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

Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

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ADVERSE DRUG REACTION REPORTS : May – Aug 2021

A total of 303 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during May–August 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
Amphotericin B	Chills
Dexamethasone	Hyperglycemia
Dolutegravir	Increased Random Glucose Level
Linezolid	Anaphylactic Reaction
LMWX Heparin	Thrombocytopenia
Nintedanib	Epistaxis
Paclitaxel	Neuropathy
Phenobarbital	Anaemia
Prednisolone	Herpes Zoster Infection
Risperidone	Hypertension
Rosuvastatin	Diabetes Mellitus
Sertraline	Dry Mouth
Telmisartan	Urticaria
Tigecycline	Diarrhoea
Vildagliptin + Metformin	Eczema

Dolutegravir induced Increased Random Glucose Level : Dolutegravir is an Integrase Strand Transfer Inhibitor (INSTI) used for the treatment of HIV infection. Although an uncommon occurrence, hyperglycaemia is a potential adverse event of dolutegravir. Healthcare professionals need to be aware of this rare but serious adverse event and close monitoring of serum plasma glucose level should be considered after initiation of any INSTI.

Nintedanib induced Epistaxis: Nintedanib is used in the treatement of idiopathic pulmonary fibrosis. It is an intracellular inhibitor of tyrosine kinases, including the receptors for the fibroblast growth factor, platelet-derived growth factor and vascular endothelial growth factor. Adverse bleeding events are reported in 10.3% of patients treated with nintedanib including 4.1% incidence of epistaxis. The drug need to be dicontinued on development of any bleeding events.

Paclitaxel induced Neuropathy: Sensory peripheral neuropathy is the most common clinical neurotoxicity associated with paclitaxel administration. The neurotoxicity is dose- and infusion-duration related, and most frequently occurs when the dose of paclitaxel administration exceeds 250mg/m^2 infused over $\geq$ 24 hours. The risk of developing neuropathy is greater in patients with preexisting condition that causes neuropathy.

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 are the drugs that are approved by the United States Food and Drug Administration (USFDA) during the period May – August 2021.

Name of the drug	Indication
Pegcetacoplan	To treat paroxysmal nocturnal hemoglobinuria
Amivantamab-vmjw	To treat a subset of non-small cell lung cancer
Piflufolastat F 18	To identify prostate-specific membrane antigen-positive lesions in prostate cancer
Sotorasib	To treat types of non-small cell lung cancer
Infigratinib	To treat cholangiocarcinoma whose disease meets certain criteria
Olanzapine and samidorphan	To treat schizophrenia and certain aspects of bipolar I disorder
Ibrexafungerp	To treat vulvovaginal candidiasis
Aducanumab-avwa	To treat Alzheimer's disease
Asparaginase erwinia chrysanthemi (recombinant)-rywn	To treat acute lymphoblastic leukemia and lymphoblastic lymphoma in patients who are allergic to E. coli-derived asparaginase products, as a component of a chemotherapy regimen
Finerenone	To reduce the risk of kidney and heart complications in chronic kidney disease associated with type 2 diabetes
Fexinidazole	To treat human African trypanosomiasis caused by the parasite Trypanosoma brucei gambiense
Belumosudil	To treat chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy
Odevixibat	To treat pruritus
Anifrolumab-fnia	To treat moderate-to severe systemic lupus erythematousus along with standard therapy
Avalglucosidase alfa-ngpt	To treat late - onset Pompe disease
Belzutifan	To treat von Hippel - Lindau disease under certain conditions
Difelikefalin	To treat moderate-to-severe pruritus associated with chronic kidney disease in certain populations
Lonapegsomatropin-tcgd	To treat short stature due to inadequate secretion of endogenous growth hormone

Reference: Novel Drug Approvals for 2021[internet] [cited Sep 5, 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 are the drugs that are approved by the Central Drugs Standard Control Organization (CDSCO) during the period May- Aug 2021.

Name of the drug	Indication
2-Deoxy-D-Glucose bulk and 2-Deoxy-D-Glucose 2.34g & 5.85g sachet	As an adjunct therapy only in moderate to severe Covid-19 patients
Capmatinib 150mg and 200mg film coated tablets	Capmatinib is a kinase inhibitor indicated for the treatment of adult patient with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal epithelia transition (MET) exon 14 skipping

Name of the drug	Indication
Rucaparib tablets 250mg	Ovarian cancer: For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA approved companion diagnostic for RUBRACA. Prostate cancer: For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic) associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.
Vigabatrin bulk and Vigabatrin powder for oral solution 500mg	For the treatment of 1) Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments; Vigabatrin for Oral Solution, USP, 500 mg is not indicated as a first line agent. 2) Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss
Cangrelor tetra sodium bulk and Cangrelor for injection 50mg/vial	Indicated as an adjunct to percutaneous coronary intervention (PCI) to reduce the risk of periprocedural myocardial infarction (MI), repeat coronary revarscularization, and stent thrombosis (ST) in patients who have not been treated with a P2Y12 platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor
Rifapentine bulk and FDC of Isoniazid and Rifapntine (300mg/300mg)	Indicated for treatment of latent tuberculosis, caused by Mycobacterium tuberculosis (For use in NTEP only)
Lemborexant tablets 5mg/10mg	Treatment for insomnia
Cetilistat bulk and Cetilistat 120 mg tablets	For the treatment of Obseity (limited to patients with both type 2 diabetes mellitus and dyslipidaemia, and with a BMI ≥ 25 kg/m2 inspite of dietary treatment and /or excersise therapy)
Benzonatate bulk and Benzonatate capsules 100mg	For the treatment of refractory cough
Cariprazine hydrochloride bulk and Cariprazine capsules 1.5mg/3mg/4.5mg and 6mg	For the treatment of Schizophrenia in adults. Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults
Gadoteridol 279.3 mg/ml for injection	For intravenous use in magnetic reasonance imaging (MRI) in adults and pediatric patients over 2 years of age for whole body MRI including the head, neck, liver, breast, musculoskeletal system and soft tissue pathologies
Darolutamide 300mg film coated tablets	For the treatment of patients with nonmetastatic castration resistant prostate cancer (nmCRPC)
8 Tetracosactide BP bulk and Tetracosactide injection BP 250 mcg/ml	Diagnostic test for the investigation of adrenocortical insufficiency

Reference: List of Drugs Approved in the year 2021 till date [internet] [cited Sep 10, 2021]. Available from:https://cdsco.gov.in/opencms/opencms/ system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY5MQ==

COVID-19 Vaccines Approved for Emergency Situation in India

Sl. No.	Vaccine	Firm and date of approval	Dosing schedule	Approved for age group	Route of administration and storage
1.	ChAdOx1 nCoV-19 Corona Virus vaccine Recombinant) [Chimpanzee Adeno vector]	M/s Serum Institute of India Pvt. Ltd. 03.01.2021	Two doses, 4 to 6 weeks apart (Overseas Data available for 12 weeks)	For ≥ 18 years age	Intramuscular, 2-8°C
2.	Whole-Virion Inactivated SARS-CoV-2 Vaccine	M/s Bharat Biotech 03.01.2021	Two doses, Day 0 & 28	For ≥ 18 years age	Intramuscular, 2-8°C
3.	Recombinant Adenovirus vector based SARS-CoV-2 liquid vaccine Gam COVID Vac (component I & II) (SPUTNIK-V)	M/s Dr. Reddy's Lab. Ltd. (Importer) 12.04.2021	Two doses, Day 0 (comp I) & Day 21 (comp II)	For ≥ 18 years age	Intramuscular, -18°C
4.	mRNA-1273COVID-19 vaccine (Moderna)	M/s Cipla Ltd. (Importer) 29.06.2021	Two doses, Day 0 & 28	For ≥ 18 years age	Intramuscular, -25°C to -15°C
5.	Recombinant Adenovirus vector based SARS-CoV-2 liquid vaccine Gam COVID Vac (component I & II) (SPUTNIK-V)	M/s Panacea Biotec Ltd 02.07.2021	Two doses, Day 0 (comp I) & Day 21 (comp II)	For ≥ 18 years age	Intramuscular, -18°C
6.	COVID-19 vaccine (Ad26.COV2-S) [recombinant] (Janssen Vaccine)	M/s Johnson & Johnson Pvt. Ltd. (Importer) 07.08.2021	Single dose	For ≥ 18 years age	Intramuscular, -25°C to -15°C & 2- 8°C
7.	COVID-19 vaccine (Ad26.COV2-S) [recombinant] (Janssen Vaccine)	Biological E Limited 18.08.2021	Single dose	For ≥ 18 years age	Intramuscular -25°C to -15°C & 2- 8°C
8.	Novel Corona Virus-2019-nCov vaccine (recombinant DNA) (2 mg)	Cadila Healthcare Limited 20.08.2021	Three doses (Day 0, 28 and 56)	For ≥ 12 years age	Intradermal 2^0C to 8^0C

Reference: COVID-19 Vaccines Approved for Emergency situation in the country. [internet] [cited Sep 15, 2021]. Available from:https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2OQ

Novel Antiviral for CMV Infection in Transplant Recipients

Maribavir or Benzimidavir is a benzimidazole ribose compound that is approved by the USFDA for treatment of cytomegaloviral (CMV) infection in solid organ & hematopoietic stem cell transplantation. The compound is a selective ATP competitor of viral protein UL97 kinase that is responsible for viral DNA assembly and movement of viral capsids from nucleus of infected cells. Currently available anti-CMV agents act by inhibiting DNA polymerase, and though effective have toxic effects like myelosuppression and nephrotoxicity. In addition to the

benzimidazole being active against resistance CMV strains, it is professed to have a favourable safety profile. It is approved for treatment against cytomegaloviral infections which are either resistant or ineffective to conventional anti-viral agents (Valganciclovir, Ganciclovir, Foscarnet, Cidofovir).

In a phase-2, open-label, dose-blinded study, response to treatment in 3 and 6 weeks was seen in higher numbers in the maribavir dose groups compared to valganciclovir group (62 and 79% with mirabavir; 62 & 67% with valganciclovir respectively) although the number of patients discontinuing the trial due to adverse effects were greater in the mirabavir group. Mostly gastrointestinal effects were reported with mirabavir in contrast to neutropenia with valganciclovir. However, a phase-3 trial (SOLSTICE) demonstrated superiority over conventional antiviral therapies and lesser side effects with Mirabavir.

Mirabavir is available as 200mg tablets. The recommended dose is 400mg BID. The dose must be increased to 800mg & 1200mg BID when CYP3A4 enzyme inducers like carbamazepine, phenobarbital & phenytoin are used.

The plasma levels of the immunosuppressants like tacrolimus, sirolimus, everolimus & cyclosporin must be strictly monitored when used along with maribavir, as it increases the immuno suppressant levels in the blood.

The most common adverse effects seen in the group trial 303, maribavir vs placebo, were taste disturbances, nausea, vomiting and abdominal pain. Contraindications are not well studied but should be used with caution in patients who are concomitantly using ganciclovir & valganciclovir, as it inhibits the activation of these drugs. Virologic failure, and use of immunosuppressants should also be monitored.

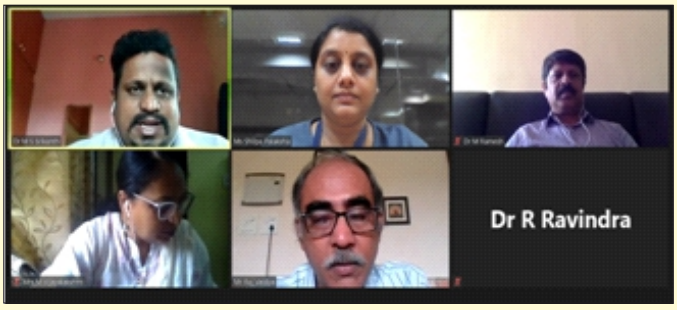
Reference: Johanmaertens et al, N Engl J Med 2019; 381:1136-1147
Takeda news releases[cited Nov 21, 2021] Available from https://www.takeda.com/newsroom/newsreleases/2021/takedas-maribavir-phase-3-clinical-trial/

DEPARTMENT ACTIVITIES

A series of webinars were organized by the Department during May to August 2021 for the benefit of Faculty and Pharm.D & Postgraduate Pharmacy Practice students and Practicing Pharmacists. The webinars were themed on 'Challenges & opportunities during the COVID-19 Pandemic' and 'Patient Safety'.

Webinar on "Challenges & Opportunities for Practicing Pharmacists During COVID-19 Pandemic"

A webinar on **'Challenges & Opportunities for Practicing Pharmacists During COVID-19 Pandemic'** was held on 12th June 2021. The webinar was conducted with an objective to provide a greater understanding of roles & responsibilities of practicing pharmacists during COVID-19 pandemic.



During the webinar

Dr. M. Ramesh, Professor & Head, Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru welcomed the gathering and briefed about objectives of the webinar. In his briefing, he mentioned that the pharmacists' role and responsibilities are expanding, and indeed pharmacists have a significant role to play during COVID-19 pandemic.

Mr. Raj Vaidya, Community Pharmacist, Hindu Pharmacy, Panaji, Goa delivered a talk on the topic *"Challenges of Community Pharmacy in India during COVID-19 Pandemic"*. In his talk, he highlighted the community pharmacists' challenging role and responsibilities during the COVID-19 pandemic and emphasized on the need & importance of considering the Pharmacists as a front-line warriors and essential staff.

Mrs. M. Vijayalakshmi, Pharmacy Officer, Department of Health & Family Welfare, Government of Karnataka delivered a talk on *"Challenges of Hospital Pharmacy in India during COVID-19 Pandemic"*. She briefed on various challenges faced by hospital pharmacists during COVID-19 pandemic and also highlighted the roles & responsibilities of hospital pharmacists in supply, procurement and inventory control of COVID-19 medications.

Mrs. Shilpa Palaksha, Asst. Professor, Department of Pharmacy Practice, JSSCP, JSS AHER, Mysuru spoke on *'Extended Services of Pharmacists During COVID-19 Pandemic'*. In her talk, she mentioned that Practicing Pharmacists could provide various extended services for the betterment of public health especially during the COVID-19 pandemic. Also, she emphasized on how small adaptation in the provision of the extended services can help in the promotion of safe and effective use of medicines in the time of pandemic.

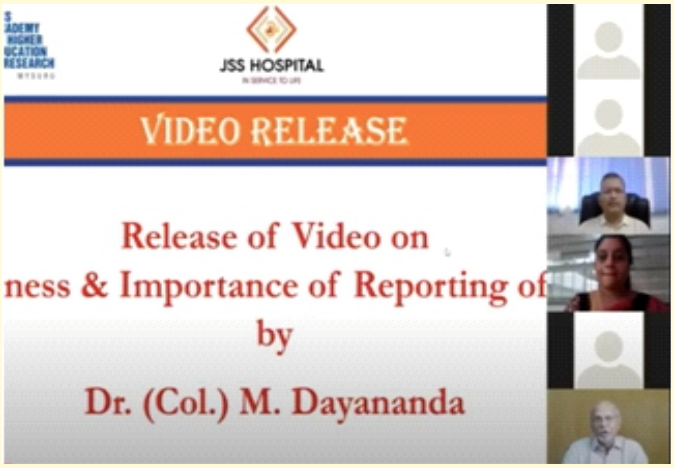
Dr. M. S. Srikanth, Lecturer, Dept. of Pharmacy Practice, JSSCP, JSS AHER, Mysuru moderated the session. Question & Answers session was quiet interesting as many participants posted questions pertaining to each topic, to which the speakers answered enthusiastically. More than 120 pharmacists participated in the webinar. Participants provided an excellent feedback on this webinar and they were happy with the content delivered through this webinar.

Webinar on 'Patient Safety'

The Regional Training Centre (RTC) for South Zone, Department of Clinical Pharmacy, JSS Medical College & Hospital, Mysuru in association with Pharmacovigilance Program of India, Indian Pharmacopeia Commission, Ghaziabad organised a webinar on **'Patient Safety'** on 23rd September 2021 as a part of 'National Pharmacovigilance Week 2021' celebrations. **Dr. M. Ramesh**, Coordinator AMC & RTC, JSS Medical College & Hospital, AND Professor & Head, Dept. Pharmacy Practice, JSS College of Pharmacy (JSSCP), JSS AHER, Mysuru welcomed the dignitaries & gathering, and highlighted on the purpose and theme of the webinar.

Dr. T. M. Pramod Kumar, Dean, Faculty of Pharmacy, JSS AHER delivered his opening remarks, and stressed that patient safety is responsibility of all the health care professionals and needs to be monitored & managed collectively in improving the overall health-related quality of life of the patients.

Dr. (Col.) M. Dayananda, Director, JSS Hospital, Mysuru delivered a keynote address after releasing a video on 'Awareness & Importance of Reporting of



Video release by Dr. (Col.) M. Dayananda

Adverse Drug Reaction (ADR)'. In his keynote address, he highlighted the importance of patient safety while providing the healthcare services. He emphasized on the importance of Pharmacovigilance in ensuring the patient safety as active and continuous vigilance on medication use is a great weapon in detecting, assessing, monitoring and preventing the medication errors and adverse events associated with the medication use process.

After the inaugural session, the first scientific session was delivered by **Dr. Shashi Bhushan**, Senior Scientific

During the welcome address

Officer, NCC-PvPI, IPC, Ghaziabad. He spoke on the topic **'Current Update of Pharmacovigilance Program of India (PvPI)'.** In his talk, he explained the basics of ADRs, and stressed on the importance and need of Pharmacovigilance. Later, he covered the structure and functions of PvPI, and discussed on the ICSR analysis. Following that **Mr. Sten Olsson**, Immediate-Past President, ISoP, UK delivered the talk on "**Components of well serving National Pharmacovigilance System**". During his talk, he emphasised on exchange of safety information in a series of communication loops. Also, he explained on the pharmacovigilance regulatory system and outlined the good governance & legal requirements for building a National Pharmacovigilance System. Following that Mr. Sten Olsson distributed the prizes to the winners of the various competitions held as a part of celebration of 'National Pharmacovigilance Week 2021'.

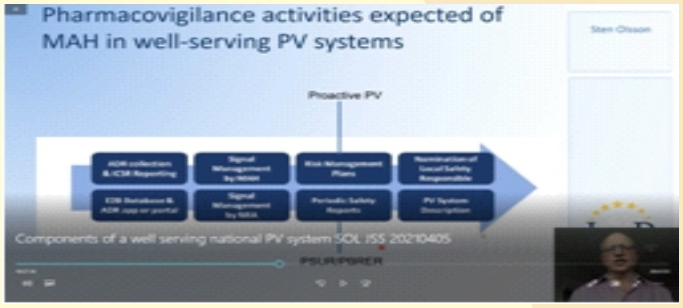
More than 350 health professions students, faculty and practicing health care professionals across the country benefited form attending the webinar. The webinar was concluded by the question & answer session followed by vote of thanks. **Mrs. Shilpa Palaksha & Mr. S. Balaji,** Faculty of Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru moderated the webinar.

Mr. Stel Olsson announcing award winners

Guest Lecture on 'Components of a Well Serving National Pharmacovigilance (PV) System'

Department organized an virtual guest lecture on the topic **'Components of a Well Serving National Pharmacovigilance (PV) System"** on 2nd June 2021 for the benefit of Pharm.D and M. Pharm Pharmacy Practice students. **Mr. Sten Olsson**, 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 participants on the requirements for setting up a national pharmacovigilance center and how national pharmacovigilance system works across the globe.

Mr. Sten, during his lecture, explained the reporting of adverse drug reactions on a national scale with special emphasis in India wherein he emphasized on the reporting structure covering who can report, where to report, how to report a suspected adverse reaction and also various modes of reporting. Later, he addressed the



Mr. Sten Olsson during his lecture

participants on pharmacovigilance activities expected of Marketing Authorization Holder (MAH) wherein Mr. Sten emphasized about the different pharmacovigilance activities carried out by MAH and its importance in pharmacovigilance. PharmD & Postgraduate Pharmacy Practice students and PhD research scholars attended and benefited from the guest lecture.

Guest Lecture on 'Risk Management Planning in Pharmacovigilance'

A virtual guest lecture on the topic **'Risk Management Planning in Pharmacovigilance'** was organised by the Department on 26th June 2021 for the benefit of PharmD and M. Pharm Pharmacy Practice students of both Mysuru & Ooty campuses. **Mr. Harshil Patel,** Deputy Manager - Pharmacovigilance, APCER Life Sciences, Inc., India and alumni of JSS College of Pharmacy, Mysuru was the resource person. The lecture was organized with the objective to enlighten participants on the importance of Risk Management Planning in Pharmacovigilance and role of pharmacist in risk management.

Mr. Harshil Patel briefed the participants on how the science of pharmacovigilance evolved and then explained about what the risk is. Later, he emphasized on risk management planning during the clinical research phases and further explained how the risk benefit analysis will help in taking decisions during the different phases of clinical research. Later, he addressed the participants on components of risk management in which he explained

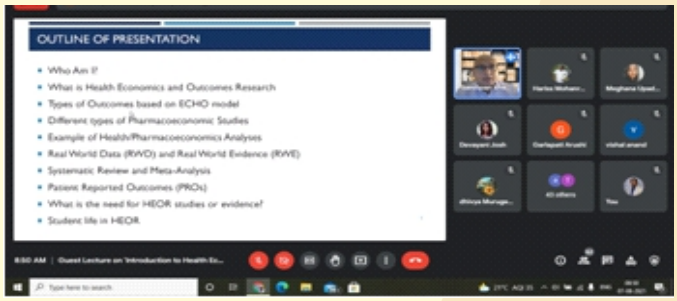
Mr. Harshil Patel during his lecture.

about how and where to collect the information on risk and how to communicate the same to stakeholders. Further, he explained about different risk minimization measures that can be incorporated in the daily practice.

PharmD, Postgraduate Pharmacy Practice students and PhD research scholars of Mysuru and Ooty campuses attended & benefited from the guest lecture by actively participating in the discussion during the interactive session.

Guest Lecture on 'Introduction to Health Economics and Outcomes Research'

Department organized a virtual guest lecture on **'Introduction to Health Economics and Outcomes Research'** on 7th August 2021 for the benefit of PharmD and M. Pharm Pharmacy Practice students. **Dr. Sandipan Bhattacharjee,** Director, Outcomes Research Methods, Otsuka Pharmaceutical Companies, New Jersey, USA was the resource person. The lecture was organized with the objective to enlighten participants on the need and importance of Health Economics and Outcomes Research.



Dr. Sandipan Bhattacharjee during his lecture

Dr. Sandipan Bhattacharjee, during his lecture, explained on different types of Economic, Clinical, Humanistic Outcomes Model and its applicability in research work. Later, he briefed the participants on different types pharmacoeconomic studies and the feasibility of carrying out systematic review and meta-analysis studies in Pharmacoeconomics. Further, he highlighted on patient reported outcomes, real world data (RWD) & real world evidences (RWE).

PharmD & Postgraduate Pharmacy Practice students and PhD research scholars attended & benefited form the guest lecture. As it was an interactive session, students actively participated in the discussion.

Workshop on 'Problem-Based Learning'

The Department of Pharmacy Practice in association with Pharmacy Education Unit (PEU) of JSS College of Pharmacy, Mysuru organised a workshop on **'Problem-Based Learning (PBL)'** on 14th August 2021 for the benefit of Faculty of JSS College of Pharmacy, Mysuru. The workshop was conducted after the inauguration of Pharmacy Education Unit of JSS College of Pharmacy, Mysuru.

Dr. R. S. Savitha, Associate Professor, Department of Pharmacy Practice**,** Faculty of Pharmacy, JSSAHER welcomed the audience. **Dr. P. A. Kushalappa,** Director (Academics), JSS AHER, Mysuru inaugurated the Pharmacy Education Unit and addressed the gathering. During his inaugural address, he highlighted the importance of PEU and briefed on the goals & objectives of PEU and Centre for Continuous Learning for Professional Excellence (CCLPE). **Dr. T. M. Pramod Kumar**, Dean, Faculty of Pharmacy, JSS AHER, Mysuru delivered the inaugural address and motivated the new office-bearers of the PEU to come-up with the innovative educational events focusing on development of knowledge & skills of the students and faculty to transform them as indispensable professionals.

Dr. M. Ramesh, Professor & Head, Dept. of Pharmacy Practice presented the overview of the workshop. In his address, he briefed on the importance of adopting PBL method of pedagogy in educational institutions to enhance the students learning experience and to increase students' abilities /skills and also to make them lifelong learners. The workshop was conducted in four sessions covering the concept & process of PBL, the roles & responsibilities of PBL facilitator, the roles & responsibilities of students as learners in PBL, followed by a hands-on session. **Mr. Atiqulla Shariff**, Research Scholar, Department of Pharmacy Practice engaged the first session of the workshop. He introduced the delegates to the goals, learning outcomes, basic elements and the concept of PBL. Further, an extensive interactive session was conducted on the process of PBL, wherein delegates were familiarized with the various steps of PBL process, designing of the PBL scenarios, organization of PBL class and assessment process in PBL. Later, **Ms. Shilpa Palaksha,** Associate Professor, Dept. of Pharmacy Practice engaged the second session. She explained the roles and responsibilities of the course faculty as PBL facilitators and demonstrated the various skills required by them to transform themselves as

Dr. P. A. Kushalappa, Director (Academics), JSS AHER, Mysuru inaugurated the PEU

effective and efficient PBL facilitators. She motivated the delegates to adopt the new responsibilities and play the role of PBL facilitators that can optimize the learning process and benefit students at large.

The last session was on roles and responsibilities of students in PBL process. **Dr. Acsah Annie Paul**, Lecturer, Dept. of Pharmacy Practice explained the facilitators' expectations from the students during the PBL process. She briefed the various roles of PBL group leader and PBL group scribe and their responsibilities in smooth conduct of the PBL session.

During the workshop, *'hands-on'* session was held and delegates were grouped into two teams. The teams were challenged with a PBL scenario, and asked to go through the steps of PBL and familiarize themselves to the PBL process.

At the end of the session, delegates were able to design the learning outcomes for the scenario provided. A total of twenty faculties from all five Departments of JSS College of Pharmacy, Mysuru attended the workshop. **Dr. Srikanth M. S.** Coordinator, PEU collated the feedback

During the Problem Based Learning session

During the 'hands-on' session

of delegates on the PBL workshop and proposed the vote of thanks. He thanked the administrators both at JSS AHER & JSS College of Pharmacy, Mysuru, CCLPE, supporting staff and delegates for their contribution towards the success of the event.

Awareness and Sensitisation Program on Adverse Drug Reaction Reporting & Monitoring

The Regional Training Centre for South Zone- PvPI, Department of Clinical Pharmacy, JSS Medical College & Hospital, Mysuru conducted an awareness session on 'Adverse Drug Reaction Reporting & Monitoring' to all the Heads of the Clinical Departments, JSS Hospital, Mysuru on 17th August 2021 at Sri Rajendra Centenary Auditorium, JSS Hospital, Mysuru.

Dr. M. Guruswamy, Medical Superintendent, JSS Hospital, Mysuru welcomed the gathering and highlighted the importance of reporting of adverse drug reaction. Later, **Dr. M. Ramesh,** Coordinator, AMC & RTC, JSS Medical College & Hospital, Mysuru briefed about the various patient safety initiatives undertaken by the AMC & RTC, and also discussed the various measures that are being implemented to prevent or minimize the adverse outcomes associated with use of medications and medical devices.

Following that **Dr. Sri Harsha Chalasani,** Deputy Coordinator engaged the session by deliberating the data on ADRs that were reported between January and June 2021. The presentation included various assessments including the top ten drugs responsible for causing ADRs, Causality Assessment, Predictability, Preventability, Severity and their Management. The session was followed by the interactions between the Heads of Clinical Departments and AMC staff on the various aspects of reporting & monitoring of ADRs. Further, **Dr. M. Ramesh** clarified the issues or concerns that did arise in the minds of the clinicians on patient safety reporting, and encouraged them to report all the suspected adverse drug reaction irrespective of its nature, severity or seriousness, and also thanked them for their constant support & cooperation extended towards the cause of patient safety.

During the awareness & sensitization session

Training on Pharmacovigilance Activities Conducted for the Postgraduate Students of Department of Pharmacology, JSS College of Pharmacy, Mysuru

The Regional Training Center for South Zone- PvPI, Department of Clinical Pharmacy, JSS Medical College & Hospital, Mysuru conducted a two-days Training Program on "Pharmacovigilance Activities" for Postgraduate Pharmacology Students of JSS College of Pharmacy, Mysuru. It was conducted at AMC Centre, JSS Hospital, Mysuru on 5th& 6th August 2021. The training was organized with the objective to enlighten students on importance of reporting of adverse drug reaction, Medication Incidents, Adverse Events Following Immunization, Materiovigilance and Hemovigilance.

Dr. M. Ramesh, Coordinator-AMC, Professor & Head, Department of Clinical Pharmacy welcomed the students and briefed them about the training schedule and introduced them to the staff of Clinical Pharmacy. Later, **Dr Sri Harsha Chalasani**, **Dr. Juny Sebastian** and **Dr. Puvvada Rahul Krishna** engaged them with the session. On day 1, initially, students were briefed about the daily activities of patient care pharmacy services such as drug

therapy monitoring, pharmacist intervention and patient safety monitoring with an special emphasis on adverse drug reaction and adverse event following immunisation.

During further sessions, an in-depth discussion on ADRs and their classification, importance of ADR reporting, monitoring and management were emphasised with practical examples. Following that students were trained on causality assessment of reported ADR. Further, they were trained on how the Severity, Predictability and Preventability of ADRs are to be assessed using various standardised scales. Also, they were briefed and trained on Vigiflow data entry with the *hands-on* session to familiarise them with the online data entry.

Later students were trained on the process of detection, reporting, monitoring and prevention of Medication Incidents on the NCC MERP adopted Medication Error Index that classifies an error according to the severity of the outcome. Further, they were exposed to various aspects of Materiovigilance including the detection, reporting, assessment and monitoring of adverse events associated with medical devices in order to generate, report, document and communicate the safety data on medical devices by adopting best practices.

On day two, students were trained on the process of adverse event following immunization (AEFI) including process of detection, reporting, assessment, documentation and communication of AEFI reports. The students were exposed to gain an understanding on the basics of Hemovigilance. Finally, *hands-on* session on medication incidents and materiovigilance was conducted taking few of the reported cases.

During the training session

Accolades

- **Ms. Jalapa Pradhan, Pharm.D Intern** was awarded with ***'Best Professional Poster Presentation'*** for her presentation of research paper entitled "Assessment of patient satisfaction, outcomes and experience measurements among patients receiving general anesthesia" during RAKCOPS International e-Conference on Drug Development organised by RAK Medical & Health Sciences University, Ras Al Khaimah, UAE held during 23rd & 24th May 2021.
- **Ms. Amruta PotdarAshok, Postgraduate Pharmacy Practice Student** was awarded with ***'Best Professional Poster Presentation'*** for her presentation of research paper entitled "Active Surveillance of Hemovigilance in a Tertiary Care Teaching Hospital: A Developing Country Scenario" during RAKCOPS International e-Conference on Drug Development organised by RAK Medical & Health Sciences University, Ras Al Khaimah, UAE held during 23rd & 24th May 2021.
- **Mr. Divyansh Sharma, V Pharm.D Student** was recognised as **"Chhattisgarh Society of Pharmaceutical Science (CGSPS) Yuva State President"** for the year 2021 by CGSPS

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 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

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