

Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

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ADVERSE DRUG REACTION REPORTS: SEP - DEC 2021

A total of 450 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during Sep – Dec 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
Amitriptyline	Constipation
Anastrozole	Cellulitis
Apremilast	Mood Swings
Atazanavir	Icterus
Carbimazole	Jaundice
Cremaffin	Urticaria
Digoxin	Gynecomastia
Escitalopram	Dry Mouth
Etoricoxib	Fixed Drug Eruption
Isoniazid	Delirium
Nimesulide	Flexural Dermatitis
Ondansetron	QT Prolongation
Paracetamol	Fixed Drug Eruption
Piperacillin / Tazobactam	Cholestasis
Sunitinib	Oral Candidiasis

Digoxin induced Gynecomastia: The mechanism of digoxin-induced gynecomastia is believed to be a direct action at estrogen receptors due to similarity in the structure of digoxin and estrogen. As digoxin and furosemide are frequently used concurrently in congestive heart failure, it is important to recognise their possible interaction as furosemide is also reported to cause gynecomastia although its exact mechanism is still not known. Early recognition of gynecomastia and removal of the offending drug can save the patient from unnecessary investigations, anxiety and also reduce the medical expenses.

Isoniazid induced Delirium: There are two psychopathological mechanisms for isoniazid-associated psychosis that can also be valid for delirium have been described: the first mechanism involves isoniazid acting as a monoamine-oxidase inhibitor, thus preventing the degradations of catecholamines and serotonin and ultimately leading to an increased concentration of these neurotransmitters; the second involves the pyridoxine deficiency induced by isoniazid, also leading to a reduction in the concentration of the neurotransmitters. The line of management include discontinuation of suspected drug while patient is continued to be monitored.

Piperacillin / Tazobactam induced Cholestasis: Rare instances of idiosyncratic liver injury have been reported in persons receiving piperacillin. The liver injury is typically cholestatic arising within 1 to 6 weeks of starting therapy. The injury can be severe, but is generally self-limited once piperacillin is stopped. The features of the hepatotoxicity resemble those of other penicillins. The cholestatic hepatitis caused by piperacillin and other penicillins can be prolonged and lead to persistent cholestasis or persistent elevations in serum alkaline phosphatase suggestive of partial bile duct loss. Most cases of liver injury related to piperacillin are linked to the combination of piperacillin with the beta-lactamase inhibitor tazobactam, which is more commonly used than piperacillin alone.

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 (US FDA) during the period September – December 2021

Name of the drug	Indication
Mobocertinib	To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations
Tisotumab vedotin-tftv	To treat recurrent or metastatic cervical cancer with disease progression on or after chemotherapy
Atogepant	To prevent episodic migraines
Maralixibat	To treat cholestatic pruritus associated with Alagille syndrome
Avacopan	To treat severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis) in combination with standard therapy, including glucocorticoids
Asciminib	To treat Philadelphia chromosome-positive chronic myeloid leukemia with disease that meets certain criteria
Ropeginterferon alfa-2b-njft	To treat polycythemia vera, a blood disease that causes the overproduction of red blood cells
Vosoritide	To improve growth in children five years of age and older with achondroplasia and open epiphyses
Maribavir	To treat post-transplant cytomegalovirus (CMV) infection/disease that does not respond (with or without genetic mutations that cause resistance) to available antiviral treatment for CMV
Pafolacianine	To help identify ovarian cancer lesions
Tezepelumab-ekko	To treat severe asthma as an add-on maintenance therapy
Efgartigimod alfa-fcab	To treat generalized myasthenia gravis
Inclisiran	To treat heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease as an add-on therapy
Tralokinumab-ldrm	To treat moderate-to-severe atopic dermatitis

Reference: Novel Drug Approvals for 2021 [internet] [cited Jan 18, 2022]. 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 September – December 2021

Name of the drug	Indication
Cabozantinib (S) - Malate bulk and Cabozantinib tablets 20mg, 40mg and 60mg	For the treatment of patients with advanced renal cell carcinoma (RCC) For the treatment of patients with Hepatocellular Carcinoma (HCC) who have been previously treated with sorafenib
Tipiracil hydrochloride bulk and FDC of 1) Trifluridine 15mg + Tipiracil 6.14mg and 2) Trifluridine 20mg + Tipiracil 8.19mg	Indicated for the treatment of (1) Adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, an antiVEGF biological therapy, and if RAS wildtype, an anti-EGFR therapy (2) Adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/ neu-targeted therapy

Selumetinib 10mg & 25mg capsule	Indicated for the treatment of Pediatric patients 3 years of age and older with neurofibromatosis type 1 (NF1) and who have symptomatic, inoperable plexiform neurofibromas (PN)
Biapenem sterile bulk and Biapenem for injection 300mg	Complicated urinary tract infections
Tafamidis soft gelatin capsules 61 mg	Indicated for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTRCM)
Molnupiravir bulk and Molnupiravir capsules 200mg	For treatment of adult patients with COVID-19, with SpO ₂ >93% and who have high risk of progression of the disease including hospitalization or death, in light of Covid 19 outbreak for restricted emergency use in the country
Selexipag bulk and Selexipag tablets 200mcg/ 400mcg/ 600mcg/ 800mcg/ 1000mcg/ 1200mcg/ 1400mcg/ 1600mcg	For the treatment of Pulmonary Arterial Hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH

Reference: List of Drugs Approved in the year 2021 till date [internet] [cited Jan 18, 2022]. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODAyOA==

How Safe are the Fluroquinolone Antibiotics?

Fluoroquinolones are widely used for the treatment of a variety of infections due to their broad-spectrum activity. However, according to some epidemiological studies their use may be of some concern. Though tendinopathy, peripheral neuropathy, carpal tunnel syndrome, and retinal detachment have been reported with fluoroquinolones, recent studies have reported their association with aortic aneurysm or aortic dissection.

The US FDA had issued a warning about rare but serious events of ruptures or tears in the aorta with fluoroquinolones in certain patients in December 2018. In their announcement, they quoted risk factors for such events as those with aneurysms of aorta or other blood vessels, hypertension, genetic disorders involving blood vessel changes (Marfan, Ehlers-Danlos syndromes), and the elderly. They recommended that fluoroquinolones be prescribed in these patients only if there is no alternative available.

The evidence for the association of fluoroquinolone use and aortic aneurysm/ dissection is conflicting. A meta-analysis of four observational studies showed a 2-to-3-fold increased risk of aortic aneurysm and it was estimated that the number needed to harm was 1301. Since, observational studies are subject to residual confounding, another cohort study of more than a million patients compared the risk of these events in pneumonia and urinary tract infection. Fluoroquinolones caused more events than azithromycin in pneumonia but there were no increased events when compared with trimethoprim + sulfamethoxazole in urinary tract infections. So, the authors concluded that the beneficial effect with appropriate choosing of fluoroquinolones may outweigh the increased risk of aneurysms.

As opposed to the above findings, another nested case-

control study found no difference in the risk of aortic aneurysm or dissection with fluoroquinolones or amoxicillin clavulanate or cephalosporins in severe infections (odds ratio – 1.73, 95% CI 1.66-1.81), though an increased risk of these events was observed across all types of infections (pneumonia, genito-urinary, intra-abdominal, soft tissue and bone infections). The authors opined that infection severity may confound the association between quinolone use and aortic disease especially since they are used more commonly in severe infections and in older patients.

Another retrospective study of patients admitted only for aortic aneurysm or dissection looked for risk of rupture, surgery or death and found a 1.8-fold increase in aortic death in patients who had received fluoroquinolones. However, the comparator group in this study was amoxicillin yet again confounding the severity of infection for which the two groups of patients were treated.

In light of these findings and until the association is made explicit in future controlled studies, it is advisable to use these drugs cautiously in patients with family history of aneurysms, connective tissue disease and the elderly. When aortic disease is detected, the drug should be stopped immediately and patient referred for appropriate surgical interventions.

Aortic disease notwithstanding, this class of drugs are associated with other major adverse effects like QTc prolongation and cardiac arrhythmias, Dysglycemia (hypo- or hyper-glycaemia), hepatotoxicity, and even CNS effects like psychosis and hallucinations. In view of all these, practicing antimicrobial stewardship in listing out conditions for fluoroquinolone use may limit adverse events as well as limit antibiotic resistance.

References:

1. Dai Xc, Yang Xx, Ma L, Tang Gm, Pan Yy, Hu Hl. Relationship between fluoroquinolones and the risk of aortic diseases: a meta-analysis *BMC Cardiovasc Disord* 2020;20(1):49
2. Gopalakrishnan C, Bykov K, Fischer MA, Connolly JG,

- Gagne JJ, Fralick M. Association of fluoroquinolones with the risk of aortic aneurysm or dissection *JAMA Intern Med* 2020; 180(12):1596-1605
3. BaggioD, Rajah MRA. Fluoroquinolone antibiotics and adverse events. *Aust Prescr* 2021.44(5):161-4

Antiviral Drug Umifenovir vs Standard Care of Therapy in Non-Severe COVID-19 Patients

A Phase III, Randomized, Double-blind, Placebo controlled, multicenter trial was conducted with an objective to test efficacy, safety and tolerability of Umifenovir in non-severe COVID-19 patients. Study enrolled adult, non-severe COVID-19 patients, randomized 1:1 on placebo or Umifenovir (800 mg BID, maximum 14 days) respectively along with standard of care. The primary endpoint for asymptotic-mild patients was time to nasopharyngeal swab RT-PCR test negativity. For moderate patients, the average change in the ordinal scale from the baseline scores on the eight-point World Health Organization (WHO) ordinal scale was assessed.

A total of 132 patients were recruited between October to April 2021, of which 9 discontinued due to various reasons. In mild-asymptomatic patients (n=82), study found that 73% patients in the Umifenovir arm were RT-PCR negative, while 40% patients in the placebo arm

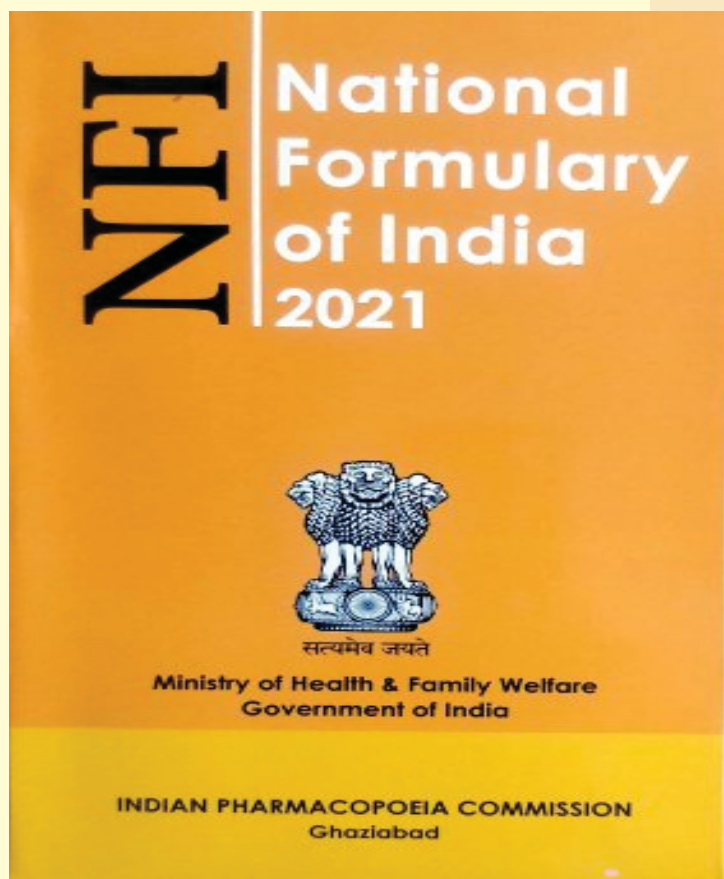
were negative (P=0.004) on day 5. However, in the moderate group (n=41), the WHO scores for the Umifenovir arm was not statistically significant (P=0.125 on day 3), while it was statistically significant in the Mild-asymptomatic group (P=0.019 on day 5).

Study concludes that, Umifenovir meets the primary and secondary endpoint criteria and exhibits statistically significant efficacy for mild-asymptomatic patients. It is efficacious, safe and well tolerated at the tested dosage of 800mg BID for maximum 14 days.

Reference: 1) Ramachandran R, Bhosle V, Reddy H, Atam V, Faridi MMA, Fatima J et al. Phase III, Randomized, Double-blind, Placebo controlled trial of Efficacy, Safety and Tolerability of Antiviral drug Umifenovir vs Standard care of therapy in non-severe COVID-19 patients . *International Journal of Infectious Diseases* 2022; 115; 62–69

National Formulary of India 2021

The sixth edition of the National Formulary of India (NFI) was launched by the Hon'ble Union Health Minister Mansukh Mandaviya in October 2021. It was published based on the principle "Do not miss critical and do not overload". The sixth edition includes only those drugs that are approved by the Central Drugs Standard Control Organization (CDSCO), the drug regulator of the country. In the sixth edition, the chapters such as Disease Modifying Anti-Rheumatic Drugs, dermatological drugs, basics of medical emergencies, antimigraine drugs, substances used in poisoning, antidotes, laxatives, anti diarrhoeals, anaphylaxis, antiallergics, antiulcer drugs, antacids, antiepileptics and anti-inflammatory drugs were revised. Around 34 therapeutic chapters were included in the sixth edition. This includes 591 drug monographs as well. The sixth edition is aligned with the National Health Programmes in the country and the National List of Essential Medicines. Further, it includes information about the drugs banned in the country. Also, it includes drugs banned in sports and immunization schedules. The sixth edition has a new addend which is not found on previous editions. That is, it has included "How to use National Formulary of India" page and also its salient features. The term availability has been replaced with



dosage forms and usual strength. The National Formulary of India helps to understand about the impact and side effects of different medicines. It is beneficial and of great help to the healthcare professionals while prescribing the medicines to the patients and thereby promotes the rational use of different medicines in the country.

The National Formulary of India 2021 **act as a guidance document for all the healthcare professionals** such as

clinicians, pharmacists, nurses, dentists. The use of NFI 2021 in daily clinical practices will play a crucial role not only in promoting the rational use of medications but also infuses the necessary knowledge and best inventory control practices of essential medications. Further, the wider the utilisation of the NFI by the healthcare professionals, the deeper would be the insights gained and fortifies the upcoming editions for the benefit of safe and quality use of medicine.

LET US ADOPT NATIONAL FORMULARY OF INDIA 2021 AND PROMOTE PATIENT SAFETY


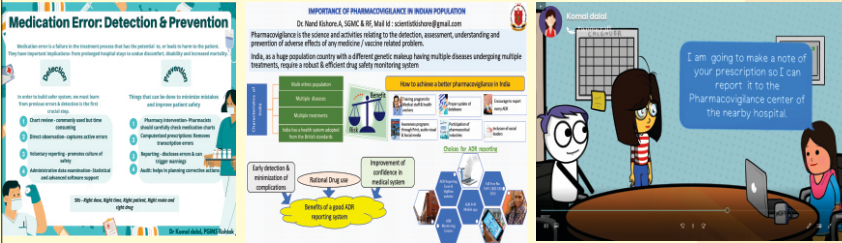
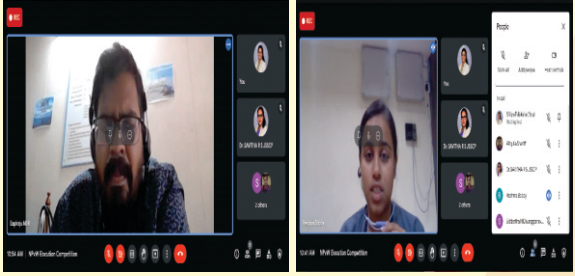
DEPARTMENT ACTIVITIES

A series of events were conducted by the Department during September to Decemeber 2021 for the benefit of the health profession students and health care professionals.

National Pharmacy Week Celebration 2021

ADR Monitoring Centre & Regional Training Centre for South Zone, Pharmacovigilance Program of India, PvPI, Department of Clinical Pharmacy, JSS Medical College & Hospital, Mysuru organized the series of events as a

part of 'National Pharmacovigilance Week 2021'. The list of events with their themes held during 17-23 September 2021 is presented below.

Date	Name of the Event	Theme(s)
17 Sept 2021	Sensitization and Awareness Campaign on Reporting of ADRs at Community Level	<p>Reporting of Adverse Drug Reactions</p> 
18 Sept 2021	Essay Writing Competition	Social Media: A Tool for Spreading Awareness on PV or PV In Patient Safety: Challenges and Perspectives
19 Sept 2021	Quiz Competition	Pharmacovigilance: A Step Towards Patient Safety
20 Sept 2021	e-Poster & Animation Competition	<p>Public Engagement in Pharmacovigilance or Medication Error: Detection & Prevention</p> 
21 Sept 2021	Elocution Competition	<p>Pharmacovigilance: A Step Towards Patient Safety</p> 

22 Sept 2021	Sensitization and Awareness Campaign at JSS Hospital, Mysuru	<p style="text-align: center;">Reporting of Adverse Drug Reactions</p> 
23 Sept 2021	Webinar on Patient Safety	Pharmacovigilance: A Step Towards Patient Safety

Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) Program for Pharm.D Interns

The Department organised a training session on '**Basic Life Support**' (BLS) and '**Advanced Cardiac Life Support**' (ACLS) for Pharm.D interns in the month of October 2021 in conjunction with JSS AHER Skills & Simulation Lab. Faculty from the JSS AHER Skills & Simulation Lab imparted the training to Pharm.D interns in two batches. Interns were provided with study materials for Basic Life Support & Advanced Cardiac Life Support well in advance to enable them to be prepared with the procedures and policies prior to their training program. The training session was held for 3 days for each of the two batches, from 21st-23rd October 2021 and 28th-30th October 2021 for Batch I and Batch II respectively. The program instructors were **Dr. K M Archana, Dr. Manthappa, Dr. S B Adarsh, Dr. Vyshnavi, Dr. S Archana, Dr. Harish and Dr. C R Venkatesh**, Faculty from JSS Medical College & Hospital, JSS AHER, Mysuru.

The first day of the program involved training of students about providing basic life support both in in-hospital and out-of-hospital scenarios. Introductory videos explaining the steps to be performed in emergencies and life saving measures in cardiac arrest were displayed and following that a *hands-on* session on cardio-pulmonary resuscitation (CPR) was held using mannequins. Dr. K M Archana briefed the interns on the emergency activation codes for JSS Hospital and its activation process during the session. This session was followed by display of additional videos demonstrating the use of automated external defibrillator (AED), pocket masks & bag masks (Ambu-bag). The frequency and depth of compressions while providing CPR were demonstrated to the interns followed by a *hands-on* session on use of AED. This was followed by a session on choking in adults and infants and first-aid measures to be taken in case of choking.



Faculty trainers demonstrating the session on Cardio Pulmonary Resuscitation

The following day of the program, a training session on advance life support was held. This session was intended only for those who successfully completed the Basic Life

Support training. During this session, the different types of treatment algorithms for different types of emergencies were taught to the participants. The different intubation techniques were also discussed.

Following that a session on ECG patterns and its reading and interpretation was held, and further interns were taught on post cardiac arrest care. All the sessions were followed by practical learning through case scenarios using mannequins. On the third day, students wrote a written objective type test followed by a practical session where they were allowed to practice what they had learned in simulated settings on different type of emergencies. Post-lunch, a practical exam was scheduled where students had to demonstrate the skills learned in scenarios with different emergency codes, and performance of participants were evaluated. All the students showed keen interest in learning various aspects of life support and opined that the program has helped



Students performing Cardio Pulmonary Resuscitation

them to develop skills that will be of use to them in future for provision of such act of life support.

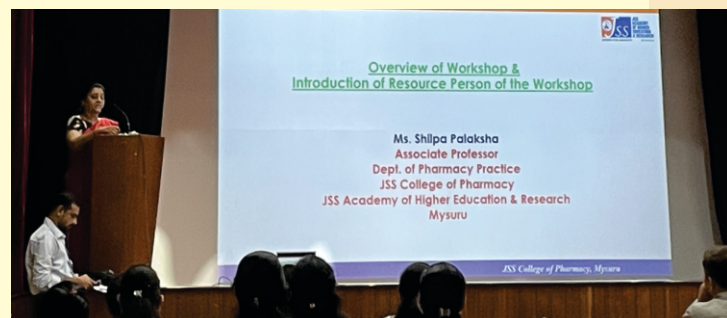
Workshop on Effective Writing of MCQs

The Department of Pharmacy Practice in association with Pharmacy Education Unit (PEU) at JSS College of Pharmacy, Mysuru conducted a workshop on 'Effective Writing of MCQs on 18th November 2021. The event began with opening remarks by **Dr. T. M. Pramod Kumar**, Dean, Faculty of Pharmacy, JSS AHER. In his opening remarks, he explained about the applications of MCQs as a tool in active-learning and assessment

methods. **Ms. Shilpa Palaksha**, Associate Professor, Dept. of Pharmacy Practice, presented the overview of the workshop. A total of forty-seven delegates from different departments of JSS College of Pharmacy, Mysuru, attended the workshop. The workshop was conducted in two sessions covering the basic concepts of writing MCQs, followed by a hands-on training session.



During the Inuagual event



Dr. Sathvik B S, Professor & Chairperson, Dept. of Clinical Pharmacy & Pharmacology, RAK College of Pharmaceutical Sciences, RAK Medical & Health Sciences University, Ras Al-Khiamah, United Arab Emirates was the resource person for the workshop. During his presentation he briefed the delegates about the

basics of writing effective MCQs such as anatomy of MCQs, criteria for good test MCQs, various levels of thinking & Bloom's taxonomy, different levels & types of MCQs, and guidelines for constructing MCQs. This introductory session was followed by the group activity.



Participants during the workshop

Mr. Atiqulla Shariff, Research Scholar, Department of Pharmacy Practice, facilitated the group activity. During

the group activity, the delegates were grouped into eight different groups and challenged with the various levels &

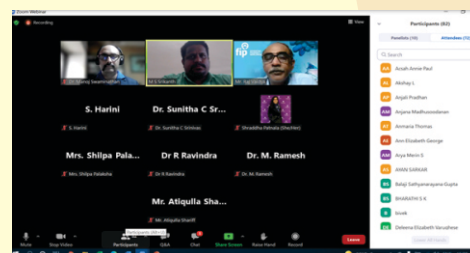
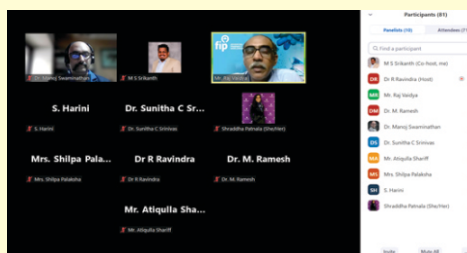
types of MCQs. Delegates were asked to identify the best MCQs, MCQs that needs improvement and overall feedback of MCQ sets. At the end of the session, the delegates were able to understand the process of designing effective MCQs in their subject area incorporating various levels and types of MCQs. **Dr. M.**

S. Srikanth, Member Secretary, PEU, JSSCP, Mysuru, assembled the feedback of delegates about the workshop during wrap-up session and proposed the vote of thanks. The event ended by thanking all the administrators both at JSS AHER & JSS College of Pharmacy, Mysuru, the resource person of the workshop and all the delegates for their contribution towards the success of the event.

Webinar on Antibiotic Stewardship Program

In view of World Antimicrobial Awareness Week-2021, Dept. of Pharmacy Practice, JSS College of Pharmacy, Mysuru in association with Karnataka State Pharmacy Council and Community Pharmacy Branch of Indian

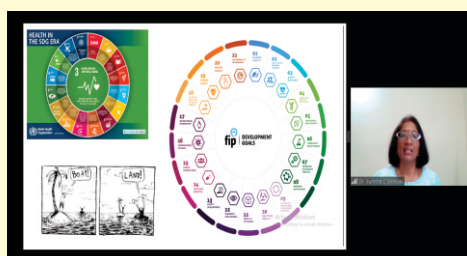
Pharmaceutical Association had jointly organized a webinar on '**Antibiotic Stewardship Program**' on 23rd November 2021. Speakers from local, national & international platform delivered various topics related to antibiotic stewardship programs around the globe.



Panel members during the webinar

The webinar began with the inaugural speech by **Mr. Raj Vaidya**, Co-lead, AMS initiative IPA-CPD and Chief Pharmacist, Hindu Pharmacy, Panaji, Goa. In his inaugural speech **Mr. Raj Vaidya**, presented the

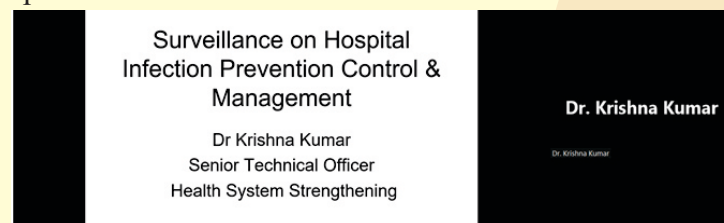
overview of the webinar and shared the importance of practicing antimicrobial stewardship program at all practice sites to combat the problem of antimicrobial resistance.



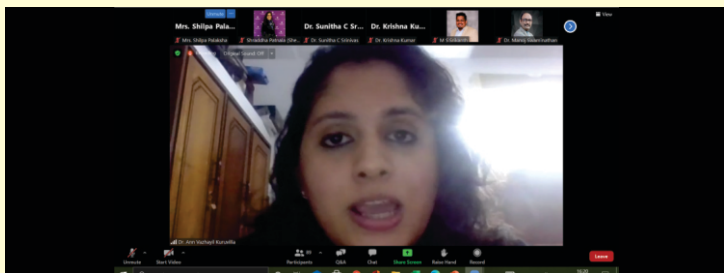
During the webinar

Dr. Sunitha C Srinivas, Visiting Professor, Rhodes University, South Africa and Adjunct Professor, University of Health Sciences and Pharmacy, St. Louis, USA spoke on Aware enough to go blue? Hallmarks of AMS around the world. **Dr. Manoj Swaminathan**, Founder / Director Vingiserve Foundation, Mumbai delivered a talk on AMR - the Unforeseen Safety Impact. **Dr. Amit Kumar Mehta**, Post-Graduate Student, Department of Health Policy Planning and Financing, London School of Economics, UK spoke on Policy developments in AMR and the status of their implementation. **Ms. Shraddha Patnala**, Founder of The Freelancing Quill, South Africa, presented the digital media perspective on AMR in Creating appropriate awareness. **Dr. Krishna Kumar**, Senior Technical

Officer vaccination, Jhpiego, Coimbatore spoke about Surveillance of hospital acquired infections. **Dr. Shobha Rani R H**, Professor & Head, Department of Pharmacy Practice, Al-Ameen College of Pharmacy, Bengaluru, delivered a talk on Evaluation of prescribing pattern of antibiotics using WHO indicators in hospitals. **Dr. S. Harini**, Junior Pharmacovigilance Associate at Coimbatore Medical College and Hospital, Coimbatore spoke about AMR: an overlooked adverse event.



During Dr. Krishna Kumar's session



Dr. Ann during the session

Dr. Ann Vazhayil Kuruvilla, Clinical Pharmacist, JSS Hospital, Mysuru presented the overview of Basic Principles in Antibiotic use for a successful AMSP Practice Real-time. **Dr. Gautam Kalyatanda**, Clinical Assistant Professor, Division of Infectious diseases and Global Health, University of Florida, Gainesville, USA

addressed on One Health and AMR. **Ms. Stephanie Lukas**, Interim Director, Global Health and Equity Education and Associate Professor, Pharmaceutical and Administrative Sciences, USA discussed about Harnessing the Power of Collaboration to Address Antimicrobial Resistance. **Dr. Rakshith U R**, Lecturer, Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru spoke on Community Pharmacy Antibiotic Stewardship programs. Around 108 delegates including pharmacy and health science students, practicing pharmacists, academicians, health care professionals attended the webinar and witnessed the currents trends of antimicrobial resistance and strategies of Antimicrobial Stewardship Programs around the globe.

Awareness Program on Adverse Drug Reaction Reporting Form, Version 1.4

Adverse Drug Reaction Monitoring Centre & Regional Training Centre, Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysuru conducted an awareness programme on 'Adverse Drug Reaction Reporting Form, Version 1.4' to the students of Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru on 9th December 2021.

This awareness session was aimed at preparing the student workforce in the transition of adverse drug reaction reporting form from version 1.3 to version 1.4. The changes were highlighted and explained using suitable examples. The students rectified their doubts pertaining to the form filling and archiving. The AMC & RTC has thus adapted ADR Reporting Form version 1.4.



Dr. Sri Harsha during the awareness program

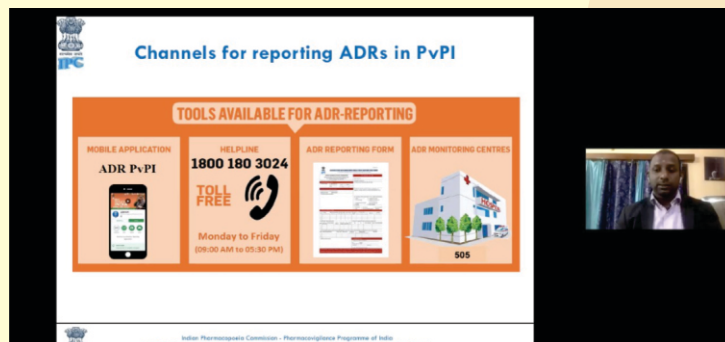
Dr. Sri Harsha Chalasani, Assistant Professor & Deputy Coordinator explained the participants on the newer version of ADR reporting form (version 1.4).

Webinar on "Essentials of Pharmacovigilance: Basics to Advanced

The Regional Training Centres of JSS Medical College & Hospital, Mysuru AND Amrita Institute of Medical Sciences, Kochi under the aegis of Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission, Ghaziabad jointly organised a half-day webinar on 'Essentials of Pharmacovigilance: Basics to Advanced' on 18th December 2021. **Dr. M. P. Narmadha**, Professor & Head, Dept. Pharmacy Practice, AIMS, Kochi welcomed the gathering. Following that **Dr (Col.) Vishal Marwaha**, Principal, ASM, AIMS, Kochi and **Dr T. M. Pramod Kumar**, Principal, JSS College of Pharmacy, JSS AHER, Mysuru gave their opening remarks. Later, **Dr Jai Prakash**, Senior Principal Scientific Officer, Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ghaziabad delivered the keynote address.

After the inaugural function, **Dr R. S. Ray**, Scientific Assistant, Indian Pharmacopoeia Commission,

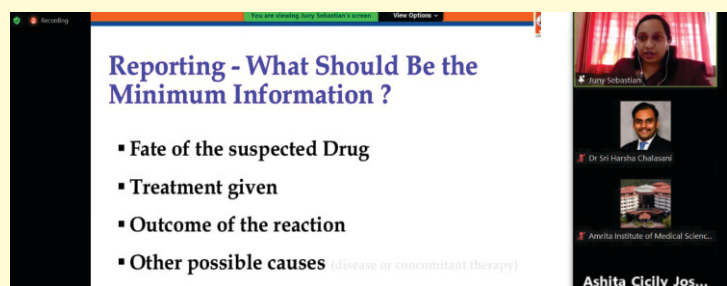
Ghaziabad delivered the first session on the topic "Current updates on Pharmacovigilance Programme". In his talk, he said that promoting safe use of medicines is a priority of Indian Pharmacopoeia Commission that functions as the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI). During his talk, he highlighted on various measures to enhance



Dr R. S. Ray during his talk

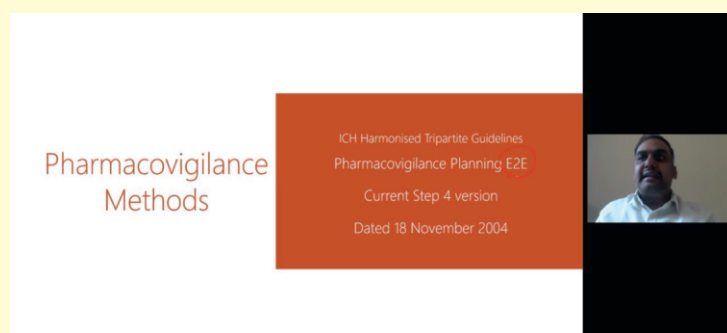
patient safety including capacity building for monitoring, surveillance, collaboration with national health programs and other organizations to increase ADR reporting and to ensure that PvPI is a vital knowledge database for Indian regulators.

The second session was on 'Reporting of Safety Information' and was delivered by **Dr Juny Sebastian**, Assistant Professor, Dept. Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru. In her talk, she emphasised the need for and importance of ADR reporting and also the mechanisms to strengthen the safety reporting. Also, she explained on ADR reporting structure including modes of reporting.



Dr. Juny Sebastian during her talk

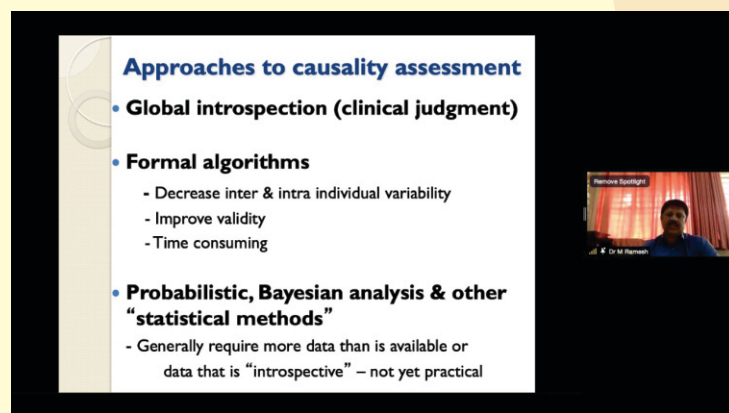
Following that, **Dr Sri Harsha**, Assistant Professor, Dept. Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru delivered a talk on 'Research Methodologies in Pharmacovigilance'. During his



Dr Sri Harsha during his talk

lecture, he outlined various important pharmacovigilance methods with their merits and demerits. Also, he discussed the methods in details by quoting recent and important published papers that adopted the pharmacovigilance methods.

Dr M. Ramesh, Coordinator, AMC & RTC, JSS Medical College and Hospital, Mysuru AND Professor & Head, Dept. Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru delivered a talk on 'Causality Assessment of Adverse Drug Reaction'. During his talk, he discussed in detail about various approaches and different methods of causality assessment. In his talk, he emphasized on applications of WHO probability scale and Naranjo's scale in the clinical practice and the issues associated with causality assessment.



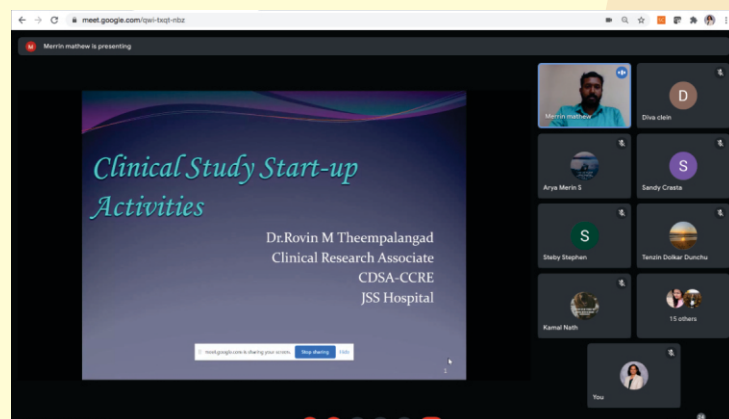
Dr. M Ramesh during his talk

Following that, **Dr Princy Louis Palatty**, Coordinator, RTC, AIMS, Kochi AND Professor & Head, Dept. Pharmacology, ASM, AIMS, Kochi delivered the talk on 'Signal Detection and Its Components'. In her talk, she highlighted the importance of signal detection in the patient safety and dealt in detail on various aspects of signal detection. Finally, **Dr Sanitha Kuriachan**, Associate Professor, Dept. Pharmacology, ASM, AIMS, Kochi delivered the concluding remarks.

Guest Lecture Series on 'Clinical Trial Start-Up Activities'

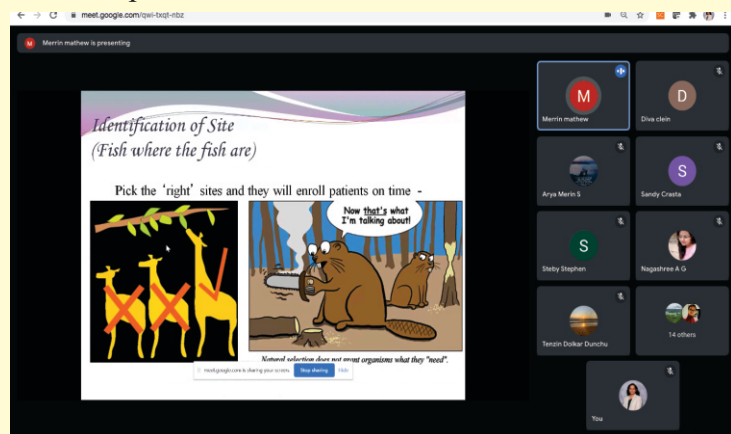
The Department of Pharmacy Practice organised a series of guest lectures on the topic '**Clinical Trial Start-Up Activities**' for the Pharm.D, Postgraduate Diploma in Clinical Research and Postgraduate Students of Pharmacy Practice from 26th-30th November 2021. **Dr. Rovin Mathew Theempalangad**, Clinical Research Associate, Clinical Development Services Agency (CDSA), Center for Clinical Research Excellence (CCRE), JSS Hospital, Mysuru delivered a series of guest lectures.

In the **first** session held on 26/11/ 2021, Dr. Rovin explained the importance of site feasibility questionnaire



Dr. Rovin Mathew during guest lecture series

and the different elements included in it. Also, he explained about the Site/ Investigator Selection, Vendor selection process in a clinical trial.



During the second session

Second session (28/11/2021) focused on 'Essential Documents' that needs to be maintained prior, during and post clinical trial with different clinical trial stakeholders. Importance of pre-study visit by the sponsor to the site and also the need of investigators meeting was discussed in second session. In the **third** session (29/11/2021), he

focused on preparation of informed consent and its translation to different languages. Also, he explained on clinical trial agreement execution and the procedures involved in ethics committee document preparation and submission during this session. In the **fourth** session (30/11/2021) of the lecture series, Dr. Rovin explained about procurement and storage of investigational product, filing procedures and about the site initiation visit. Also, he discussed on different files, that need to be maintained at the site throughout the study such as Trial Master File, Investigator Site File/Regulatory Binder and Pharmacy File.

All the **four** sessions were attended by Postgraduate Diploma in Clinical Research, Postgraduate Pharmacy Practice and Pharm.D students. Dr. Rovin shared his experiences of site start-up activities during each of the sessions. Also, he highlighted the practical difficulties faced by a site in completing the activities before the start of the study. Students got an opportunity to interact with the speaker and clarify all their doubts. Students expressed that the all four sessions were very useful. The series of guest lectures was conducted using video communication platform, Google meet.

Health Screening Camp Conducted at Mysuru City

Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru in collaboration with NSS Unit of JSS College of Pharmacy, Mysuru and Indian Pharmaceutical Association (IPA), Mysore Local Branch organized a Health Screening Camp on 15th December 2021 at three different locations Viz., Akashvani Circle, Kukrahalli Lake gate and Lalith Mahal Arch between 6.00 AM and 9.00 AM. The aim of the health screening camp was to sensitize the people about the importance of regular monitoring of health and safe use of medications. During the camp, interested public were screened for

blood pressure and blood glucose levels.

A total of 274 people were monitored for their blood pressure and blood glucose levels. At the time of monitoring, 86 people were found with elevated blood glucose level and 87 people were found with elevated levels of blood pressure. People who were identified with the elevated levels of blood pressure and blood glucose levels were advised on Non-Pharmacological management and suggested to consult physician for further diagnosis & treatment. A good response from public was observed and they have appreciated the effort



During the health screening camp

Awards and Accolades

- The **Adverse Drug Reaction Monitoring Centre (AMC), Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysuru** secured First place among the Top 10 AMCs of the 395 AMCs located across the country as declared by the National Coordination Centre, Pharmacovigilance Program of India (PvPI) during the celebration of "**National Pharmacovigilance Week 2021**" held during 17th – 23rd September 2021
- **Dr. Jaidev Kumar BR, Faculty** received **Best Mentor Award** during the International Symposium on Medication Therapy Management 2021 (ISMTP-2021) held from 12th-14th November 2021
- **Mr. Vishal Anand S S (Pharm.D Intern)** received "**Association of Pharmacy Professionals (APP) Unique Student Award**" in Post-Graduate category during APP 10th International virtual convention hosted by Vels Institute of Science, Technology and Advanced Studies (VISTAS), Chennai, Tamil Nadu during December 11-12, 2021
- **Ms. Navneetha B (M.Pharm Pharmacy Practice student)** secured **Second Prize in Essay Writing Competition** held on 18th September 2021 as part of the "**National Pharmacovigilance Week 2021**" organised by the Regional Training Centre for South Zone under PvPI, Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysuru
- **Ms. Reshma Bobby and Mr. Mothilal (Pharm.D Interns)** secured **100% marks in the quiz competition** held on 19th September 2021 as part of the "**National Pharmacovigilance Week 2021**" organised by the Regional Training Centre for South Zone under PvPI, Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysuru
- **Ms. Ayemen Fatima (IV Pharm.D student)** secured **Second Prize in e-Poster Competition** held on 20th September 2021 as part of the "**National Pharmacovigilance Week 2021**" organised by the Regional Training Centre for South Zone under PvPI, Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysuru
- **Ms. Reshma Bobby (Pharm.D Intern) and Ms. Bijisha Baburaj Nair (IV Pharm.D student)** Secured **First and third Prize respectively in Elocution Competition** held on 21st September 2021 as part of the National Pharmacovigilance Week 2021 organised by the Regional Training Centre for South Zone under PvPI, Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysuru
- **Ms. Meghana Upadhya (V Pharm.D student)** secured **International Symposium on Medication Therapy Management 2021 (ISMTP-2021)** Award for top 7 SOAP note analysis & online presentation
- **Mr. Gona Oliver Joel (Research Scholar)** was awarded PhD Degree on 23rd December 2021 by JSS Academy of Higher Education & Research, Mysuru for successfully completing his doctoral research entitled 'Assessment of pharmacist-initiated optimization of pharmacotherapy in patients with acute coronary syndrome'. He carried out his research work under the supervision and guidance of **Dr. M. Ramesh, Professor & Head, Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, 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.

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

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