

# Clinical Pharmacy

A Newsletter of Drug and Prescribing Information

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## ADVERSE DRUG REACTION REPORTS: JAN - APR 2018

A total of 471 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during January to April 2018. 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
Atropine .....	Delirium
Carboplatin .....	Asthenia
Cefixime .....	Fixed Drug Eruption
Ciprofloxacin .....	Seizure
Dexamethasone .....	Euphoria
Fosphenytoin .....	Dyskinesia
Imatinib .....	Lichen Planus
Iron sucrose .....	Joint Pain
Isoniazid .....	Henoch Schonlein Purpura
Isoniazid .....	Pellagroid Dermatitis
Metronidazole .....	Urticaria
Phenobarbital .....	Behavioural Changes
Piperacillin+Tazobactam .....	Bullous Pemphigoid
Tropicamide .....	Eye Irritation
Zidovudine .....	Lipodystrophy

### Imatinib induced Lichen Planus

Imatinib induced Lichen Planus is a rare dose dependent cutaneous adverse reaction which can occur within few weeks to months after initiation of intramuscular Imatinib. This dose dependence suggests that imatinib-related cutaneous reactions are mediated by changes in tyrosine kinase signal transduction mechanism rather than immunologic mechanism. The treatment includes topical corticosteroids as well as oral antihistamines. However, the reaction may reoccur once the drug is rechallenged.

### Isoniazid induced Henoch Schonlein Purpura

Henoch Schonlein Purpura is a subtype of leukocytoclastic vasculitis which commonly occur in children characterized by inflammation and bleeding in the small blood vessels in skin, joints, intestines and kidneys. It is a rare complication of anti-tubercular therapy (ATT) with IgA deposits with involvement of other autoantibodies such as antineutrophil cytoplasmic antibody (ANCA), and other inflammatory mediators. The skin lesions of ATT-induced vasculitis typically improve upon withdrawal of the suspected medication and can be controlled with the administration of antihistamines and corticosteroids.

### Piperacillin+Tazobactam induced Bullous Pemphigoid

Bullous Pemphigoid is an autoimmune skin disease characterized by intense itching and burning sensation of the skin. The mechanism includes deposition of IgG autoantibodies at the basement membrane zone targeting bullous pemphigoid antigen 1&2 result in surge of immune cells in affected area. Unclear events cause separation along the dermoepidermal junction and eventually stretch bullae. However, there is no cure but symptoms can be relieved with the treatment of corticosteroids (topical and oral).

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 0821-2335577 or SMS to 9035664802 (Format: ADR / IP or OP Number/ Name of the patient/ Ward)

## DRUGS APPROVED BY CDSCO, INDIA

The following are the drugs that are approved by the Central Drugs Standard Control Organization (CDSCO) during the period January - April 2018

DRUG	STRENGTH	INDICATION
Emtricitabine + Tenofovir Alafenamide	200mg/200mg + 10/25 mg Tablets	In combination with other antiretroviral agents for treatment of Human Immunodeficiency Virus type-1 (HIV-1) infection in adults and adolescents with aged 12 years and older
Clofarabine	20 mg/20ml Injection	For the treatment of patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This indication is based upon response rate
Netupitant+ Palonosetron	300 mg + 0.5 mg Capsule	For the prevention of acute and delayed nausea and vomiting associated with highly emetogenic Cisplatin-based cancer chemotherapy - For the prevention of acute and delayed nausea and vomiting associated with moderate emetogenic cancer chemotherapy in adult
Cadexomer Iodine Powder or Cadexomer Iodine Ointment	100 % w/w (contain 0.9 % w/v Iodine) or 500 mg (contains 0.9% w/v iodine)	For the treatment of chronic exuding wounds such as leg ulcers, pressure ulcers and diabetes ulcers infected traumatic and surgical wounds
Dalfampridine	10 mg Film coated extended release tablet	For treatment to improve walking in patients with multiple sclerosis (MS)
Ulipristal Acetate	5 mg tablets	For the pro-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age
Riociguat	0.5mg/1.0mg/1.5mg/ 2.0mg/2.5 mg tablet	For the treatment of persistent/ recurrent chronic Thromboembolic pulmonary Hypertension (CTEPH) WHO Group 4) After surgical treatment or imoperable CTEPH to improve exercise capacity and WHO function

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

## Restrictions on Usage of Oxytocin in India

After several years of deliberations on restricting or prohibiting the oxytocin injection to prevent its rampant misuse by dairy and horticulture industry, the Union Ministry of Health & Family Welfare has come out with a notification restricting the manufacture and distribution of oxytocin formulations for domestic use. From 1<sup>st</sup> July 2018, manufacturing and distribution of this drug has been restricted to Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), a public sector company. KAPL will supply the drug to registered hospitals and clinics in public and private sector directly. Moreover, the label of the product should bear barcodes to ensure traceability and its sale will not be allowed through a retail chemist in any form or name. As a first step to control its entry into the country, the

government has already banned the import of oxytocin. However, private companies can produce the drug if it is intended for export purposes.

The government's action is aimed at preventing the widespread misuse of this so-called 'wonder drug' by the dairy and horticulture industry in the country. It is widely misused in the dairy industry where livestock are injected with it to make them release milk at a convenient time. Many farmers also misuse this drug to plump up vegetables. What is alarming is the fact that several studies have proved that sustained use of oxytocin drug can cause hormonal imbalance in humans and ruin the reproductive system of animals, and cutting their life span substantially.

The drug oxytocin has medical use as it causes uterine contractions thereby inducing labour naturally and controls post-delivery bleeding. But, while trying to restrict its manufacture and distribution, the government should ensure that there is no shortage of this critical medicine which was included in the National List of Essential Medicines (NLEM) as a critical and lifesaving drug as it takes effect sooner than most other uterotonic drugs. In a country like India where, as per WHO report, five women die every hour from

complications developed during childbirth with heavy blood loss caused by haemorrhage being a major factor, ready availability of oxytocin should be a high-priority.

**References:** 1. Minutes of the 78<sup>th</sup> Meeting of Drugs Technical Advisory Board (DTAB) held on 12th February, 2018 at DGHS, Nirman Bhawan, New Delhi

2. The Gazette of India Notification - [http://www.cdsc.nic.in/writereaddata/GSR%20411\(E\).pdf](http://www.cdsc.nic.in/writereaddata/GSR%20411(E).pdf)

## Is New Blood Pressure Guidelines Make People Anxious?

In November 2017, American College of Cardiology (ACC)/American Heart Association (AHA) have come out with the new guidelines for the detection, prevention, management and treatment of high blood pressure. As per these guidelines, high blood pressure should be treated earlier with lifestyle changes and in some patients with medication at 130/80 mm Hg rather than previous cut-off 140/90 mm Hg.

Following are the blood pressure categories in the new guidelines:

Normal: Less than 120/80 mm Hg;

Elevated: Systolic between 120-129 and diastolic less than 80mm Hg;

Stage 1: Systolic between 130-139 or diastolic between 80-89mm Hg;

Stage 2: Systolic at least 140 or diastolic at least 90 mm Hg;

Hypertensive crisis: Systolic over 180 and/or diastolic over 120mm Hg, with patients needing prompt changes in medication if there are no other indications of problems, or immediate hospitalization if there are signs of organ damage.

Nevertheless, the following are the concerns raised by few researchers and cardiologists:

"First, wider disease definitions mean more people are labelled as unwell, even if they have low risk of a disease".

Labelling a person as having hypertension increases their risk of anxiety and depression, as compared to the risk for people with the same blood pressure who aren't labelled as hypertensive.

"Second, it means more people may experience serious adverse effects from treatments".

"Third, in countries without universal health coverage, such as the United States, people newly diagnosed with hypertension may face difficulties gaining insurance coverage for a 'pre-existing' condition".

Although, experts says that while patients at higher risk for cardiovascular disease benefited from these stricter guidelines, those with lower risk had more harm than benefit from the intensive treatment recommendations.

The 2017 ACC/AHA guidelines would classify an additional 31 million adults in the United States and 2.4 million Australians as having hypertension.

**Reference:** 1. 2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. <https://doi.org/10.1161/HYP.0000000000000065>

2. Katy J. L. Bell, Jenny Doust, Paul Glasziou. Incremental Benefits and Harms of the 2017 American College of Cardiology/American Heart Association High Blood Pressure Guideline. JAMA Internal Medicine, 2018; DOI: 10.1001/jamainternmed.2018.0310

## DEPARTMENT ACTIVITIES

### 4<sup>th</sup> Asia Pacific Pharmacovigilance Training Course

Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research (JSS AHER), Mysuru organized 4<sup>th</sup> Asia Pacific Pharmacovigilance Training Course from 29<sup>th</sup> Jan 9<sup>th</sup> Feb 2018 at JSS College of Pharmacy, Mysuru. The course was conducted in collaboration with Uppsala Monitoring Centre (UMC), the World Health Organisation (WHO) Collaborating Centre for International Drug Monitoring located in Sweden. The course aimed at building Pharmacovigilance capacities amongst healthcare professionals providing solid practical foundations for those working in medicine safety and updates for experienced staff in the Asia Pacific region and beyond.

This course had drawn 32 attendees from national regulatory authorities, pharmaceutical companies, academia, contract research organisations, and the healthcare sector in 12 countries in Asia and other parts of the world. The two-week training course was taught by field experts from JSS College of Pharmacy, Mysuru and UMC, as well as by external



*Inauguration of Training Course*

speakers from India and abroad. Thirty-one internationally known experts from Sweden, Switzerland, Singapore, United Kingdom, Australia, the Netherlands, Scotland, Morocco, Kenya and India participated in the program as speakers and trainers. The training course covered wide range of issues relating to medicine safety; from medication errors, health impacts of low quality medicines to effects of inappropriate use of medicines and adverse reactions to drugs and vaccines.

## Workshop on Pharmacovigilance: Basics to Advanced

The Department of Clinical Pharmacy located at JSS Hospital, Mysuru, as a part of 'Southern Regional Resource Centre for Pharmacovigilance Programme of India (PvPI), extended the technical support and expertise to Department of Pharmacology, Pondicherry Institute of Medical Sciences (PIMS), Pondicherry in the conduct of a national level 'Workshop on Pharmacovigilance: Basics to Advanced' on 16<sup>th</sup> & 17<sup>th</sup> February 2018. The theme of the workshop was 'Medication use without harm for enhanced patient care'.

The workshop aimed to provide insights on Pharmacovigilance in order to advance the knowledge and develop skills amongst healthcare professionals. **Dr. M. Ramesh**, Professor & Head, **Mrs. Juny Sebastian** and **Mr. Krishna Undela**, Lecturers, Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru were the resource persons for this workshop. A total of 60 healthcare professionals, postgraduate medical students from different institutions located across the country attended this workshop.



*Dr. M. Ramesh, Mrs. Juny Sebastian and Mr. Krishna Undela delivering the lectures*

## Interdisciplinary Education on 'Trends in Vaccination and Medication Errors'

Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru in collaboration with Department of Community Health Nursing, JSS College of Nursing conducted an inter disciplinary education programme on 28<sup>th</sup> March 2018 at Dr. Sri. Shivarathri Rajendra Bhavana, JSS Hospital campus.

This education programme, intended for the benefit of the Nursing, Pharm.D and Masters in Pharmacy Practice students. This program was housed by three speakers, **Ms. Juny Sebastian**, **Mr. Krishna Undela** and **Mr. Sri Harsha Chalasani**, Lecturers from Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru. After the formal inauguration, Ms. Juny Sebastian has delivered her talk on 'Transportation, Storage and Administration of Vaccines'. Ms. Juny Sebastian in her talk emphasised on the need for proper storage and administration of various vaccines. Mr. Krishna Undela

delivered a talk on 'Adverse events following immunization' with an emphasis on basic science on how to classify adverse events to vaccines. Mr. Sri Harsha Chalasani delivered a talk on 'Medication errors and their implications on patient safety'.



*Speaker & Participants during the Session*

The session was well received by the participants. The academic administrators of Nursing faculty gave a positive feedback and requested for more such educational sessions in future.

## Seminar on Immunization Dialogue

Department of Pharmacy Practice organized a half-day 'Seminar on Immunization Dialogue' on 6<sup>th</sup> February 2018 at Dr. Sri Rajendra Centenary Auditorium, JSS Hospital, Mysuru. The objective of the seminar was to update the Health Care Professionals (Doctors, Pharmacists and Nurses) who are involved in the immunization process on Safe & Quality Use of Vaccines.

**Dr. Jyoti Jain**, Head, South Asia & Asia Coordinator for the Global Antibiotic Resistance Partnership (GARP) Project, Centre for Disease Dynamics, Economics & Policy (CDDEP), New Delhi, **Dr. M.D. Ravi** and **Dr. S.N. Prashanth**, Professors from Department of Pediatrics, JSS Hospital, Mysuru and **Ms. Juny Sebastian**, Lecturer, Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru were the speakers for the seminar.

During the seminar, the speakers discussed various aspects



*Speaker & Participants during the Seminar*

of safe and quality use of vaccines such as transport and storage of vaccines, safe administration practices, basics of Adverse Events Following Immunization (AEFI), vaccine advocacy and importance of effective communication in case of an AEFI to the media/public. There were 152 healthcare professionals including postgraduate and internship students of medical, nursing and pharmacy, Practicing Pharmacists, Nurses and Pediatricians and Teaching Faculties of Pharmacy, Nursing and Pediatric Department attended the seminar.

## Continuous Professional Development Program for Community Pharmacists

Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru conducted Continuous Professional Development (CPD) program on 'Patient medication counseling' for Practicing Pharmacists of Mysuru district on 16<sup>th</sup> February 2018 at JSS College of Pharmacy, Mysuru.

The objective of this program was to train the practicing pharmacists in Mysuru district on importance of patient medication counseling and communication skills required for counseling. **Mrs. Savitha R.S.**, Assistant Professor, Department of Pharmacy Practice delivered the talk on 'Communication Skills in Patient Counseling'. **Mrs. Shilpa Palaksha**, Assistant Professor, Department of Pharmacy Practice delivered a talk on 'Patient medication counseling' and **Mr. Srikanth M.S. & Mr. Balaji S.** discussed few case studies on patient medication counseling. About 39 practicing pharmacists from various parts of Mysuru district attended and benefited from the workshop.



*Speakers & Participants during the Program*

## Guest Lectures on Pharmacovigilance

Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru organised a series of Guest Lectures in the area of Pharmacovigilance from 1<sup>st</sup> – 8<sup>th</sup> February 2018 at JSS College of Pharmacy, Mysuru. The aim of this series of guest lectures was to provide an in-depth understanding and exposure to some of the essential components in the area of Pharmacovigilance to Pharm.D and Post Graduate Diploma in Pharmacovigilance students. These lectures were delivered by some of the speakers who attended the '4<sup>th</sup> Asia Pacific Pharmacovigilance. Training Course' held at JSS

College of Pharmacy, Mysuru from 29<sup>th</sup> January to 9<sup>th</sup> February 2018.



*Mr. Sten Olsson Delivering a Lecture....*

## Guest Lecture on Pharmacy's Societal Imperative in India

**Dr. Donald E Letendre**, Dean & Professor, University of Iowa College of Pharmacy, USA visited the JSS College of Pharmacy, JSS AHER Mysuru on 30<sup>th</sup> April 2018 and delivered a lecture on 'Addressing the Challenges Imposed by Pharmacy's Societal Imperative in India'. During this lecture, he briefed about roles and responsibilities of Clinical Pharmacist in USA. He appreciated the initiatives taken by the JSS Colleges of Pharmacy in Mysuru and Ooty, and Pharmacy Council of India to introduce the patient-oriented Pharmacy Course (M. Pharm Pharmacy Practice & Pharm.D).

Dr. Donald also visited the Department of Clinical Pharmacy located at JSS Hospital, Mysuru and interacted with the HoD and Staff of the Department. During this visit he was briefed about the various Clinical Pharmacy services provided by the Department at JSS Hospital and other Practice sites in Mysuru



*Dr. Donald with Principal & Staff*

## Health Screening Camp

Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru organized a 'Health Screening Camp' for the public of Mysuru on 16<sup>th</sup> March 2018 at Bhugathalli during NSS Camp organized by JSS College of Pharmacy, Mysuru. The aim of the health screening camp was to sensitize the people about the importance of regular monitoring of chronic diseases and safe use of medications. During the camp, blood pressure and blood glucose levels of the villagers were screened. A total of 118 people were monitored for their blood pressure and blood glucose levels. During the monitoring, 30 people were found with elevated blood glucose level and 20 people were found with elevated levels of blood pressure. People



*Staff & Students during Health Screening Camp*

who were detected with the elevated levels of blood pressure and/or blood glucose were advised for life style modifications and suggested to consult physician for further diagnosis and treatment.

## Participation in National Deworming Day

As part of the Pharmacovigilance Programme of India (PvPI), Department of Clinical Pharmacy located at JSS Hospital, Mysuru along with District Health & Family Welfare Society, Mysuru participated in the National Deworming Day (NDD) held on 12<sup>th</sup> February 2018.

The aim of participation of the Clinical Pharmacy Department was to monitor the adverse events, if any, due to administration of Albendazole on National Deworming Day.



*Staff Participation in National Deworming Day*

### Awards

Department of Pharmacy Practice, JSS College of Pharmacy, JSS AHER, Mysuru received **Best Poster Presentation Award** for one of the research papers titled '**Adverse Drug Reactions in Elderly Patients: A Systematic Review and Meta-analysis**' which was presented during International Conference on Challenges, Opportunities and Newer Directions of Pharmacovigilance and Clinical Research in India conducted by Parul Institute of Pharmacy, Vadodara on 5<sup>th</sup> & 6<sup>th</sup> January 2018

Association of Pharmaceutical Teachers of India awarded **Shri. Ishwar N. Hukkeri Memorial Award** on 24<sup>th</sup> March 2018 for one of the research articles titled 'Assurance of Adverse Drug Reaction reporting and monitoring by Clinical Pharmacist in a Tertiary Care Teaching Hospital' authored by Mr. Himanshu Patel, Shobha Churi, Parthasarathi Gurumurthy and Dr. Ramesh Madhan published in Indian Journal of Pharmacy Practice, May 2016; 9(1):26-31

JSS College of Pharmacy, JSS AHER, Mysuru Ranked 10<sup>th</sup> in National Institutional Ranking Framework (NIRF) – 2018, Ministry of Human Resource Development, Govt. of India

**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 through

**Toll free - 1800-425-0207; 0821-2335577**

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**Your suggestions are welcome. Please send your comments/suggestions to the editors at: [clinicalpharmacy@jssuni.edu.in](mailto:clinicalpharmacy@jssuni.edu.in)**

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