Adverse Drug Reaction Monitoring and Regional Training Centre Department of Clinical Pharmacy, JSS Medical College and Hospital JSS Academy of Higher Education & Research, Mysuru

Report on Pharmacovigilance Activities (July 2019- December 2020)

The Department of Clinical Pharmacy located at JSS Medical College and Hospital, Mysuru is identified as the Regional Training Centre of Pharmacovigilance Programme of India for the states of Karnataka, Kerala, Tamil Nadu and the Union Territory of Puducherry. It has been actively involved in the building up and advocacy of the Pharmacovigilance Programme of India through awareness programs, imparting training and research. The activities of this centre focused to create awareness and inculcate adverse drug reaction reporting culture amongst health care professionals and health professions students and also to upgrade knowledge and skills of Patient Safety Pharmacovigilance Associates and Coordinators working in various ADR Monitoring Centers in the area of patient safety. A total of ten activities were carried out during the period July 2019 to December 2020, and the brief report on each of the activities are given below.

On 2nd August 2019, in asociation with the Special Interest Group (SIG) - Quality and Safe Use of Medicine, a Guest Lecture on 'Medication Therapy Management was conducted. Dr. John

Jacob, MTM Pharmacist, Operations and Planning, Walgreens Boots Alliance and Affiliate Assistant Professor, University of Florida, Nova Southeastern University was the speaker. During his lecture, he briefed the participants (PharmD & Postgraduate Pharmacy Practice Students) on the roles and responsibilities of pharmacist in Medication Therapy Management (MTM) and the importance of patient safety. During his lecture, Dr. Jacob also discussed in detail about the core components, process and outcome, scope and



rationale of MTM. Also, he explained about the scope of MTM in ambulatory patients.

On 27th August 2019, **Dr. Salahuddin Khan Ghori**, Deputy Medical Superintendent, JSS Hospital, Mysuru delivered a guest lecture on "*Pearls and Pitfalls in Patient Safety: Role of Clinical Pharmacists in Hospitals*" on the behest of the Department of Pharmacy Practice, JSS College of Pharmacy – Mysuru & Special Interest Group – Quality & Safe Use of Medicine for the benefit of Pharm.D (Interns) and Post Graduate students of Pharmacy Practice. The role of



clinical pharmacist alongside with doctors in hospital was emphasised throughout the session and latest advancements in the patient safety frame-work, such as computerised physician order entry system (CPOE), promotion of unit dose dispensing systems to facilitate the rational use of medicines, assisting the doctors and nurses in optimising the therapeutic benefits were discussed in detail. Also, he highlighted the importance of pharmacist's role in achieving the better patient outcomes. During 30th September to 4th October 2019, **Mr. Sten Olsson**, Adjutant Faculty, JSS Academy of Higher Education & Research, Mysuru is one of the original staff members of the Uppsala Monitoring Centre (UMC) since 1978 and a seasoned Pharmacovigilance expert has delivered series of guest lectures for the benefit of aspiring pharmacovigilance associates. Mr. Sten Olsson addressed the students on the topic titled "*Pharmacovigilance in Public Health Programmes*" that focussed on integrating the concepts and activities of Pharmacovigilance into the public health programmes across the global platforms. During his lecture, he outlined on various stakeholders involved in public health programmes, pharmacovigilance and how to bring them together in order to implement the pharmacovigilance activities successfully. This series was concluded with an emphasis on synergistic collaboration amongst the societies that may leverage the available resources to aid the drug and patient safety.



On 24th & 25th October 2019, the Regional Training Center for South Zone- PVPI located at Department of Clinical Pharmacy, JSS Medical College and Hospital, Msyuru in association with Nirmala College of Pharmacy (NCP), Muvattupuzha, Kerala organized a two days **'National Workshop on Pharmacovigilance: Basics to Advanced'** at Nirmala College of Pharmacy, Muvattupuzha. The workshop was conducted under the banner of NILA (Nirmala Ignites Learning Aspiration) Module 9 with the theme of **'Medication use without harm to**

enhance patient care'. Dr. M Ramesh, Professor & Head, Dr. Juny Sebastian and Dr. Sri Harsha Chalasani. Lecturers, Department of Pharmacy Practice were the speakers of the two days' workshop. During the workshop, Dr. M Ramesh delivered the crux of the workshop on the topic [•]*Pharmacovigilance* Global and **Perspectives**' he National and emphasized that, the burden of adverse drug reactions (ADRs) in the global



scenario is high and accounts for considerable morbidity, mortality, and extra-cost to the patients and currently, India's contribution to global safety database reaches 3% and the completeness score is 0.93 out of 1. Also, he highlighted that National Coordinating Centre is

taking several measures to enhance patient safety including capacity building for monitoring, surveillance, collaboration with national health programs and other organizations to increase ADR reporting.

On 10th February 2020, The ADR Monitoring Center and Regional Training Center for the

South Zone located at Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysuru participated in the *National Deworming Day* (NDD) along with **District Health & Family Welfare Society, Mysuru.** The information on Adverse Drug Reactions to Albendazole were distributed to the respective school authorities, participating healthcare professionals and to school students, so as to enable them to contact the AMC centre in case of adverse event(s) arising from the use of Albendazole. Also, beneficiaries were educated about the importance of reporting of Adverse Drug Reactions and also about the possible adverse reactions that can occur with the use of Albendazole and further measures to be taken to manage the reported events.



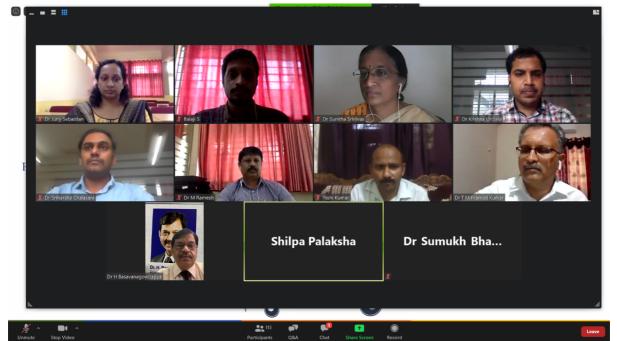


On 5th March 2020, The Department of Clinical Pharmacy in collaboration with Special Interest Group "Quality and Safe use of Medicines" organized a guest lecture on "Haemovigilance". The lecture was delivered by Dr. P. Associate Pallavi, Professor. Department of Immunohematology and Transfusion, Blood JSS Hospital. Mysuru. Her talk focused on Haemovigilance covering the areas of detection, reporting, analyzing and documentation of blood and blood related products transfusion reactions

and various activities undertaken by the JSS Hospital blood bank. She emphasized on how the transfusion reactions should be reported and the transfusion product specific details, nature of adverse reaction and its outcome should be reported.

On 29th July 2020, the Regional Training Center for South Zone, Department of Clinical Pharmacy, JSS Medical College & Hospital, Mysuru in association with Pharmacovigilance Program of India (PvPI), Indian Pharmacopeia Commission (IPC), Ghaziabad has conducted Webinar on "Advanced Pharmacovigilance" with a theme: *Research in Pharmacovigilance in the age of COVID-19* for the benefit of Coordinators and Patient Safety Pharmacovigilance Associates working in Adverse Drug Reaction Monitoring Centres, PvPI, India. The webinar was organised with an objective to reinforce the importance of pharmacovigilance research and disseminate various strategies to improve quality in pharmacovigilance activities among healthcare professionals. For this webinar, Dr T M Pramod Kumar, Principal, JSS College of Pharmacy, JSS AHER, Mysuru, Dr H Basavana Gowdappa, Dean, Faculty of Medicine, JSS

AHER, Mysuru, **Dr Jai Prakash**, Principal Scientific Officer, PvPI, Indian Pharmacopeia Commission, Ghaziabad, **Dr M Ramesh**, Professor & Head, Dept. Pharmacy Practice, JSSCP,



JSS AHER, Mysuru, **Dr Juny Sebastian**, Faculty, Dept. Pharmacy Practice, JSSCP, JSS AHER, Mysuru, **Dr Sunitha Chandrashekar Srinivas**, Visiting Professor, Rhodes University, Grahamstown, South Africa & Honorary Consultant, Karuna Trust, Mysuru, **Dr Sri Harsha Chalasani**, Faculty, Dept. Pharmacy Practice, JSSCP, JSS AHER, Mysuru, **Dr Krishna Undela**, Faculty, Dept. Pharmacy Practice, JSSCP, JSS AHER, Mysuru, **Mr Rishi Kumar**, Scientific Assistant, NCC-PvPI, IPC, Ghaziabad were speakers and **Mrs Shilpa Palaksha**, Assistant Professor, Dept. Pharmacy Practice, JSSCP, JSS AHER, Mysuru moderated the session.

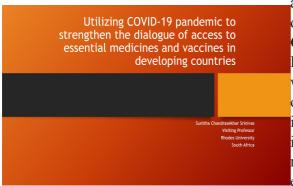
On 7th August 2020, a webinar on the topic "Catalysing opportunities to strengthen pharmacovigilance during COVID 19 pandemic" was conducted for the benefit of PharmD

and postgraduate Pharmacy Practice students. Dr. Sunitha Chandrashekar Srinivas, Visiting Professor, Rhodes University, Grahamstown, South Africa was the resource person. The webinar was organised with an objective to catalyse the opportunities to strengthen pharmacovigilance activities during COVID-19 pandemic and to promote & disseminate pharmacovigilance research among the students of health profession programs. It was well noted by her talk



that, as a health care professional, one must closely monitor the situation and have to set- up a taskforce to recommend and communicate how one can take consistent approaches together to support our clients, protect our employees and our business during this pandemic.

On 12th August 2020, a webinar was conducted on 'Utilising COVID-19 Pandemic to Strengthen the Dialogue of Access to Essential Medicines and Vaccines' for the benefit of health professions students. The webinar was organised with an objective to identify the need



and the importance of access to essential medicines during this COVID-19 pandemic. **Dr. Sunitha Chandrashekar Srinivas,** Visiting Professor, Rhodes University, Grahamstown, South Africa was the speaker. In her lecture, she said "we find ourselves in one of the most challenging situations in history". She highlighted that as the pandemic increasingly affects countries with underresourced health infrastructure and services, it is an ethical imperative to ensure that all people in all

countries of the world are able to access essential medicines including those medicines that are under international control.

On 19th December 2020, the Regional Training Center for South Zone, Department of Clinical Pharmacy, JSS Medical College & Hospital, Mysuru in association with Pharmacovigilance Program of India (PvPI), Indian Pharmacopeia Commission (IPC), Ghaziabad and Department of Pediatrics, JSS Medical College, JSS AHER, Mysuru organised a national level webinar on *"Vaccine Safety: Basics to Advanced"*. This 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. During the opening remarks, **Dr. K Jagadish Kumar**, Professor & Head, Department of Pediatrics, JSSMC & Hospital, JSS AHER, Mysuru highlighted the importance of introduction of new vaccines and its safety monitoring. Following that **Dr. T. M. Pramod Kumar**, Dean, Faculty of Pharmacy, JSS AHER, Mysuru stressed on the importance of collective efforts required from all the healthcare professionals in the process of vaccine safety surveillance in ensuring the patient safety. **Dr. H Basavanna Gowdappa**, Dean, Faculty of Medicine, JSS AHER, Mysuru delivered the inaugural address. During his talk, he highlighted and stressed on the importance



of clinical development of vaccines and its safety reporting while briefing the history of vaccine safety reporting taking the example of Rabies vaccine. **Dr Jai Prakash**, Officer (I/C), PvPI & Senior Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad was the keynote speaker. In his keynote address, he explained the relevance of the program in the current scenario and highlighted the importance of immunization programs for a country and the roles to be played by the healthcare professionals in identifying, reporting and managing adverse events following immunizations. Also, he explained the role of PvPI and AMCs in the safety monitoring of vaccines especially during the upcoming introduction of COVID-19 vaccines. **Dr. M. D. Ravi**, Professor, Department of Pediatrics, JSS Medical College and Hospital, JSS AHER, Mysuru; **Dr. S N Prashanth**, Professor, Department of Pharmacology at the Postgraduate Institute of Medical Science & Research, Kolkata; **Dr. Juny Sebastian**, Faculty, Dept. Pharmacy Practice, JSSCP, JSS AHER, Mysuru and **Dr. A. Pramod Kumar**, Associate Professor, Chebrolu Hanumaiah Institute of Pharmaceutical Sciences, Guntur were the speakers during the webinar.
