

ADVERSE DRUG REACTION REPORTS : Sep-Dec 2020

A total of 269 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during Sep – Dec 2020. 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
Aceclofenac	Tongue swelling
Acenocoumarol.....	Nose bleeds
Budesonide	Redness of eye
Cefotaxime	Fever, chills, desaturation
Disulfiram	Seizure
Donepezil	Hypersalivation
Griseofulvin	Erythematous patches
Low molecular weight heparin	Melena
Meropenem	Hypersensitivity reaction
Olanzapine	Akathisia
Phenobarbital	Somnolence
Remdesivir	Chills
Risperidone+Trihexyphenidyl	Xerostomia
Rosuvastatin	Multiple erythematous papules
Tigecycline	Erythematous maculopapular rash

Aceclofenac induced tongue swelling

Tongue swelling is a consequence of local increase in permeability of subcutaneous or submucosal capillaries and postcapillary venules causing local plasma extravasation in response to mediators such as histamine, bradykinin. Patients with a history of atopy are at higher risk of development of similar allergic reactions. Aceclofenac needs to be discontinued and the swellings normally subside in around 24 hours or more and generally resolve without any sequelae.

Donepezil induced hypersalivation

Donepezil, an indirect muscarinic stimulant primarily inhibit acetylcholinesterase enzyme and increase acetylcholine to stimulate muscarinic and nicotinic receptors which results in an increased saliva flow. Despite this compelling mechanism, hypersalivation is a rare reaction with Donepezil. The drug needs to be withdrawn or alternative drug therapy needs be considered as a management strategy for this problem.

Budesonide induced redness of eye

Use of steroid can cause a rise in intraocular pressure. People with diabetes mellitus, have a family history of any ocular problems such as open-angle glaucoma or rheumatoid arthritis and are very nearsighted are the susceptible individuals for this reaction. The risk increases as duration and dose increases. Routine screening is indicated for anyone who is on longterm steroid therapy. Raised intraocular pressure can be reversed by stopping the drug.

DRUGS APPROVED BY US FDA

The following are the drugs that are approved by United State's Food and Drug Administration (US FDA) during the period September to December 2020

Name of the drug	Indication
Belantamabmafodotin-blmf	Multiple myeloma
Nifurtimox	To treat chagas disease in certain pediatric patients younger than age 18
Risdiplam	To treat spinal muscular atrophy
Oliceridine	To manage acute pain in certain adults
Viltolarsen	To treat duchenne muscular dystrophy
Satralizumab-mwge	To treat neuromyelitis optica spectrum disorder
Clascoterone	To treat acne
Somapacitan-beco	Growth hormone
Copper cu 64 dotatate injection	To help detect certain types of neuroendocrine tumors
Pralsetinib	To treat non-small lung cancer
Atoltivimab, maftivimab, and odesivimab-ebgn	To treat ebola virus
Remdesivir	To treat COVID-19
Lonafarnib	To treat rare conditions related to premature aging
Lumasiran	To treat hyperoxaluria type 1
Setmelanotide	To treat obesity and the control of hunger associated with proopiomelanocortin deficiency, a rare disorder that causes severe obesity that begins at an early age
Naxitamab-gqgk	To treat high-risk refractory or relapsed neuroblastoma
Gallium 68 psma-11	For detection and localization of prostate cancer
Berotrastat	To treat patients with hereditary angioedema
Tirbanibulin	To treat actinic keratosis of the face or scalp
Margetuximab (anti-her2 mab	To treat her2+ breast cancer
Relugolix	To treat advanced prostate cancer
Ansuvimab-zykl	To treat ebola
Vibegron	To treat overactive bladder

Reference: Novel Drug Approvals for 2020 [internet] [cited Jan 13, 2021]. Available from: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020>

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 to December 2020.

Name of the drug	Indication
Carbetocin bulk and Carbetocin injection 100 mcg/ml	Prevention of postpartum haemorrhage due to uterine atony
Netarsudil mesylate bulk and Netarsudil ophthalmic solution 0.02%w/v	For the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension
Risdiplam powder for oral solution 60mg	For treatment of Spinal Muscular Atrophy (SMA) in patients 2 months of age and older
FDC of Azelnidipine 8mg and Telmisartan 40mg tablet	For the treatment of Stage-II hypertension

Reference: List of new drugs approved in the year 2020 till date. [internet] [cited Jan 10, 2021]. Available from: https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/

Comparative Sheet for Different COVID-19 Vaccines under Indian Government Supply

INDICATOR	COVISHIELD	COVAXIN
Type of Vaccine	Recombinant COVID -19 Vaccine based on Viral Vector Technology	Whole-Virion inactivated Corona Virus Vaccine
No.of doses in each vial	10	20
Shelf Life	6 Months	6 Months
Expiry date available on vial	Yes	Yes
Vaccine Vial Monitor	Not Available	Not Available
Route	Intramuscular (IM) Injectable	Intramuscular (IM) Injectable
Physical appearance of vaccine	Clear to slightly opaque, colourless to slightly brown	Whitish translucent
Dose	0.5ml each dose	0.5ml each dose
Course	2 doses	2 doses
Schedule	4- weeks apart	4-weeks apart
Vaccination during pregnancy	Not recommended	Not recommended
Vaccination <18 years of age	Not recommended	Not recommended
Vaccination to lactating mother	Not recommended	Not recommended
Storage and transportation	+2 ⁰ C to +8 ⁰ C at all levels	+2 ⁰ C to +8 ⁰ C at all levels
Freeze sensitive	Yes	Yes
Discard the vaccine vial, if	‘Frozen’ and ‘frozen and thawed’	‘Frozen’ and ‘frozen and thawed’
Discard Vial, if	Solution is discolored or visible particles are observed	Presence of particulate matter or other coloration
Adverse event following immunization (AEFI)	Some mild AEFI may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills, arthralgia and nausea	Some mild AEFIs may occur like injection site pain, headache, fatigue, fever, body ache, abdominal pain, nausea and vomiting, dizziness- giddiness, tremor, sweating, cold, cough and injection site swelling
	Paracetamol may be used to provide symptomatic relief from post vaccination adverse reactions	
	Vary rare events of demyelinating disorders have been reported following vaccination with this vaccine without the usual causal relationship	
	As with other IM injections, COVISHIELD should be given with caution to individuals with thrombocytopenia	
Any other instruction	—	Shake well, before use Use of Chloroquine, Corticosteroids may impair antibody response

Reference: Letter from additional secretary of national health mission, Government of India, (DO No. T-22020/14/2020-Imm) dated 14th January 2021.

A Drug That Surpasses Remdesivir in COVID-19 Management

Researchers from a University in California have identified a molecule that is nearly 30 times more potent than remdesivir for COVID-19 treatment. The researchers from Icahn school of medicine at Mount Sinai, University of California, San Francisco published their finding online on SCIENCE Journal. The molecule that is a member of a class of compounds known as didemnins, is approved for treatment of multiple myeloma in some countries. Plitidepsin, that is marketed as Aplidin by Spanish Manufacturer PharmaMar is claimed to have comparable antiviral activity against SARS-CoV-2 strain as well as the newly discovered more contagious strain, the B117 variant from the UK. The investigators found that some host proteins that are involved in gene-to-protein translation are critical for replication of many viral pathogens. It occurred to them that targeting such proteins could block SARS-CoV-2, which led them to evaluate plitidepsin.

Plitidepsin is derived from a sea squirt (*Aplidium albicans*) that is found off the coast of Spain. Expression of human protein eEF1A can send cellular signals that can give rise to cancer, and during an infection, it interacts with coronavirus's nucleocapsid protein facilitating the entry of the virus. Plitidepsin inhibits this protein in the host and it is hypothesized that future viral resistance to drug is avoided as the drug is not directly acting on the virus.

Preclinical studies in human cells and Vero e6 cells (kidney cells from African Green Monkeys), demonstrated a cytostatic effect of plitidepsin. The viral genomic RNA was reduced though not statistically significant. Mouse models showed reduced infection in lungs when given as prophylactic. The authors note that plitidepsin can reduce replication of SARS-CoV-2 by 2 orders of magnitude and has reduced lung inflammation in vivo and is a potential candidate for further studies. Adverse effects with plitidepsin include raised liver enzymes in patients treated for multiple myeloma. The authors are currently pushing for phase 3 clinical trials of the drug while simultaneously studying its in vitro antiviral activity against other viruses. Whether plitidepsin will be added to the corona virus armament or not remains to be seen.

References: White KM et al, *Plitidepsin has potent preclinical efficacy against SARS-CoV-2 by targeting the host protein eEF1A*. *Science* 25 Jan 2021. DOI: 10.1126/science.abf4058

McNamara D, *Plitidepsin could treat COVID-19, preclinical data suggest*. *Medscape Medical News*. Available from https://www.medscape.com/viewarticle/944807#vp_1 accessed on 29th Jan 2021.

DEPARTMENT ACTIVITIES

Training on Cardio Pulmonary Resuscitation

Department of Pharmacy Practice organized Cardio Pulmonary Resuscitation (CPR) training for teaching and non-teaching staff of JSS College of Pharmacy, Mysuru from 21st– 30th September 2020 at Simulation Center, JSS Old Hospital, Mysuru. The staff were divided into ten batches of 11 each for the training. The instructors team was led by Dr. Archana, Assistant Professor, Emergency Medicine, JSS Medical College & Hospital, Mysuru. The training provided an insight on clinical interventions for the immediate emergency management of cardiac arrest, heart attack and other life threatening medical emergencies as well as knowledge and skills to apply those interventions.

During the training, the staffs were trained in essential skills individually, as part of a team, in different learning stations based on simulated clinical scenarios. The staff learned the basics of resuscitation like chest compressions, adult and infant breaths, management of choking in adults and infants.



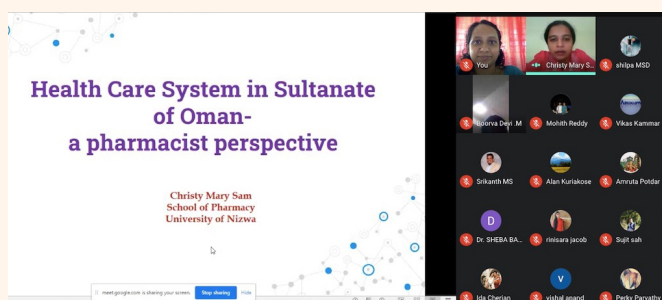
During CPR training session

Simulated situations like electric shock, road traffic accident, sudden collapse, choking of substance were explained and performed to impart practical knowledge. CPR training imparted to the staff helped them to gain knowledge on how to act during emergency situations and save a life of a person in danger.

Guest Lectures Organised

Guest Lecture on “Health Care System in Sultanate of Oman – A Pharmacist Perspective”

Department of Pharmacy Practice organized a guest lecture on '*Health Care System in Sultanate of Oman – A Pharmacist Perspective*' on October 10, 2020. **Mrs. Christy Mary Sam**, Clinical Instructor, School of Pharmacy, University of Nizwa, Sultanate of Oman delivered the lecture.



During the Guest Lecture

Mrs. Christy, in her lecture, explained about the health care system in Sultanate Oman in general giving detailed

information about the country's health care policies for the Oman nationals and expatriates. Also, she explained about the requirement and the process of licensure exams for a pharmacist in Sultanate of Oman and regulation in opening community pharmacies. She explained about various roles of pharmacist in the health care system. During her lecture, she stressed on the role of clinical pharmacists including involvement in the real time patient care, preparation of total parenteral nutrition and cytotoxic drugs and therapeutic drug monitoring. Also she explained about the Pharmacovigilance activities at the Sultanate Oman and the role of clinical pharmacist in the reporting and monitoring of ADRs.

A total of 70 PharmD, Postgraduate Pharmacy Practice students and PhD scholars of Pharmacy Practice Department attended the guest lecture. At the end of the session, students interacted with the speaker to clarify their doubts on health care system in Sultanate of Oman. There was discussion on Health Vision 2050 of Sultanate of Oman, role of pharmacists in total parenteral nutrition and cytotoxic drugs. And the session was concluded with vote of thanks from Dr. Juny Sebastian, Lecturer at Department of Pharmacy Practice

Guest Lecture on 'Working Approach for Research in Pharmacy Practice'

Department of Pharmacy Practice in association with Alumni Association, JSS College of Pharmacy, Mysuru organized an e-guest lecture on the topic “*Working Approach for Research in Pharmacy Practice*” on 7th October 2020 for the benefit of PharmD and M. Pharm Pharmacy Practice students. **Dr. Jimmy Jose**, Associate Professor, School of Pharmacy, College of Pharmacy and Nursing, University of Nizwa, Sultanate of Oman and also the alumni of JSSCPM was the resource person. The lecture was organized with an objective to provide insights into Pharmacy Practice related research.



During the Guest Lecture

Dr. Jimmy Jose started the lecture by explaining about the purpose of conducting a research by saying, “Research is

formalized curiosity”, adding on he further explained the importance of conducting a patient-centered research. He emphasized on the importance of research component in every job profile. Ideology of interest/motivation to do a research was explained effectively i.e. “to have a curiosity to learn something new, analyze, bring a output about a topic and contribute to the field involved”. Also, the concept of research in pharmacy practice was highlighted and adding on speaker explained about the opportunities/advantage of multiple arenas of research.

Comprehensive explanation about the significant elements in research was conveyed to the audience, such as identifying topics for research, planning for the conduct, challenges ought to be faced while planning the study, planning on the requirements of the project, continuous preparation of proposal's ideology to get clarity with the plan of the project, analysis of results, disseminating results. Later on, during the lecture, the speaker said, “Outcomes speak for you” thereby remarkably encouraging the student community to carry out research. Also, he further briefed on case reports, case series, narrative reviews and systematic reviews. At the end of the session, he gave insights about various opportunities to be a part of research society.

Students of fifth & sixth year PharmD and II M. Pharm Pharmacy Practice students attended the guest lecture. As it was an interactive session, students actively participated in the discussion. The whole discussion was done on an online (zoom) platform.

Guest Lecture on 'Overview of Data Management and Medical Coding'

Department of Pharmacy Practice in association with Alumni Association, JSS College of Pharmacy, Mysuru organized a e-guest lecture on the topic **“Overview of Data Management and Medical Coding”** on 16th October 2020 for the benefit of PharmD and M. Pharm Pharmacy Practice students. **Ms. Saranya Lisa Rajan**, Manager, Clinical data Coding, IQVIA, Bangalore and alumni of JSSCP Mysuru was the resource person. The lecture was organized with the objective to enlighten students about various stages of drug development and importance of clinical data management & medical coding.

Ms. Saranya Lisa Rajan started the lecture by giving a brief idea about various stages of drug development, i.e. how a new chemical entity with anticipated benefits survives to become a drug through various stages of drug discovery. Also, she explained about principles of Good Clinical

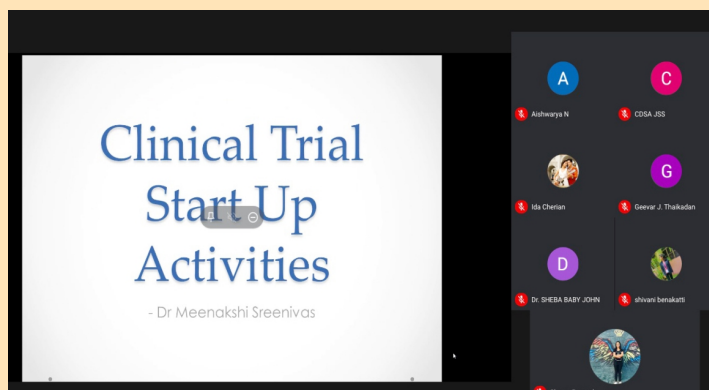
Practice and its importance in clinical trial. Difference between clinical research, clinical trial and types of clinical trial was highlighted by the speaker. In addition, she explained about clinical data management by saying “it's a process of collecting, cleaning, managing of subject related data with compliance with regulatory requirements and to aid the other departments with high quality data to facilitate further process” and explained about the different components and roles of various personnel involved in clinical data management process. Also, she emphasized the importance of medical coding in clinical data management to standardize the medical terms in the clinical data obtained to minimize discrepancies.

Further, Ms. Saranya gave insights about various job opportunities for PharmD graduates. Students of fifth & sixth year PharmD and II M. Pharm Pharmacy Practice students attended the guest lecture. As it was an interactive session, students actively participated in the discussion. The whole discussion was done on an online (zoom) platform.

Guest Lecture on Clinical Trial Start-up Activities

Dr. Meenakshi Srinivas, Clinical Research Associate, Clinical Development Services Agency (CDSA), Center for Clinical Research Excellence (CCRE), JSS Hospital, JSS AHER, Mysuru delivered a series of guest lectures on **'Clinical trial start-up activities'** to Post Graduate Diploma in Clinical Research Students of JSS College of Pharmacy, Mysuru.

All the sessions were attended by Post Graduate Diploma in Clinical Research students. She shared her experiences in the site start-up activities as a Clinical Research Associate during the session. Also, she expressed the practical difficulties faced by the site in completing the activities before the start of the study. Students got an opportunity to interact with her and clarify all their doubts on the topics addressed.



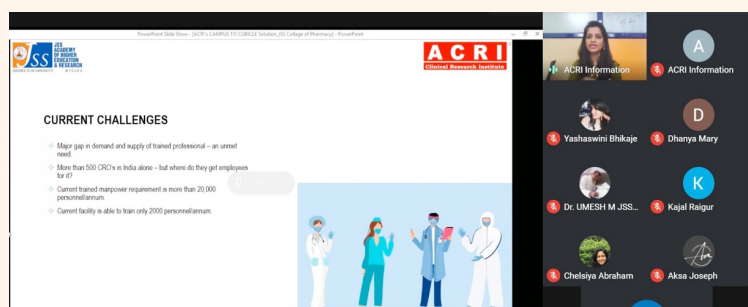
During the Session

Guest Lecture on 'Emerging Career Opportunities in Clinical Research and Clinical Data Management – Impact During COVID-19'

The Department of Pharmacy Practice organized a guest lecture on the topic **'Emerging Career Opportunities in Clinical Research and Clinical Data Management – Impact During COVID-19'** on 30th November 2020 for the benefit of PharmD and M. Pharm Pharmacy Practice students. **Dr. Smitha Vikram** and **Dr. Divya Sunil** from Avigna Clinical Research Institute (ACRI) were the resource persons.

Dr. Smitha Vikram, trainer at ACRI explained about the basics of clinical trials and the personals involved in the different stages of clinical trials and their responsibilities. Also, she explained about the regulatory submissions that required for the approval of a molecule from regulatory bodies and highlighted the current challenges in the clinical research field.

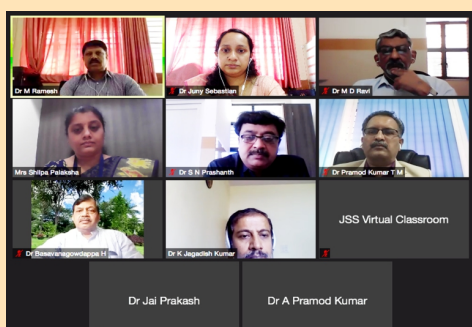
Dr. Divya Sunil, trainer at ACRI emphasized on vaccine development for COVID-19 and challenges in the development and conduct of clinical trials. Also, she spoke on opportunities for PharmD students in the area of Clinical Research and in Clinical Data Management in the Post COVID era. Students of fifth & sixth year Pharm D, I & II M. Pharm Pharmacy Practice and Research Scholars of Dept. Pharmacy Practice attended the guest lecture. As it was an interactive session, students actively participated in the discussion. The whole discussion was done on an online (zoom) platform



During the Session

Webinar on Vaccine Safety: Basics to Advanced”

A national webinar on *'Vaccine Safety: Basics to Advanced'* was organized by Adverse Drug Reaction Monitoring Centre (AMC) & Regional Training Center for South Zone under Pharmacovigilance Program of India (PvPI) in association with Department of Clinical Pharmacy and Department of Pediatrics, JSS Medical College (JSSMC) & Hospital, Mysuru on December 19, 2020. This webinar was conducted with the objectives to provide insight into importance of immunization programs and how vaccines work, vaccine safety reporting & risk communication and importance of vaccine clinical trials & mitigating challenges.



During the inaugural session of the webinar

The webinar started with welcome address by **Dr. M. Ramesh**, Coordinator, AMC, JSSMC & Hospital, Mysuru and Professor & Head, Dept. Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru. The importance of introduction of new vaccines and safety monitoring was highlighted during the opening remarks delivered by **Dr. K. Jagadish Kumar**, Professor & Head, Dept. Pediatrics, JSSMC & Hospital, JSS AHER, Mysuru and **Dr. T. M. Pramod Kumar**, Dean, Faculty of Pharmacy, JSS AHER, Mysuru. **Dr. H. Basavanagowdappa**, Dean, Faculty of Medicine, JSS AHER, Mysuru delivered the inaugural address. During his address he explained the history and importance of vaccine safety reporting. **Dr. Jai Prakash** Officer (I/C), PvPI & Secretary-cum-Scientific-Director (I/C), Indian Pharmacopoeia Commission, Ghaziabad was the keynote speaker. He explained the relevance of the program in the current scenario and the importance of immunization programs and the safety reporting of adverse events following immunizations. Also, he explained the role of PvPI and AMCs in the safety monitoring of vaccines especially for COVID-19 vaccines.

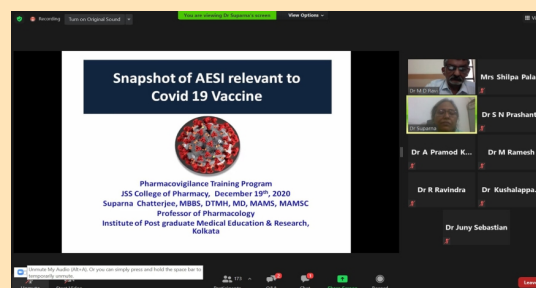
After the inaugural session, **Dr. S. N. Prashanth**, Professor, Dept. Pediatrics, JSSMC & Hospital, JSS AHER, Mysuru gave an informative session on *'Basics of Immunology'*. He explained the purpose of vaccination and the history of immunization programs. Also, he differentiated the features between Innate & adaptive Immunity and how vaccine work. He described the immunization schedule followed in India with general instruction to be followed during immunization process. He explicates some of the myths about vaccination and how to proceed with immunization during pandemic. He concluded his talk by answering some of the immunization related questions of parents during Pandemic.

Dr. Juny Sebastian, Faculty, Dept. Pharmacy Practice, JSSCP, JSS AHER, Mysuru delivered the second session on *'Vaccine safety surveillance'*. Dr. Juny explained vaccine pharmacovigilance and various reasons of low public tolerance on adverse events to vaccines when compared to drugs. She narrated the impact of vaccine safety scars in the immunization programs of various countries by giving past examples. She explained the concept of adverse events following immunization and its types with examples in each of the categories. She concluded her talk by briefly explaining the new causality assessment algorithm of World Health Organization.

The third session on *'Vaccine Safety: Risk Communication'* was delivered by **Dr. A. Pramod Kumar**, Associate Professor, Chebrolu Hanumaiah Institute of Pharmaceutical Sciences, Guntur and Deputy Coordinator, MDAMC, Materiovigilance Program of India (MvPI), NRI Medical College & Hospital, Guntur, Andhra Pradesh. He briefed the participants on the process of risk communication and highlighted the importance of vaccine safety risk communication.

Dr. M. D. Ravi, Professor, Department of Pediatrics, JSS Medical College & Hospital, Mysuru spoke on *'Vaccine Clinical Trials: Importance, Designs and Challenges'*. He explained about various phases of vaccine clinical trials with his vast experience of conducting it at various levels. Also, he described the special precautions that needs to follow while conducting clinical trials for vaccines. Dr. M.D. Ravi concluded his talk by giving some of the take home messages including Vaccine clinical trials are different from drug trials, data capture has to be very rigorous and accurate as vaccine licensing is more difficult than drug licensing, and active surveillance is a mandatory requirement'.

Dr. Suparna Chatterjee, Professor of Pharmacology at the Institute of Postgraduate Medical Education & Research, Kolkata delivered the talk on *'Snapshot of Adverse Events of Special Interest (AESI) relevant to COVID-19 Vaccines'* She spoke about assessment of safety and efficacy of public health emergency vaccines and shared her experience as an investigator.



During the educational session

Mrs. Shilpa Palaksha, Assistant Professor, Department of Pharmacy Practice moderated the webinar. Many of the participants expressed that the webinar was very informative and clarified several of their practical doubts. A total of 950 participants including health professions students, faculty members of health professions institutions and practicing health care professionals attended the webinar and benefited.

Awards / Recognitions

Dr. M. Ramesh, Professor & Head, Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Mysuru received appreciation award for his contribution towards advancements of research at JSS College of Pharmacy, Mysuru during the year 2019. He received the award during the research meeting of JSS AHER, Mysuru held on September 16, 2020.



Dr. M. Ramesh receiving the award during JSSAHER, Mysuru research meeting

Dr. M. Ramesh, Professor & Head, Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Mysuru was awarded with "**Association of Pharmacy Professionals (APP) Innovative Researcher Award-2020**" during the 9th APP Annual International Convention organized by APP Rajasthan State Branch in collaboration with Sunrise University, Alwar, Rajasthan, India held during 19-20 December 2020. This award was conferred to him for his unique contribution towards virtual anticoagulation clinic, innovative comprehensive patient safety studies, JSS MINDs Initiatives, and mobile app based poison information services that were crux in promoting the safe and quality use of medicines.



Dr. M. Ramesh receiving the award during virtual 9th APP convention



Dr. Jehath Majid Syed was awarded with '**Association of Pharmacy Professional (APP) Best PharmD Student-2020 Award**' at national level during the 9th APP Annual International Convention organized by APP Rajasthan State Branch in collaboration with Sunrise University, Alwar, Rajasthan, India held during 19-20 December 2020. She received the award for her outstanding academic performance in her PharmD program pursued at JSS College of Pharmacy, JSS AHER, Mysuru.

The Drug & Poison Information Service

The Department of Clinical Pharmacy 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 in resolving any medication related problems that might arise 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.

24x7 Mobile Number: 6363539153, Toll free Number - 1800-425-0207

Landline Number: 2335555, Extn - 5577

E-mail: dic.jssc@jssuni.edu.in; pic.jssc@jssuni.edu.in; Website: www.picjsscpm.jssuni.edu.in

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

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