JSS UNIVERSITY

Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

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ADVERSE DRUG REACTION REPORTS: MAY - AUG 2017

A total of 709 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during May to August 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
Acitretin	.....	Retinoic acid syndrome
Amlodipine	.....	Psoriasis
Amoxicillin	.....	Eruptive pustulosis
Atropine	.....	Psychosis
Clonazepam	.....	Dysarthria
Dapsone	.....	Toxic epidermal necrolysis
Doxorubicin	.....	Congestive cardiac failure
Folic acid	.....	Dysgeusia
Linezolid	.....	Discolouration of tongue
Methotrexate	.....	Mucositis
Phenylephrine	.....	Conjunctivitis
Povidone iodine	.....	Erythematous rash
Prochlorperazine	.....	Dystonia
Tramadol	.....	Erythema annulare
Valproic acid	.....	Hyperammonemia

Acitretin induced retinoic acid syndrome

Acitretin induced retinoic acid syndrome is a serious adverse drug reaction which is characterized by fever, respiratory distress, interstitial pulmonary infiltrates, pleural and pericardial effusion, episodic hypotension, weight gain, and acute renal failure. The exact mechanism behind this reaction is unclear. Systemic glucocorticoids are the treatment of choice for this reaction. Supportive care like oxygen and mechanical ventilation may be needed in severe cases.

Doxorubicin induced congestive heart failure

Doxorubicin induced congestive heart failure can be seen in very young and very old individuals, patient receiving high doses of doxorubicin and patients with history of cardiovascular diseases. The proposed mechanism was increased oxidative stress due to increase in the levels of reactive oxygen species and lipid peroxidation and also decreased levels of antioxidants and sulfydryl groups. Diuretics, low dose hydralazine, isosorbide dinitrate are the treatment options for doxorubicin indced congestive heart failure.

Linezolid induced discolouration of tongue

Linezolid induced discoloration of tongue is a self limiting disorder. It is characterized by abnormal hypertrophy and elongation of filiform papillae on the surface of the tongue. The symptoms include tickling or burning of the tongue, nausea, dysgeusia and unattractive appearance of the tongue. Discontinuation of the suspected medication and maintaining good oral hygiene will helpful in the management of reaction.

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 US FDA during the period May - August 2017

DRUG	BRAND	INDICATION
Cardiology/Vascular Diseases		
Betrixaban	Bevyxxa	For the the prophylaxis of venous thromboembolism
Dermatology		
Guselkumab	Tremfya	For the treatment of moderate-to-severe plaque psoriasis
Genetic Disease		
C1 Esterase Inhibitor Subcutaneous [Human]	Haegarda	For the routine prophylaxis to prevent hereditary angioedema attacks
Hematology		
L-glutamine oral powder	Endari	For the treatment of sickle cell disease
Coagulation Factor IX (Recombinant), GlycoPEGylated	Rebinyn	For the treatment of hemophilia B
Hepatology		
Glecaprevir and pibrentasvir	Mavyret	For the treatment of chronic HCV genotype 1, 2, 3, 4, 5 or 6
Sofosbuvir, velpatasvir, and voxilaprevir (FDC)	Vosevi	For the treatment of hepatitis C
Infections and Infectious Diseases		
Delafloxacin	Baxdela	For the treatment of acute bacterial skin and skin structure infections
Benznidazole	--	For the treatment of Chagas disease
Rabies Immune Globulin (Human)	KedRab	For the post-exposure prophylaxis of rabies infection
Musculoskeletal		
Sarilumab	Kevzara	For the treatment of active rheumatoid arthritis
Neurology		
Edaravone	Radicava	For the treatment of amyotrophic lateral sclerosis
Oncology		
Inotuzumab ozogamicin	Besponsa	For the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia
Enasidenib	IDHIFA	For the treatment of relapsed or refractory acute myeloid leukemia with IDH2 mutation
Tisagenlecleucel	Kymriah	For the treatment of refractory B-cell precursor acute lymphoblastic leukemia
Durvalumab	Imfinzi	For the treatment of advanced or metastatic urothelial carcinoma
Neratinib	Nerlynx	For the treatment of HER2 breast cancer

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 May - August 2017

DRUG	STRENGTH	INDICATION
Pomalidomide	1mg/2mg/3mg/4mg Capsules & Bulk	In combination with dexamethasone, for patient with multiple myeloma
Sofosbuvir +Velpatasvir	400 mg + 100 mg Tablet	For the treatment of adult patients with chronic hepatitis C virus, genotype 1,2,3,4,5 or 6 infection
Osimertinib	40 mg/80 mg Film coated Tablets	For the treatment of patient with metastatic epidermal growth factor receptor (EGFR)
Argatroban Hydrate	250 mg/2.5 ml Bulk & Injection	For prophylaxis or treatment of thrombosis in adult patients with heparin induced thrombocytopenia (HIT)
Mirabegron	25 mg/50 mg Prolonged Release Tablet	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome
Delamanid	50 mg Tablet	For the use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability
Efonidipine Hydrochloride Ethanolate	10 mg/20mg/40mg Bulk & Tablets	Indicated for the management of hypertension, renal parenchymal hypertension, angina

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

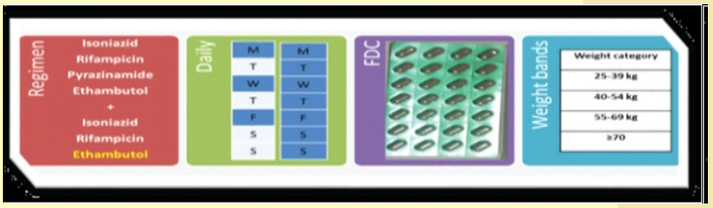
Change of Tuberculosis Regimen from Thrice a Week to Daily

Tuberculosis (TB) is one of the top 10 causes of death worldwide. India accounts for one fourth of the global TB burden. In 2015, an estimated 28 lakh cases occurred and 4.8 lakh people died due to TB. An estimated 1.3 lakh incident multi-drug resistant TB patients emerge annually in India.

In view of high TB relapse cases, under the national strategic plan by the Central Tuberculosis Division, Karnataka state has taken a decision to move from the intermittent drug regimen (thrice-a-week) to daily regimen of TB drugs. Under the new daily drug regimen, TB patients will be given fixed drug combinations (FDCs) three or four drugs in specific dosages in a single pill on a daily basis. The drugs will also be administered in a more scientific manner according to the patient's weight.

The World Health Organisation revised its TB management guidelines in 2010, recommending that the daily drug regimen be adopted under Revised National Tuberculosis Control Programme (RNTCP). In January this year, the Supreme Court also directed the Union Health Ministry to replace the thrice-a-week treatment regimen with a daily dosage "to curb relapse and deaths during treatment." In March 2016, RNTCP revised its technical and operational guidelines and added daily regimen for treatment of TB. Himachal Pradesh, Sikkim, Bihar, Maharashtra and Kerala last year implemented this shift in treatment strategy for drug sensitive TB patients. In Karnataka, it was implimented on 13th October 2017 in few districts. This is a major shift in the TB treatment policy being made by the Central TB Division since 1997.

The biggest advantage for the patient under the new regimen will be reduced pill burden, as instead of seven tablets, patients need to consume only 2 or 3 tablets, according to his/her weight band. However, increased pharmacovigilance might be needed in order to observe the safety issues of daily regimen. Hence, more clinical monitoring of patients will be required to manage adverse drug reactions.



References: 1. http://www.thehindu.com/news/national/ karnataka/ state-shifts-to-daily-drug-regimen-for-tb-patients/article19872908.ece

2. TB India 2017 - https://tbcindia.gov.in/ WriteReadData/ TB%20India%202017.pdf

Delamanid: A New Anti-Tuberculosis Drug Approved by Govt. of India

On 2nd August 2017, Central Drugs Standard Control Organization approved for marketing Mylan's new class of anti-TB drug, Delamanid to treat multi-drug resistant TB (MDR-TB) specifically.

Delamanid is indicated for use as part of an appropriate combination regimen for pulmonary MDR-TB in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. The recommended dose for adults is 100 mg twice daily for 24 weeks. The pharmacological mode of action of delamanid involves inhibition of the synthesis of the mycobacterial cell wall components, methoxy-mycolic and keto-mycolic acid.

Last year, the government launched Bedaquiline drug to treat MDR-TB for 600 patients across India. It was the first drug launched after four decades to treat TB. It has been made available in five cities Delhi, Mumbai, Chennai, Guwahati, and Ahmedabad.

Now, Delamanid is launched for those patients who are irresponsive to most of the first or second line of TB treatment. Japan's Otsuka Pharmaceutical developed Delamanid and it licenses Mylan subsidiary to market Delamanid in India. In 2014, it received approval in Europe, Japan, and South Korea.

A senior health ministry official mentioned that at least 400 patients in India will likely have access to delamanid as part of the government's conditional access programme in the next six months. The Revised National Tuberculosis Control Programme (RNTCP) will now begin drafting the protocol to administer delamanid in combination with other drugs to MDR-TB patients.

References: 1. https://news.medgenera.com/mylan-delamanid-mdr-tb-india-tuberculosis/

2. EMA Summary of Product Characteristics - http://www.ema.europa.eu/docs/en_GB/document_library/EPAR__Product_Information/human/002552/WC500166232.pdf

DEPARTMENT ACTIVITIES

Continuing Medical Education (CME) on Pharmacovigilance

Department of Clinical Pharmacy, JSS Medical College & Hospital, Pharmacovigilance Programme of India (PvPI) Regional Training Centre for South Zone, Mysuru, Karnataka in collaboration with ADR Monitoring Centre (AMC), Department of Pharmacology, Amala Institute of Medical Sciences, Kerala and PvPI, IPC, Ghaziabad organized one day CME on Pharmacovigilance at Amala Institute of Medical Sciences, Thrissur, Kerala on 27th May 2017.

The objectives of this CME was to widely propagate an effective and sustainable ADR monitoring system by fostering a culture of ADR reporting among doctors, dentists, nurses and

Organizers of CME on Pharmacovigilance

pharmacists and building an effective Pharmacovigilance network in the country. A total of 138 healthcare professionals (Registered Medical Practitioners: 39, Pharmacists: 29, Medical & Pharmacy Students / Interns: 70) from the states of Kerala, Karnataka, Tamil Nadu and Pondicherry attended the CME.

Dr. M Ramesh, Dr. Justin Kurian, Mrs. Juny Sebastian and Mr. Krishna Undela from Department of Clinical Pharmacy, JSS Medical College & Hospital were the resource persons for this CME.

Workshop on Clinical Research and Evidence Based Medicine

A workshop on clinical research and evidence based medicine was conducted by Department of Pharmacy Practice at JSS College of Pharmacy, Mysuru on 11th & 12th July 2017. This workshop was aimed to provide highlights of drug development process and concepts & clinical applications of evidence based medicine. Students of V Pharm.D and II M.Pharm Pharmacy Practice and Pharmacology attended this workshop. Mr. Tapankumar Shah, Country Head, Clinical Operations, Astra Zeneca Pharma India Pvt Ltd, Bangalore was a speaker and workshop resource person.

During the inaugural event, Mr. Tapankumar Shah, Dr. T M Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru, Dr. M. Ramesh, Professor & Head, Department of Pharmacy Practice, Mr. Himanshu Patel, Coordinator and Department staff & students were present. On day one, he discussed drug development process from industry perspective with real life stories of success and failure of few drug molecules. Also, he had discussed evidence based approach to select most effective treatment for individual patient taking diabetes as an example.

Mr. Tapankumar Shah with Workshop Participants

On day two, during forenoon session workshop on critical appraisal of composite end points in clinical study was conducted which thoroughly covered concepts, needs, interpretations and clinical applications of studying composite end points. During afternoon session, participants had opportunity to have 'hands on' session on research protocol writing and its presentation.

Participants had great opportunity to interact with the speaker and discussed on research questions and planning of their academic research projects. Participants appreciated all the sessions of two days program and provided the positive feedback. We thank Mr. Tapankumar Shah for his incredible support and courage extended to us in conducting the said workshop.

Training of Pharm.D Students in Basic Life Support (BLS) and Advanced Cardiovascular Life Support (ACLS)

Basic Life Support (BLS) course offered by American Heart Association (AHA) was provided to fifth Year Pharm.D students on 26th July 2017 at Rajendra Auditorium, JSS College of Pharmacy, Mysuru. During the course, the students got training in essential skills individually, as part of a team, and as team leader in different learning stations based on simulated clinical scenarios. The students learned the basics of resuscitation like chest compressions, adult and infant breaths, management of choking in adults and infants etc. Realistic simulations were focused on the following key concepts: proficiency in recognizing and initiating early management of periarrest conditions, of chocking and the supportive care, identifying and treating, recognizing other life-threatening clinical situations such as cardiac arrest and providing initial care, applying BLS algorithms and effective resuscitation team dynamics.

Students on BLS & ACLS Training

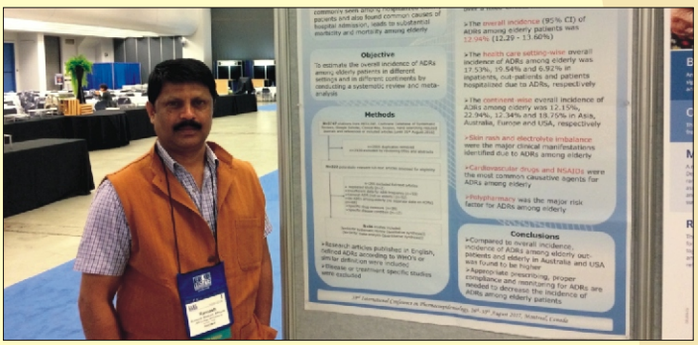
Advanced Cardiovascular Life Support (ACLS) course offered by AHA was provided to Pharm.D Interns on 27th & 28th July 2016 at Rajendra Auditorium, JSS College of Pharmacy, Mysuru. During the course, the students got training in essential skills individually, as part of a team, and as team leader in different learning stations based on simulated clinical scenarios. Realistic simulations were focused on the following key concepts: proficiency in basic life support care, recognizing and initiating early management of peri-arrest conditions, managing cardiac arrest, identifying and treating ischemic chest pain and acute coronary syndromes, recognizing other life-threatening clinical situations such as stroke and providing initial care, ACLS algorithms and effective resuscitation team dynamics.

Faculty Attended 33rd International Conference on Pharmacoepidemiology held at Montreal, Canada

Dr. M. Ramesh, Professor & Head, Department of Pharmacy Practice, JSS College of Pharmacy, JSS University, Mysuru attended the 33rd International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) held at Palais Des Congress De Montreal, Montreal, Canada from 26th – 30th August 2017.

He attended the preconference workshop from 26th-27th August 2017 on the selected sessions on Pharmacoepidemiology, effectiveness & outcome research, pharmacovigilance & signal detection and advanced drug utilization evaluation. Through attending this pre conference workshop, he benefited to gain greater understanding on the advanced aspects of the various topics covered. Also, he attended the main conference from 28th-30th August 2017 that dealt with various topics related to Pharmacoepidemiology and drug safety issues. Through attending the main conference, he had an opportunity to get exposed and gain understanding on concepts, methods and advancements in the area of Pharmacoepidemiology and therapeutic risk management. During the main conference, he presented three research papers entitled (i) Assessment of Impact of Pharmacist-Psychiatrist Collaborative Patient Education on Medication Adherence and Quality of Life in Patients with Bipolar Disorder (ii) Impact of Adverse Drug Reactions on Daily Living of Patients on Anti-Psychotic Medications (iii) Incidence of Adverse Drug Reactions among Elderly Patients: A Systematic Review and Metaanalysis. Also, he attended few of the oral presentations of scientific research papers on various topics related to Pharmacoepidemiology and pharmacovigilance.

Dr. M. Ramesh was awarded with 'ICPE 2017 Scholarship' that enabled him to attend this conference. As a scholarship privileges he received complimentary registration to pre conference workshop, main conference, access to educational sessions, complimentary membership of ISPE for one year and travel grant of $1540 USD to cover up meeting related expenses. 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.



Dr. M. Ramesh with one of his posters during the 33rd ICPE 2017

Visit of Student from Howard University, USA

As a part of MoU between JSS University, Mysuru and Howard University, Washington, USA, Mr. Ronald Smith from Howard University, USA arrived at JSS College of Pharmacy, Mysuru under student study exchange program. He underwent training in the Department of Clinical Pharmacy, JSS Hospital, Mysuru. The purpose of the experiential program was to expose the student 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 five weeks, which commenced from 31st August 2017. During the training period, student was introduced to various Clinical Pharmacy Services and ambulatory patient care services provided at the experiential study site (JSS Hospital, Mysuru) of JSS College of Pharmacy, Mysuru. Following which, student was posted one week each in Medicine and Pediatric Departments.

During his clinical posting, he could understand the therapeutic management of most of the common diseases seen in India and appreciate the differences that exist in the management of such diseases in United States. Also, student was exposed to various departments like Pulmonology and DOTS centre, Immunization centre, Cardiology, Emergency, Psychiatry, Dermatology and Gastroenterology. During his clinical posting, he had opportunity to review various clinical cases from the different departments, and discussed them with his facilitator.

Also, he presented a case on malaria and its treatment at the practice site as part of his clinical assignments required for posting. He attended the case presentations on all days along with Pharm.D Interns of JSS University, Mysuru. Also, he was posted to Asha Kirana Hospital and Bharath Hospital & 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 his clinical rotation, he was posted for a week at Govt. Head Quarters Hospital, Ooty which is a practice site of JSS College of Pharmacy, Ooty to provide him an opportunity to understand the healthcare delivery system at Government settings.

Mr. Ronald Smith with Principal and Department Staff

JSS University, Mysuru, in collaboration with Uppsala Monitoring Centre (UMC), Sweden organizing the fourth Asia Pacific Pharmacovigilance Training Course from 29th January to 9th February 2018.

JSS University's Asia Pacific Pharmacovigilance Training course offers a programme to about 30 professionals each year. Previous courses have taken place in Mysuru in February 2015, January 2016 and January 2017.

Participants study topics essential to effective pharmacovigilance, including sessions to strengthen the performance of members of the WHO Programme, such as pharmacovigilance best practice and tools, signal detection, regulatory aspects and reporting culture. Training, built around lectures, workshops and hands-on exercises, takes place in an open and engaging environment.

For futher details please visit www.jssuni.edu.in /JSSWeb/UDHP.aspx?PID=15

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. :

Toll free - 1800-425-0207; 0821-2335577; Extn. 5577;

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

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