

Editors:

Dr. G. Parthasarathi, Dr. M. Ramesh, Ms. Karin Nyfort-Hansen, Ms. Juny Sebastian and Mr. Krishna Undela

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ADVERSE DRUG REACTION REPORTS: Sept-Dec 2017

A total of 546 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during September to December 2017. 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
Amlodipine	Psoriasiform lesions
Amlodipine+Atenolol	Psoriasis
Azithromycin	Maculopapular rash
Betamethasone	Myopathy
Bortezomib	Pitting edema
Colistin	Thrombocytopenia
Gemcitabine	Tinnitus
Imatinib	Multiple exfoliative lesions
Levetiracetam	Hypersensitivity syndrome
Lithium	Polyuria
Metoprolol	Psoriasis
Piroxicam	Fixed drug eruption
Quetiapine	Photo contact dermatitis
Topiramate	Choroidal effusions

Betamethasone Induced Myopathy

Glucocorticoid induced myopathy is the most common type of drug induced myopathy. The mechanism is due to decrease in the rate of protein synthesis and increasing the rate of protein catabolism which leads to muscle atrophy. Treatment includes discontinuation of the drug and replace with fluorinated glucocorticoids such as dexamethasone.

Lithium Induced Polyuria

Lithium induced polyuria is a condition which is characterized by abnormally large production or passage of urine. The possible mechanism may be due to interference with release of anti diuretic hormone which results in excessive urination. Correcting electrolytes level and medications such as thiazide diuretics and amiloride will be beneficial in the treatment.

Topiramate Induced Choroidal effusions

Topiramate induced choroidal effusions is a rare ocular adverse effect. The exact mechanism is unknown. The effect can be seen within two weeks after initiation of topiramate. Discontinuation of the drug, use of cycloplegics, and topical corticosteroids are the treatment options in managing the reaction.

DRUGS APPROVED BY US FDA

The following are the drugs that are approved by the US FDA during the period September - December 2017

DRUG	BRAND	INDICATION
Dermatology		
Hydrogen peroxide	Eskata	For the treatment of seborrheic keratoses
Ozenoxacin	Xepi	For the treatment of impetigo
Endocrinology		
Semaglutide	Ozempic	For the treatment of type 2 diabetes mellitus
Ertugliflozin	Steglatro	For the treatment of type 2 diabetes mellitus
Genetic Disease		
Vestronidase alfa-vjvk	Mepsevii	For the treatment of Mucopolysaccharidosis VII
Hematology		
Emicizumab-kxwh	Hemlibra	For the prevention or reduction of bleeding episodes in patients with hemophilia A
Immunology		
Tocilizumab injection	Actemra	For the treatment of CAR T cell-induced severe or life-threatening cytokine release syndrome
Infections and Infectious Diseases		
Dolutegravir and rilpivirine	Juluca	For the treatment of HIV-1 infection in adults
Letermovir	Prevymis	For the prevention of cytomegalovirus following allogeneic hematopoietic stem cell transplant
Zoster Vaccine Recombinant, Adjuvanted	Shingrix	For the prevention of herpes zoster (shingles)
Secnidazole	Solosec	For the treatment of bacterial vaginosis
Oncology		
Coplanlisib	Aliqopa	For the treatment of follicular lymphoma
Acalabrutinib	Calquence	For the treatment of mantle cell lymphoma
Axicabtagene ciloleucel	Yescarta	For the treatment of relapsed or refractory large B-cell lymphomas
Abemaciclib	Verzenio	For the treatment of HR+, HER2- breast cancer
Ophthalmology		
Voretigene neparovec	Luxturna	For the treatment of vision loss due to confirmed biallelic RPE65-mediated inherited retinal disease
Netarsudil ophthalmic solution)	Rhopressa	For the treatment of glaucoma or ocular hypertension
Latanoprostene bunod ophthalmic solution	Vyzulta	For the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension
Rheumatology		
Triamcinolone acetonide extended-release injectable suspension	Zilretta	For the treatment of osteoarthritis knee pain

Reference: <https://www.centerwatch.com/drug-information/fda-approved-drugs/>

DRUGS APPROVED BY CDSCO, INDIA

The following are the drugs that are approved by the Central Drugs Standard Control Organization during the period September - December 2017

DRUG	STRENGTH	INDICATION
Brivaracetam	50mg/75mg/100mg Film Coated Tablets	As adjunctive therapy in the treatment of partial -onset seizures in patients 16 years of age and older with epilepsy
Treosulfan	5g/vial Injection	For the conditioning treatment prior to haematopoietic stem-cell transplantation
Ribociclib	200 mg Film Coated Tablets	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of post menopausal women with the hormone receptor (HR)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced or metastatic breast cancer
Dienogest	2mg Tablet	For the management of pelvic pain associated with endometriosis
Apremilast bulk	10 mg/20 mg/30 mg Film Coated Tablets	For treatment of patients with moderate to severe plaque psoriasis who are candidate for phototherapy or systemic therapy
Arbekacin bulk	200mg/4ml Injection	Treatment of following infections caused by methicillin resistant staphylococcus aureus (MRSA), sepsis pneumonia
Midostaurin	25 mg Capsules	<ul style="list-style-type: none"> In combination with standard induction and consolidation chemotherapy followed by single agent in maintenance of therapy for adult patients with newly diagnosed with acute myeloid leukemia (AML) who are FLT-3 Mutation positive. For the treatment of adult patients with advanced systemic mastocytosis (Advanced SM)
Tenofovir Alafenamide Fumarate	25 mg Capsules	For the treatment of chronic Hepatitis B virus infection in adults with compensated liver disease
Arteolane Maleate and Piperazine Phosphate	37.5 mg +187.5 mg Dispersible Tablets	Indicated in children aged 6 months to 12 years for the treatment of: <ul style="list-style-type: none"> Acute uncomplicated <i>Plasmodium falciparum</i> malaria infection Acute uncomplicated <i>Plasmodium Vivax</i> malaria infection
Macitentan	10 mg Tablets	Macitentan is an endothelin receptor antagonist (ERA) indicated for the treatment of Pulmonary arterial hypertension (PAH, WHO group I) to delay disease progression

Reference : <http://www.cdsc0.nic.in/forms/list.aspx?lid=2034&Id=11>

New Tool for Better Management of Antibiotic Usage

The U.S. Food and Drug Administration announced a new approach to get critical updates regarding antibiotics and antifungal drugs to health care professionals as part of an overall effort to combat antimicrobial resistance. The agency created a website that will provide direct and timely access to information about when bacterial or fungal infections are likely to respond to a specific drug (<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm575163.htm>). This approach is intended to aid health care professionals in making more informed prescribing decisions that will both benefit their patients and prevent the spread of resistant bacteria.

The new approach was included by Congress as part of the 21st Century Cures Act, allows the FDA to simultaneously update the breakpoints for multiple drugs that have the same

active ingredient and share that information transparently via a dedicated FDA web page that will list FDA-recognized breakpoints. The FDA will leverage the work done by standards-development organizations that develop breakpoints, and recognize them when the FDA agrees that they are appropriate. In addition, companies can submit data to support alternative breakpoints, if they disagree with the recognized standard.

Drug manufacturers will have to update their labeling to reference the FDA web page containing the breakpoint information. They will no longer have to continuously update their labeling with new breakpoint information, making the process more efficient and, it is expected, more timely.

Reference : <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm588836.htm>

Beta Blockers Improve the Survival Rate of Metastatic Melanoma Patients?

Use of a specific type of β -blocker may enhance the effectiveness of immunotherapy in the treatment of metastatic melanoma, according to a retrospective chart review.

Researchers report that patients with metastatic melanoma who received immunotherapy at their cancer center while taking a pan- β -blocker, such as propranolol, lived longer than patients who received immunotherapy alone or other types of β -blockers.

Specifically, among 195 patients with metastatic melanoma who were treated with immunotherapy (interleukin-2, cytotoxic t-lymphocyte associated protein 4, and/or programmed cell death-1 agents) between 2000 and 2015, the 5-year overall survival rate was about 70% for the group receiving pan- β -blockers (n = 17) vs about 25% for the groups taking β 1-selective blockers (n = 45) or no β -blockers at all (n

= 133). This retrospective analysis is reinforced by results showing that β Adrenergic Receptor blockade enhances the control of murine melanoma growth by anti-(α)PD-1 checkpoint blockade. However, this effect was most significant when β -blocker was combined with dual α PD-1 + high dose interleukin-2 therapy and was reproduced by selective blockade of β 2Adrenergic Receptors. These results identify a novel strategy that can be quickly introduced to potentially increase the number of patients who benefit from immune-based therapies.

Reference : Kathleen M Kokolus, Ying Zhang, Jeffrey M Sivik, Carla Schmeck, Junjia Zhu, Elizabeth A Repasky et al. Beta blocker use correlates with better overall survival in metastatic melanoma patients and improves the efficacy of immunotherapies in mice. *OncoImmunology* 2018;7(3). Available from <http://www.tandfonline.com/doi/abs/10.1080/2162402X.2017.1405205?journalCode=koni20>

Is Ibuprofen linked to Men's fertility problems?

According to a study published as a Proceedings of the National Academy of Sciences, men who take high doses of ibuprofen for months may be at greater risk of fertility issues and also other health problems, such as muscle wastage, erectile dysfunction and fatigue.

The men of 18 to 35-year-olds who took part in the study developed a disorder called "compensated hypogonadism" within two weeks of having 600mg of ibuprofen twice a day. The condition arises when the body has to boost levels of testosterone because normal production in the testes has

fallen. This is more common in older men than younger ones.

Ibuprofen appears to affect the pituitary gland that's involved in production of the male hormone testosterone, as well as other processes linked to sperm production. This reaction may be a reason of concern for the fertility of men who use these drugs for a long time as this reaction would lead to continuously low levels of testosterone.

Reference: <http://www.pnas.org/content/early/2018/01/03/1715035115>

DEPARTMENT ACTIVITIES

Advanced Level Workshop on Pharmacovigilance

Department of Pharmacy Practice organized an 'Advanced Level Workshop on Pharmacovigilance' in association with National Coordination Center - Pharmacovigilance Programme of India (PvPI); and Regional Training Center, JSS Medical College & Hospital on 8th & 9th December 2017

at JSS College of Pharmacy, Mysuru. The aim of this workshop was to provide training in order to advance the knowledge and develop skills amongst technical associates and coordinators of Adverse Drug Reaction Reporting & Monitoring Centres (AMCs) of PvPI, Ministry of Health &

Family Welfare, Govt. of India located in the States of Karnataka, Kerala, Puducherry & Tamil Nadu.

During these two days of workshop, several topics were covered including medication use without harm, Pharmacoepidemiology & study design, Pharmacovigilance methods, Extended scope of Pharmacovigilance, Signal detection, Pharmacovigilance in special population, Materiovigilance, Hemovigilance and Monitoring of radiation related adverse event. Also, a visit to the Regional Training Center for South Zone located at JSS Hospital, Mysuru was arranged during the workshop.

A total of 32 participants from 24 adverse drug reaction reporting & monitoring centers located in South of India

attended this workshop. Pharmacovigilance experts from JSS College of Pharmacy, JSS Medical College & Hospital and JSS Dental College & Hospital, Mysuru, were the resource persons.



Workshop participants with speakers and coordinators

Health Screening Camps

Department of Clinical Pharmacy organized Health Screening Camps in multiple places for the benefit of public of Mysuru City on 21st September 2017 and 10th October 2017. During the camp, blood glucose testing and blood pressure measurement were carried out with the aim of sensitizing the general public about the importance of undergoing regular health checkup to detect the chronic diseases such as Diabetes and Hypertension at the early stages for the better control.



Health screening camp at Lalith Mahal Palace Gate

A total of 631 people were monitored for their blood pressure and blood glucose levels. All those people who were identified with elevated levels of blood pressure and blood glucose levels were advised on non-Pharmacological management and suggested to consult a physician for further screening and management. First year students of postgraduate Pharmacy Practice and Pharm.D interns were actively participated in the health screening camps and provided counseling services.



Health screening camp at Balbhavan

Outreach Program to Create Awareness about HPV Infection and Vaccine

Out reach programs were conducted at different schools within Mysuru city to create awareness about the importance of Human Papilloma Virus (HPV) infection and vaccination among adolescent girls. The programs were conducted during 8th to 16th December 2017 in Good Shepherded Convent School, JSS High School, Flos Carmeli Convent School and Lions School.

The education sessions focusing on the HPV infection, risk factors, management, complication, precautions and availability of HPV vaccine. Following to the education session, the students were given a printed information leaflet about the same in English and Kannada depending on their preferences.

The programs were well appreciated by the school authorities and the students.

Many of the students and teachers actively participated in the question and answer session following each of the education session to clarify their doubts.



During the outreach program

Visit of Ms. Seema Gupta from Australia

Ms. Seema Gupta, Accredited Consultant Pharmacist and experienced Community Pharmacist, Melbourne, Australia visited the Department of Clinical Pharmacy at JSS Hospital, Mysuru on 8th October 2017. She had an initial interaction with Dr. M. Ramesh, Professor & Head, Department of Clinical Pharmacy and Dr. T. M. Pramod Kumar, Principal, JSS College Pharmacy, Mysuru followed by an interaction



Ms. Seema Gupta Delivering a Lecture

with staff of Clinical Pharmacy Department. During this interaction, she was briefed about the various clinical pharmacy services offered at the practice sites both in hospital & community settings. Also, Ms. Seema interacted with fifth and sixth year Pharm.D and M. Pharm Pharmacy Practice students. Followed by the interaction, she delivered

Visit of Student from University of North Carolina, USA

As a part of MoU between JSS University, Mysuru and University of North Carolina(UNC), Chapel Hill USA, two students Ms. Bianka Ajith Patel and Mr. William Heilman from UNC arrived at JSS College of Pharmacy, Mysuru under student study exchange program. The purpose of the experiential program was to expose the students to an international clinical rotation focused on public health and infectious diseases that are common in developing countries. The length of the experiential training was for a period of 5 weeks, which commenced from 3rd October 2017. UNC students were introduced to Clinical Pharmacy department activities including ambulatory patient care services. During their posting period, they were posted to Medicine and Paediatrics department for a period of one week each to learn about most common diseases and clinical pharmacy activities provided at these Departments. Also, they were posted to Asha Kirana Hospital and Bharath Hospital and

a lecture on 'Role of Clinical Pharmacist in Advancing Patient Care and De-Prescribing'. Ms. Seema discussed few clinical cases on managing 'Depression and Anxiety in the Older Patients' and highlighted the important aspects to be considered during the review of medication therapy of older patients.

Institute of Oncology for a period of one week to learn about various opportunistic infections associated with HIV and Cancer management, respectively. Towards the end of their clinical rotation, they were posted for a week at Govt. Head Quarters Hospital, Ooty which is a practice site of JSS College of Pharmacy, Ooty to provide them an opportunity to understand the healthcare delivery system at Government settings.



UNC Students with the Principal, JSSCP, Mysuru

Guest Lecture on 'Drug Safety Overview - An Industrial Perspective'

Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru organized a guest lecture on the topic “Drug Safety Overview - An Industrial Perspective” on 7th October 2017. Dr. Rahul Jain D, Project Manager, Bioclinica, Mysuru delivered the lecture. The aim of this lecture was to provide an overview and workflow of Pharmacovigilance in industry settings. Dr. Rahul Jain, during his talk, covered aims and objectives of Pharmacovigilance, workflow of safety report processing, importance and applications of aggregated safety reporting. Also, he discussed about skills and training required for Pharm.D/ M. Pharm (Pharmacy Practice)

graduates to work effectively in the area of industrial Pharmacovigilance.



Dr. Rahul Jain during his talk

Guest Lecture on 'Hemovigilance'

The Department of Pharmacy Practice, JSS College of Pharmacy, Mysuru organized a Guest Lecture on 'Hemovigilance' on 23rd November 2017 at JSS Hospital, Mysuru. Dr. Rashmi B.K, Senior Resident, Department of Immunohematology and Blood Transfusion, JSS Hospital, Mysuru delivered a lecture on 'Detection, Reporting, Analyzing and Documentation of Blood Transfusion Reactions'. In her talk, she explained about the process and procedures involved in the detection and reporting of Hemovigilance. Also, she briefed about the roles of blood bank in Hemovigilance. Pharm. D and M. Pharm Pharmacy Practice students attended and interacted with the speaker to

clarify their doubts on reporting of adverse reactions due to blood transfusions.



Dr. Rashmi B K delivering a lecture

Faculty Attended Tenth Asian Conference on Pharmacoepidemiology held at Brisbane, Australia

Mr. Krishna Undela, Lecturer, Department of Clinical Pharmacy attended the International Society for Pharmacoepidemiology's (ISPE's) 10th Asian Conference on

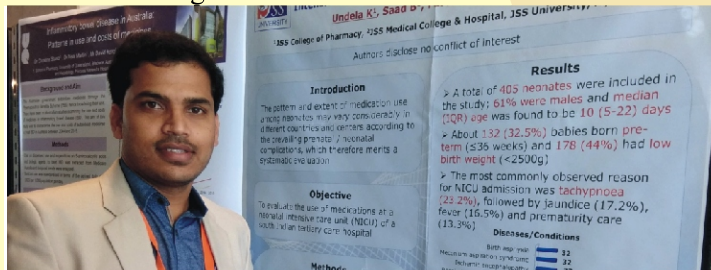
Pharmacoepidemiology (ACPE) held at University of Queensland, Brisbane, Australia from 29th - 31st October 2017. Mr. Krishna Undela delivered a talk on 'Principles of

Descriptive Pharmacoepidemiological Study Designs' during Track B Educational Session on 'Non-database Pharmacoepidemiology: Learning Through Examples from Resource-Limited and Resource-Rich Countries' on 29th October 2017. During afternoon session, he acted as an instructor for the workshop on 'Practical skills in protocol writing and statistical analytic programming relevant to Pharmacoepidemiology'.

He attended the main conference on 30th & 31st October 2017 that dealt with various topics related to Pharmacoepidemiology and drug safety issues. During the main conference, he presented two research papers entitled (i) Medication-Use Evaluation at a State-of-the-Art Neonatal Intensive Care Unit of a South Indian Tertiary Care Hospital; (ii) Usage of Anti-infectives at a Neonatal Intensive Care Unit of a South Indian Tertiary Care Hospital. Also, he attended few of the oral presentations of

scientific research papers on various topics related to Pharmacoepidemiology and Drug Safety.

During this conference, he had an opportunity to meet and network with internationally recognized experts in the area of Pharmacoepidemiology and drug safety. Also he had an opportunity to exchange research ideas and current practices with fellow delegates for the mutual benefit.



Mr. Krishna Undela with one of his posters during the 10th ACPE 2017

Awards / Honors

1. **Ms. Savitha R.S.** and **Ms. Juny Sebastian**, Department of Clinical Pharmacy received **Best Oral Presentation awards** and **Ms. Aakanksha Sharma** and **Ms. Smruthi Ebi** students of Department of Clinical Pharmacy received **Best Poster Presentation awards** during 8th Asian Association of Colleges of Pharmacy Conference held at JSSUniversity, Mysuru from 27th -29th October 2017.
2. **Ms. Mintu Mathew**, Post Graduate Student of Department of Clinical Pharmacy received **Best Poster Presentation** award during National Seminar on Recent Advancements in the Management of Psychiatric Disorders held at Al-Shifa College of Pharmacy, Kerala on 3rd & 4th November 2017.
3. **Dr. G. Parthasarathi**, Professor, Department of Clinical Pharmacy was elected as a Scientific Committee Member for International Society of Pharmacovigilance (ISoP)
4. **Mr. Srikanth M.S.**, Research Scholar, Department of Clinical Pharmacy received a **Travel grant** of \$1300 USD plus Complimentary Registration to attend ISPOR 20th Annual European Congress at Glasgow, Scotland from 4th - 8th November 2017.
5. **Mr. Krishna Undela**, Lecturer, Department of Clinical Pharmacy received **ACPE 2017 Scholarship** to attend International Society for Pharmacoepidemiology's (ISPE's) 10th Asian Conference on Pharmacoepidemiology (ACPE) held at University of Queensland, Brisbane, Australia from 29th - 31st October 2017.

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. We can also 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. :

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

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