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

Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

Prepared by :
Department of Clinical Pharmacy
JSS College of Pharmacy at
JSS Hospital, Mahatma Gandhi Road
Mysuru – 570004

Editors : Dr. M. Ramesh, Ms. Karin Nyfort-Hansen, Dr. Savitha R.S, Dr. Juny Sebastian, Dr. M. Umesh

Volume 25, Number 2 **May - August 2021**

ADVERSE DRUG REACTION REPORTS : JAN - APR 2021

A total of 269 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during Jan – April 2021. The following are some of the suspected ADRs that were either reported to or detected by the Department of Clinical Pharmacy. In most of the cases, there was a change in drug therapy e.g. cessation of suspected drug or reduction in dose, and/or either specific or symptomatic treatment for the suspected ADR.

DRUG(S)	REACTION
Amiodarone	SIADH (Syndrome of inappropriate secretion of antidiuretic hormone)
Amlodipine	Lichen planus
Aspirin	Haematuria
Atorvastatin	Acute Hepatitis
Carbamazepine	Erythema multiforme
Colistin	Nephrotoxicity
Eribulin	Insomnia
Irinotecan	Constipation
Oxcarbazepine	Lichenoid Drug Eruption
Packed Red Blood Cell	Acute Respiratory Distress Syndrome
Phenytoin	Toxic Epidermal Necrolysis
Pregabalin	Angioedema
Rifampicin	Pruritis
Teneligliptin	Urticaria
Tramadol	Agitation

Atorvastatin Induced Acute Hepatitis: Statin-induced hepatitis is a rare but severe reaction. Liver injury usually develops within 3–4 months after the start of therapy. Proposed mechanisms include functional CYP3A polymorphisms, drug interactions due to inducers/inhibitors of CYP3A enzyme and autoimmune phenotype. Monitoring liver enzymes especially when co-prescribed with other hepatotoxic drugs can prevent serious injury.

Phenytoin induced Toxic Epidermal Necrosis (TEN): Phenytoin induced TEN is commonly seen in the age group of 30-65 years and occurs in the first 2 months of anti- epileptic therapy. Genetic basis for SJS & TEN have been attributed to inherited or acquired deficiency in phase 2 detoxification enzymes or from an elevated cytochrome P450 (CYP 450) isoform(s). Few studies have also indicated an association between HLA*1502 and phenytoin induced SJS/TEN. Topiramate or Levetiracetam (antiepileptic drugs) will be the treatment of choice when phenytoin or carbamazepine has induced SJS/TEN.

Amiodarone Induced Syndrome of Inappropriate Antidiuretic Hormone (SIADH): SIADH associated with amiodarone causes hyponatremia and it is mostly seen in age group above 60 years caused by several conditions, such as central nervous system disorders, malignancies, various nonmalignant lung diseases, hypoadrenalism and hypothyroidism. The levels of sodium will be normal within days to a month after amiodarone withheld. A case report suggests that in the setting of hyponatremia, the patient's amiodarone was held and there was an improvement. Persistent hyponatremia may be treated with the intravenous (IV) normal saline & fluid restriction, with close monitoring of sodium levels periodically .

We encourage you to report all suspected adverse drug reactions to Department of Clinical Pharmacy. Adverse drug reaction reporting forms are available at all nursing stations. Alternatively you may call Department of Clinical Pharmacy on 2335555 Extn. 5577 or SMS to 9035664802 (Format: ADR / IP or OP Number/ Name of the patient/ Ward)

DRUGS APPROVED BY US FDA

The following drugs are approved by the United States Food and Drug Administration (USFDA) during the period January – April 2021

Name of the drug	Indication
Loncastuximab tesirine-lpyl	To treat certain types of relapsed or refractory large B-cell lymphoma
Dostarlimab-gxly	To treat endometrial cancer
Drospirenone and estetrol	To prevent pregnancy
Viloxazine	To treat attention deficit hyperactivity disorder
Dasiglucagon	To treat severe hypoglycemia
Ponesimod	To treat relapsing forms of multiple sclerosis
Tivozanib	To treat renal cell carcinoma
Serdexmethylphenidate and Dexmethylphenidate	To treat attention deficit hyperactivity disorder
Melphalan flufenamide	To treat relapsed or refractory multiple myeloma
Fosdenopterin	To reduce the risk of mortality in molybdenum cofactor deficiency Type A
Casimersen	To treat Duchenne muscular dystrophy
Trilacicilib	To mitigate chemotherapy-induced myelosuppression in small cell lung cancer
Evinacumab-dgnb	To treat homozygous familial hypercholesterolemia
Umbralisib	To treat marginal zone lymphoma and follicular lymphoma
Tepotinib	To treat non-small cell lung cancer
Voclosporin	To treat lupus nephritis
Cabotegravir and Rilpivirine (co-packaged)	To treat HIV
Vericiguat	To mitigate the risk of cardiovascular death and hospitalization for chronic heart failure

Reference: Novel Drug Approvals for 2021[internet] [cited May 2, 2021]. Available from: https://www.fda.gov/ drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021

DRUGS APPROVED BY CDSCO, INDIA

The following drugs are approved by the Central Drugs Standard Control Organization (CDSCO) during the period January - April 2021

Name of the drug	Indication
Atropine Sulfate Ophthalmic Solution USP 0.01% w/v (Additional Strength)	It is indicated to control the progression of myopia in children of 5 years and above
Colistimethate Sodium For Injection IP 3 MIU/ 4.5 MIU (Additional Strength)	For the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contraindicated or may be ineffective because of bacterial resistance
Dapagliflozin Tablets 10 mg (Additional Indication)	For the treatment of patients of Chronic Kidney Disease (CKD) up to Stage III (eGFR of greater than or equal to 30ml/min/1.73m2)
Brivaracetam Oral Solution 10mg/ml (Additional Dosage Foam)	As adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy

Drospirenone Tablets 4 mg (Additional Strength)	Drospirenone is a Progestin intended for its use by females of reproductive potentials to prevent pregnancy
Apomorphine Hydrochloride 5 mg/ml solution for infusion in 20ml vial Apomorphine Hydrochloride10 mg/ml solution for injection in 3ml cartridge (Additional pack size & strength)	For the treatment of disabling motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease which persist individually titrated treatment with Levodopa (with a peripheral decarboxylase inhibitor) and/or other dopamine agonists
Thyroxine Sodium Tablets 88mcg/200mcg (Additional Strength)	For the treatment of Hypothyroidism
Brivaracetam injection 50mg/5ml (10mg/ml) (Additional dosage form & New route of administration)	As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy
Aripiprazole powder and solvent for prolong-release suspension for injection 300mg/vial and 400 mg/vial (Modified Dosage Form)	Indicated for the treatment of dry eye signs and symptoms
Pancreatin Tablets USP 200mg (Additional Strength/New dosage form/ New Indication)	Indicated in combination with a proton pump inhibitor in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy
Pemetrexed for injection 100mg/500mg (Additional Indication)	In combination with pembrolizumab and platinum chemo therapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations
Ibuprofen solution for infusion 400mg/ 100ml (New Dosage Form)	Indicated in adults for the short term symptomatic treatment of acute moderate pain, and for the short-term symptomatic treatment of fever, when administration by intravenous route is clinically justified when other routes of administration are not possible
Cholecalciferol oral drops 800IU/ml (Additional Strength/New dosage Form)	For the treatment of vitamin D3 deficiency
Osimertinib Tablets 40mg and 80mg (Additional Indication)	treatment after complete tumour resection in patients with nonsmall cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations Osimertinib as monotherapy is indicated for adjuvant
Dexamethasone Tablets 6 mg (Additional Strength)	Dexamethasone is indicated for treatment of variety of disorders in which systemic glucocorticoids are indicated including: **Neurology:** Cerebral oedema (only with symptoms of intracranial pressure evidenced by computerised tomography) caused by a primary or metastatic brain tumour, craniotomy or head injury. **Dermatology:** Initial treatment of extensive, severe, acute, skin diseases responding to glucocorticoids, e.g. erythroderma, pemphigus vulgaris. **Autoimmune disorders/rheumatology:** Initial treatment of autoimmune disorders like systemic lupus erythematodes, in acute gouty arthritis, acute arthritis carditis, ankylosing spondylitis, psoriatic arthritis, severe progressive course of active rheumatoid arthritis, severe systemic course of juvenile idiopathic arthritis (Still's disease). **Haematological disorder:** Idiopathic thrombocytopenic purpura in adults. Oncologists only- for steroid responsive neoplastic disease like leukemias and lymphomas in adults only.

Dolutegravir Dispersible Tablets 10mg (Additional Dosage Form)	In combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus type1 (HIV-l) infection in adults (treatment-naive or-experienced) and in pediatric patients (treatment-naive or -experienced but integrase strand transfer inhibitor [INSTI]-naive) aged at least 4 weeks and weighing at least 3 kg
Sildenafil Citrate Oral Spray 12.5% w/v (Additional Dosage Form)	For the treatment of Erectile Dysfunction in men
DrospirenoneTablets 4mg (New Dosage Form)	Drospirenone is a Progestin intended for its use by females of reproductive potentials to prevent pregnancy

Reference *:* List of Drugs Approved From Snd Till 31 May 2021 [internet] [cited June 2, 2021]. Available from:https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzM1MQ

ACE Inhibitor Prevents LVEF Decline Associated with Trastuzumab

Treatment of human epidermal growth factor receptor 2 (HER2)-positive breast cancer patients with trastuzumab is highly effective. However, trastuzumab-associated decline in the left ventricular ejection fraction (LVEF) and clinical heart failure often prompt interruption and discontinuation of treatment. Hence, a prospective randomized study was conducted to evaluate the preventive impact of an ACE inhibitor or beta blockers on the left ventricular ejection fraction (LVEF) during treatment of trastuzumab and chemotherapy. The study population was women with early stage HER2 positive breast cancer undergoing (neo) adjuvant chemotherapy with trastuzumab were randomized to receive either once daily lisinopril (10mg), carvedilol (10mg) or placebo during treatment with trastuzumab and further stratified by anthracycline use (AC+T versus non AC+T). In a follow up to the initially presented primary endpoint of overall cardiotoxicity, study measured the protective effects of lisinopril or carvedilol to prevent a trastuzumab induced LVEF decrease to less than 50% over the course of therapy as well as the impact on LVEF decrease by >10% within normal LVEF levels.

The study enrolled a total of 468 women (mean age was 51±10.7 years) with HER2 over expressing early-stage breast cancer from 127 community-based oncology practices and a prespecified minimum target of 189 (40%) patients were treated with AC+T and 279 (60%) with non AC+T. Baseline cardiac risk factors of this study population included obesity and an elevated blood pressure. Patients in the anthracycline group were younger and without hypertension. A small, not clinically relevant decrease in LVEF was observed during trastuzumab therapy in all patients which was not significantly altered by any of the cardiac interventions. The rate of LVEF decline to <50% was much more frequent in patients treated with an anthracycline than those with a non-anthracycline containing regimen (21% vs 4.1%). Treatment with lisinopril averted the decline in LVEF in the AC+T group compared to placebo (10.8% vs 30.5%, p=0.045). A smaller but not significant effect was seen by carvedilol. The incidence of cardiotoxicity manifesting as LVEF decrease by ≥10% within the normal range was similar in both AC+T and the non AC+T arms, and not affected by either lisinopril or carvedilol

Patients treated with anthracyclines prior to trastuzumab demonstrated a decrease in LVEF to below normal levels in a larger than previously reported number of women in this community based setting. The trastuzumab-anthracycline induced decline in LVEF could be prevented with concurrent treatment with lisinopril, which was tolerable even in patients without hypertension.

Reference : Pamela N, Roy Tamura, Jeffrey Krischer, Worta J. McCaskill-Stevens, Maya Guglin. ACE Inhibitor Prevents LVEF Decline After Breast Cancer Drugs. J Clin Oncol 39, 2021. Available from: http://10.0.4.176/ JCO.2021.39.15_suppl.509

DCGI Approves Anti-COVID Drug Developed by DRDO for Emergency Use

An anti-COVID-19 therapeutic application of the drug 2-deoxy-D-glucose (2-DG) has been developed by the Institute of Nuclear Medicine and Allied Sciences (INMAS), DRDO in collaboration with Dr Reddy's Laboratories (DRL), Hyderabad. Clinical trial results have shown that this molecule helps in faster recovery of hospitalised patients and reduces supplemental oxygen dependence. The higher proportion of patients treated with 2-DG showed RT-PCR negative conversion in COVID patients. The drug will be of immense benefit to the people suffering from COVID-19.

In April 2020, during the first wave of the pandemic, INMAS-DRDO scientists conducted laboratory experiments with the help of the Centre for Cellular and Molecular Biology (CCMB), Hyderabad and found that this molecule works effectively against the SARSCoV-2 virus and inhibits viral growth. Based on these results, the Drugs Controller General of India permitted a Phase-II clinical trial of 2-DG in COVID-19 patients in May 2020. The DRDO, along with its industry partner Dr. Reddy's Laboratories (DRL), Hyderabad started clinical trials to test the safety and efficacy of the drug in COVID-19 patients. In Phase-II trials (including dose-ranging) conducted from May to October 2020, the drug was found to be safe in COVID-19 patients and showed significant improvement in their recovery. Phase IIa was conducted in six hospitals and Phase IIb (dose-ranging) clinical trial was conducted at 11 hospitals all over the country. Phase-II trial was conducted on 110 patients.

Based on successful results, DCGI further permitted the Phase III clinical trials in November 2020. The Phase-III clinical trial was conducted on 220 patients between December 2020 to March 2021 at 27 COVID hospitals in Delhi, Uttar Pradesh, West Bengal, Gujarat, Rajasthan, Maharashtra, Andhra Pradesh, Telangana, Karnataka and Tamil Nadu. In 2-DG arm, a significantly higher proportion of patients improved symptomatically and became free from supplemental oxygen dependence (42% vs 31%) by Day-3 in comparison to Standard of Care (SoC), indicating an early relief from Oxygen therapy/dependence. A similar trend was observed in patients aged more than 65 years. On May 1, 2021, DCGI granted permission for the Emergency Use of this drug as an adjunct therapy in moderate to severe COVID-19 patients. The drug comes in powder form in the sachet, which is taken orally by dissolving it in water. It accumulates in the virus-infected cells and prevents virus growth by stopping viral synthesis and energy production. Its selective accumulation in virally infected cells makes this drug unique.

Reference : DRDO Newsletter June 2021. Available from https://www.drdo.gov.in/sites/ default/files/newsletter-document/June%20NL%202021%20for%20web.pdf

Evaluating Patients with Post-COVID Conditions

The Centers for Disease Control and Prevention (CDC), USA has developed interim guidance to assist health care providers in evaluating patients with post-COVID conditions, including new, returning and ongoing health problems occurring more than four weeks after infection with SARS-CoV-2.

The guidance refers to "post-COVID conditions" as the umbrella term for physical and mental health consequences experienced by individuals after SARS-CoV-2 infection, including patients who initially had mild or asymptomatic acute infection. The frequency and severity of post-COVID conditions in children and adolescents are unknown, according to the CDC.

According to CDC, there are multiple possible onset patterns for post-COVID conditions including, but not limited to: (A) persistent symptoms and conditions that begin at the time of acute COVID-19 illness; (B) new-onset late sequelae following asymptomatic disease or a period of acute symptom relief or remission; or (C) an evolution of symptoms and conditions that include some persistent symptoms (e.g., shortness of breath) with the addition of new symptoms or conditions over time (e.g., cognitive difficulties).

Some post-COVID conditions share similarities with other post-viral syndromes like myalgic encephalomyelitis /chronic fatigue syndrome (ME/CFS), dysautonomia (e.g., postural orthostatic tachycardia syndrome) or mast cell activation syndrome, according to the guidance.

Providers are encouraged to use patient-centered approaches to optimize quality of life and function. This approach will allow health care providers and patients to use shared decision-making and focus on treating specific symptoms or conditions, within the medical home model. A comprehensive management plan to improve physical, mental and social well-being also may be helpful.

Evidence suggests that post-COVID conditions occur in children and adolescents but the true frequency and severity are unknown at this time. Expert view suggests pediatricians are in an ideal position to identify and care for children with impairments following COVID-19. Since, post-COVID symptoms are not random complaints but often are consistent among children, experts suggest that listening to and validating patient's experiences is most important. The guidance also supports use of telehealth for follow-up, and provide timely evaluation and care.

Common Symptoms among People with Post-COVID Conditions

Dyspnea or increased respiratory effort	Abdominal pain
Fatigue	Diarrhea
Post-exertional malaise* and/or poor endurance	Insomnia and other sleep difficulties
Brain fog," cognitive impairment	Fever
Cough	Lightheadedness
Chest pain	Impaired daily function and mobility
Headache	Pain
Palpitations and/or tachycardia	Rash (e.g., urticaria)
Arthralgia	Mood changes
Myalgia	Anosmia or dysgeusia
Paresthesia	Menstrual cycle irregularities

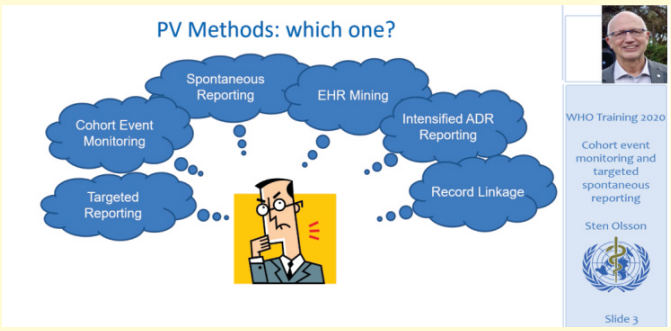
* Post-exertional malaise is the worsening of symptoms following even minor physical or mental exertion, with symptoms typically worsening 12 to 48 hours after activity and lasting for days or even weeks.

Source : Centers for Disease Control and Prevention

DEPARTMENT ACTIVITIES

Webinar on 'Cohort Event Monitoring and Targeted Spontaneous Reporting'

Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru organized an e-guest lecture on the topic **"Cohort Event Monitoring and Targeted Spontaneous Reporting"** on 24th April 2021 for the benefit of PharmD and M. Pharm Pharmacy Practice students. **Mr. Sten Olson, Immediate Past President, International Society of Pharmacovigilance** and Adjunct Faculty, JSS Academy of Higher Education & Research, Mysuru was the resource person. The lecture was organized with the objective to enlighten students about methods of reporting ADRs particularly in public health program with special emphasis on Cohort Event Monitoring and Targeted Spontaneous Reporting.



Speaker during the lecture

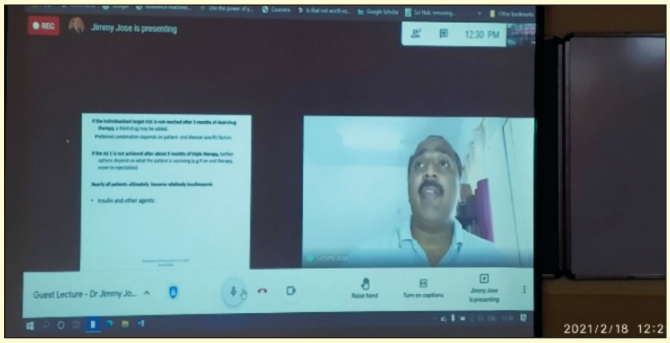
Mr. Sten Olson, during his lecture, explained the different Pharmacovigilance methods and highlighted the importance and applications of pharmacovigilance methods in public health. He explained the objectives, principles, process, timelines and the merits & demerits of Cohort Event Monitoring (CEM). He explained CEM with the example of his own experience with implementing CEM Program in African Malaria programmes. Later, he spoke about Targeted Spontaneous Reporting, and explained the principles, importance, advantages and disadvantages and its feasibility of implementing in public health program. Also, he discussed the WHO strategies for integrating pharmacovigilance in public health.

The vast experience of the speaker enabled the participants to understand and gather several aspects related to CEM and Targeted Spontaneous Reporting that may benefit them in applying their knowledge gained through this session in their career. Students of fifth & sixth year PharmD, I &II M. Pharm Pharmacy Practice students and PhD research scholars attended the guest lecture.

GUEST LECTURES

Pharmacotherapy of Diabetes Mellitus

The Department of Pharmacy Practice organized a series of guest lectures from January to April 2021 on the virtual platform. The topics were varied and international speakers delivered the lectures for the benefit of both Pharm D and M Pharm Pharmacy Practice students. The first of these was a Guest Lecture series on Diabetes



Dr. Jimmy Jose delivering the lecture

Mellitus that took place on 26th January and 18th February 2021. **Dr. Jimmy Jose**, **Associate Professor, University of Nizwa, Oman** & Adjunct Faculty at JSS Academy of Higher Education & Research, Mysuru spoke on **'Pharmacotherapeutics of Diabetes Mellitus'.** During his lecture Dr Jimmy Jose explained the pathophysiology of Diabetes Mellitus, including Maturity Onset Diabetes of the Young (MODY) and Latent autoimmune diabetes in adults (LADA), pharmacology of drugs used in the management, and on the right selection of the medication for the patients with other comorbid conditions. In the second session, Dr Jimmy Jose reiterated the need for selection of the right drug and the importance of lifestyle modifications in patients with diabetes mellitus for better management. At the end of the session, the students participated in an interactive quiz on Kahoot® platform based on the topic covered. Students expressed that the lecture series was very informative and gave valuable information of current management of diabetes.

Career Opportunities

Mr. Nidhin Mohan, **President - New Island Pharmacy, USA** and alumni of JSS College of Pharmacy, Mysuru gave an e-guest lecture on the topic **"Career Opportunities for Pharmacy Practice Students"** on 30th January 2021. Mr. Nidhin discussed on the various areas of practice of pharmacy professionals across the globe and highlighted the current scenario in United States. He explained the daily activities of a community pharmacist quoting a example for each of the activities including immunization, COVID-19 management, health screening, medication adherence, medication synchronization programs, compounding, collaborative work relationship. Also, he enlightened the participants about specialized daily activities of a community pharmacist such as nuclear medicine, palliative care, smoking cessation, nutritional counseling, preparation of infusions, total parenteral nutrition, dialysis and pain management. Later, he explained the concept of medication therapy monitoring and its importance in a

Dr. Nidhin Mohan during the Session

community pharmacy setting. During his lecture, he explained its process, different component of medication therapy monitoring such as adherence checking, refills needed, new therapy needed, identifying barriers, interactions, analyzing proper usage of medications. The session was concluded with an interactive spell wherein the speaker answered to the questions raised by the participants.

HIV/AIDS Research

Department of Pharmacy Practice along with Alumni Association of JSS College of Pharmacy, Mysuru organized an e-guest lecture on the topic **"My Experiences Gained from Journeying with HIV/AIDS Research: An Update"** on 19th February 2021. **Dr. R. Rajesh, Assistant Professor, Dept. Pharmacy Practice, Manipal College of Pharmaceutical Sciences, MAHE** and alumni of JSS College of Pharmacy, Mysuru interacted with the interns and post graduate students and gave them a brief history of events that led him to conduct research in the area of HIV/AIDS. He spoke about the nuances of choosing a thurst area, and aspects to be considered while choosing a particular field for continuing their research as a research

Participants attending the session

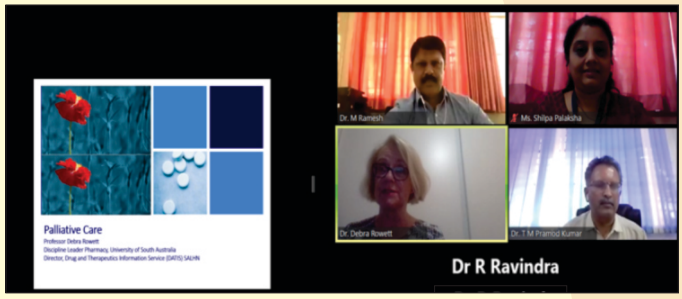
scholar. He explained about the importance of educational intervention in increasing the adherence behavior among patients receiving ART medications with his research

findings. During his lecture, he explained the process, different component of medication therapy monitoring such as adherence checking, refills needed, new therapy needed, identifying barriers, interactions, analyzing proper usage of medications. Later, he spoke on importance of continuous monitoring of ADRs and Drug-Drug Interactions to ART regimens and concomitant medications for better patient safety. Dr. Rajesh concluded his talk by encouraging students to inculcate the habit of writing review articles during undergraduate program that can develop skills in writing research articles and applying for funded projects.

Palliative Care

On 18th March 2021, **Dr. Debra Rowett, Professor and Discipline Leader Pharmacy, School of Pharmacy and Medical Sciences at the University of South Australia** and Director of the Drug and Therapeutics Information Service (DATIS), Southern Adelaide Local Health Network, who is also an adjunct faculty at JSSCP, JSS AHER, Myusru spoke on **"Palliative Care"** for the benefit of PharmD and M. Pharm Pharmacy Practice students. The objective of the session was to provide an insight into and also on aspects in the area of advanced palliative care. After initial introductions, Dr. Debra began her lecture by explaining what palliative care is, who needs it, where it is provided and the complete process of palliative care. Dr. Debra explained using case scenarios the role of pharmacists in palliative care.

Detailed explanation was given to make students understand how to manage the pharmacotherapy in palliative care. Later, she interacted with the students asking them to identify the difference in care provided in Australia and Indian Scenario. Students were very enthusiastic and actively participated in sharing their day-to-day experience with Dr. Debra. She expressed her willingness to be part of their learning and share updated information with all of them through exchange of guidelines and relevant articles.



Debra Rowett during the session

Continuous Professional Development Programs for Practicing Pharmacists

CPD on Professional Responsibilities of Community Pharmacist

Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Mysuru conducted a series of **Continuing Professional Development (CPD)** programs from January to March 2021. The first CPD program was held on 23rd January 2021 at JSS College of Pharmacy, Mysuru. The CPD program **'Professional Responsibilities of Community Pharmacists'** for Practicing Community Pharmacists was inaugurated by **Dr. T M Pramod Kumar**, Principal, JSS College of Pharmacy, Mysuru. The program was also attended by **Mr. Umesh Babu**, President, Mysore Chamarajanagar District, Government Pharmacists Association.

Inauguration of CPD on Professional Responsibilities of Community Pharmacist

Dr. M Ramesh, Head, Department of Pharmacy Practice briefed the participants about the objectives of the program. He mentioned that the program was conducted with an objective to provide a greater understanding of professional responsibilities and the role of community pharmacists in the different health care sectors. During his briefing, he stated that the current and the forthcoming CPD programs would enable the participants to improve the professional standards of community pharmacy practice and realise the societal needs of the profession in advancing public health.

Mrs. Shilpa Palaksha, Asst. Professor, Department of Pharmacy Practice led the first session on **'Public Healthcare Services of Practicing Pharmacists'**. In her talk, she highlighted the role of community pharmacists in public health care services and stressed upon the importance of community pharmacists taking part in various horizons of services viz. smoking cessation, national health programs and de-addiction program etc. The second session on **'Professional Services of Practicing Pharmacists'** was delivered by **Dr. Srikanth M S**, Lecturer, Department of Pharmacy Practice. He briefed the participants on different services

of community pharmacists including long-term care in patients with their special medication needs, senior care pharmacists, providing education, advocacy etc. **Dr. Siddartha N Dhurappanavar**, Clinical Pharmacist, Department of Pharmacy Practice led the last session on **'Healthcare Services in COVID-19 Era'**. He discussed on how pharmacists can manage the patient distress by providing triaging and basic consultations via Telemedicine & Telehealth during COVID-19 Era. A total of 26 practicing pharmacists from various parts of Mysuru district attended this program. Feedback from the

CPD on Role of Pharmacists in Immunization

The second CPD program on the topic **'Role of Practicing Pharmacists in Immunization'** for Practicing Community Pharmacists was conducted on 13th February 2021 at JSS College of Pharmacy, Mysuru. The program was attended by **Dr. T M Pramod Kumar** and **Mr. Mahesh Kumar V,** Ex-President, Mysore Chamarajanagar District Government Pharmacists Association and **Dr. M. Ramesh**, Prof. & Head, Dept of Pharmacy Practice. During this CPD Programme, **Mrs. Shilpa Palaksha** spoke about **'Basics of Immunology and Vaccination'**.

Inauguration of CPD on Role of Pharmacists in Immunization

She initially focused her talk on basics of immune system, and continued her discussion on types of Immunization, vaccine mechanism and later concluded with the explanation on different types of vaccines. The second session on **'Importance of safety monitoring of Vaccines'** was delivered by **Dr. Juny Sebastian**, Staff of Department of Pharmacy Practice. In the initial part of the session, she spoke on the special need for vaccine pharmacovigilance emphasizing the reasons for low public tolerance to adverse events to vaccines versus drugs. Also, she explained about the importance of adverse events following immunization (AEFI) surveillance, classification of AEFI, components of AEFI surveillance and reporting timelines of AEFI.

Dr. M.S. Srikanth, Staff of Dept. of Pharmacy Practice briefed the participants on **'Safety monitoring of COVID-19 Vaccine'.** Following that by participants shared their practical experience of handling of COVID-19 vaccination. A total of 20 practicing pharmacists from various parts of Mysuru district attended this program. Participants provided a positive feedback on the program and expressed that they were benefited from this program.

CPD on Online Pharmacy

CPD Program on **'Online Pharmacy: Boon or Bane to Indian Healthcare System'** was held on 27th March 2021 at JSS College of Pharmacy, Mysuru.

After the inauguration, **Mrs. Shilpa Palaksha**, spoke about **'Online Pharmacy : Challenges & Opportunities'**. She initially focused her talk on defining online pharmacy, need for it and then elaborated on challenges of online pharmacy for pharmacists, healthcare system and consumers. She ended her talk by discussing the opportunities a pharmacist can foresee in online pharmacy. **Mr. Atiqulla Shariff**, Research Scholar at the department, delivered a talk on **'Regulatory requirements for *Online Pharmacies : Global and Indian Scenario'***. In his talk, he briefed about the existing regulatory requirements to establish online pharmacies in various countries. Also, he spoke on various agencies across the globe responsible for regulating the functioning of online pharmacies and updated the existing laws & regulations in India related to establishment and system of working of online pharmacies. Later, he presented the

CPD on Online Pharmacy

Interactive session on Online Pharmacy

views of various stakeholders of online pharmacy system in India such as government officials involved in drafting the regulations for online pharmacy system in India, The All India Organization of Chemist & Druggists (AIOCD), administrative members of Digital Health Platforms (DHP), fellow pharmacists, the general public and the professional organizations such as Indian Medical Association (IMA). Later, he described the experiences of general public on healthcare delivery through online pharmacies in a global scenario and concluded his session by discussing the challenges in implementation of online pharmacy in Indian healthcare system.

Workshop on Good Clinical Practice & Regulatory Updates

The Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru in collaboration with Clinical Development Services Agency (CDSA) - Centre of Clinical Research Excellence (CCRE), JSS Academy of Higher Education & Research, Mysuru & Institutional Human Ethics Committee, JSS Medical College & Hospital, Mysuru organised a workshop on **'Good Clinical Practice & Regulatory Updates'** for the newly inducted members of Institutional Human Ethics Committee, JSS College of Pharmacy, Mysuru on 12th February 2021. **Dr. Sri Harsha**, Faculty, Dept. of Pharmacy Practice, JSS College of Pharmacy, Mysuru welcomed the gathering and invited Dr. T. M. Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru to deliver the inaugural address.

Following the inaugural address of **Dr. T. M. Pramod Kumar**, Principal, JSS College of Pharmacy, Mysuru, **Dr. Pratibha Pereira**, Member Secretary - Clinical Development Services Agency (CDSA) - Centre of Clinical Research Excellence (CCRE), JSS Academy of Higher Education & Research, Mysuru delivered the talk on **'Overview of Good Clinical Practice (GCP)'**. During her talk, members were introduced to the essence of The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and brief history that led to its origin. During her session, she said "The ethical guidelines in place today were primarily a response to past wrongful conduct of clinical trials, and the most notable one was an experiment in Tuskegee, Alabama, in which treatment was withheld from 400 African American men with syphilis so that scientists could study the course of the disease. Also, she said that the various ethical guidelines were developed in the 20th century in response to such studies." In adition, she covered some of the influential codes of ethics and regulations that guide ethical clinical research involving Nuremberg Code (1947), Belmont Report (1979) and Declaration of Helsinki (2000).

The second session on **"Ethics Committee (EC) & Ethical Considerations in Clinical Research"** was delivered by **Dr. R. N. Suresha**, Professor of Pharmacology, JSS Medical College & Hospital, Mysuru. During his session he discussed the roles and responsibilities, Do's and Dont's of ethics committee

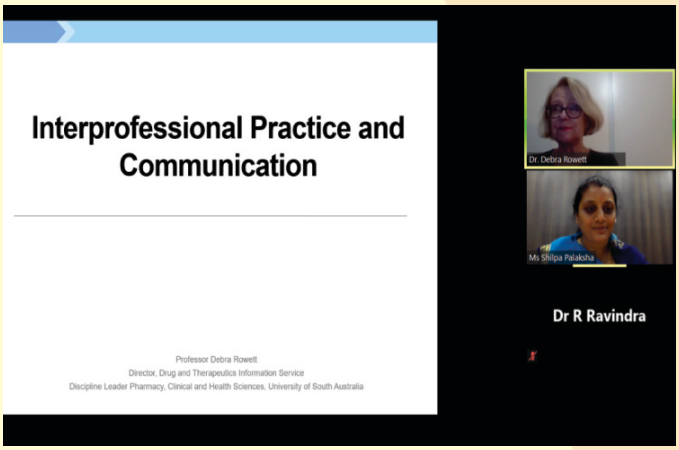
Participants of the workshop with speakers

members in the clinical research. He emphasised that 'The Ethics Committee should review every research proposal on human subjects to evaluate the possible risks to the subjects. Also, he mentioned that the ethics committee should evaluate the adequacy of documents for ensuring privacy, confidentiality and justice. And he highlighted the importance of ensuring that a research proposal has been scientifically reviewed before an ethical review and decisions should be taken through formal meetings and not merely through circulation of proposals. Further, he briefed on progressive review, monitoring of ongoing clinical studies and protocol deviations & violations.

Later, **Dr. Pratibha Pereira** delivered the last session on **"Highlights of New Drugs and Clinical Trials (CT) Rules 2019"**. During her session, she addressed the participants on the various chapters involved in the new CT rules and their aim to promote clinical research in India by providing for a predictable, transparent and effective regulation for clinical trials and by ensuring faster accessibility of new drugs to the Indian population. She highlighted the important aspects of CT and said that new rules have reduced the time for approving applications, which has now come down to 30 days for drugs manufactured in India and 90 days for those developed outside the country and new rules has removed regulations on tests conducted on animals in case of drugs approved and marketed for more than two years in well-regulated overseas drug markets. A special emphasis was made to all the members that the ethics committee will require to monitor the trials and decide on the amount of compensation in cases of adverse events. With this session, the event was concluded with a question & answer session followed by the vote of thanks.

Interprofessional Practice and Communication

Department of Pharmacy Practice, JSS College of Pharmacy (JSSCP), Mysuru organized an e-guest lecture on the topic **"Interprofessional Practice and Communication"** on 21st April 2021 for the benefit of PharmD and M. Pharm Pharmacy Practice students. The lecture was organized with the objective to educate PharmD and M.Pharm students about incorporating the concept of inter professional practice and also the need of good communication in practice as a member of a healthcare team. **Dr. Debra Rowett**, Professor and Adjunct Faculty at JSSCP, JSS AHER, Myusru was the resource person.



The session in progress

Dr. Debra Rowett started her lecture by defining interprofessional practice and further explained the need of interprofessional practice and necessary elements required. She described the inter-professional practice process adopted at the University of South Australia where she is a Discipline Leader. Later in her lecture, she emphasized on the communication skills required for the process of interprofessional practice.

During her lecture, Dr. Debra gave tips to the students on how to prepare for such communication. Also, she advised them to take most advantage to learn from the interprofessional team and highlighted about importance of collaboration with other health care professionals, value and ethics, the language, cooperative attitude, team work and respect to the colleagues that can make interprofessional practice a success. At the end of session students were given opportunity to ask question, which Dr. Debra was delighted to answer.

Training of Pharmacovigilance Associate

The Department of Clinical Pharmacy, JSS Hospital, Mysuru which is a Regional Training Centre for South Zone, Pharmacovigilance Program of India (PvPI) imparted the training to **Dr. S. Vanendra Yadav, Jr. Pharmacovigilance Associate at Mysore Medical College & Research Institute, Mysuru** on pharmacovigilance activities during 5th & 6th April 2021.

During his two-days training, he was trained on various aspects of Adverse Drug Reaction (ADR) Monitoring and Adverse Event Following Immunization (AEFI). On day 1, he was trained on the process of ADR reporting, analyzing and communication of reported events using VigiFlow platform. Following that he was explained about the software and database and provided a hands-on session on vigiflow entry and documentation. On Day 2, the trainee was primed on process of Adverse Event Following Immunization (AEFI), Materiovigilance and Medication Incidents followed by hands-on session on AEFI. The training was imparted by Dr Sri Harsha Chalasani, Deputy Coordinator, AMC, JSS Medical College & Hospital,and Dr Puvvada Rahul Krishna, Ex Pharmacovigilance Associate & Research Scholar of Department of Pharmacy Practice. Dr. Vanendra Yadav expressed his gratitude to the department for providing a supportive environment and making his training session a memorable one.

During Hands-on Session on VigiFlow

Awards and Accolades

Dr. Ann Vazhayil Kuruvilla, Clinical Pharmacist received **'Best e-Poster Presentation Award'** for her research poster entitled 'Antibiotic Utilization in Surgery Department of a Tertiary Care Hospital' during the 9th APP (Association of Pharmacy Professionals) Annual International Convention held on 19th-20th December 2020. The Department congratulates her and wishes her all the very best.

Dr M. Ramesh was nominated as Member of Panelists for the selection of Post Doctoral Research Fellow (PDRF) at NIPER, Hajipur held on 19th January 2021.

Dr. M. Ramesh was nominated as a Member of Selection Committee for Recruitment of Junior Pharmacovigilance Associate at KR Hospital, Mysuru under the PvPI, IPC, Ghaziabad.

Dr Ann Vazhayil Kuruvilla was nominated as Member of Antimicrobial Stewardship Committee of JSS Hospital, Mysuru

Doctoral Award - Mrs. Savitha R.S, Assoc. Professor, Department of Pharmacy Practice has been awarded 'Doctor of Philosophy by JSS AHER, Mysuru in Faculty of Pharmacy. Her doctoral research work was on 'Assesment of Clinical & Economic Impact of Pharmacist Intervention in Patients with Chronic Kidney Disease' carried out under the guidance of Dr. M. Ramesh, Prof. & Head, Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru.

The Drug & Poison Information Service

Our Department can help you with any questions you might have on the use of medicines or the management of poisoned patients. Also, we can assist you with any medication related problems you face in your daily practice. The services are made available on all working days and it is provided free of cost. We request you to avail the drug and poison information services.

We extended our services 24*7 from 8th October 2018 for the benefit of HCPs and Patients.
24* 7 Mobile Number: 6363539153, Toll free Number - 1800-425-0207
Landline Number: 2335555, Extn - 5577
E-mail: dic.jsscp@jssuni.edu.in; pic.jsscp@jssuni.edu.in;
Website: www.picjsscpm.jssuni.edu.in

Your suggestions are welcome. Please send your comments/suggestions to the editors at: dic.jsscp@jssuni.edu.in

To,

_____

_____

Book - Post