE GIFT OF LIFE TO OTHERS"*

# WORLD BLOOD DONOR DAY
# JUNE 14TH 2022

**For clarifications/ feedback, write to:**

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