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## ADVERSE DRUG REACTION REPORTS : Jan–Aug 2020

A total of 455 Adverse Drug Reactions (ADRs) were reported or detected by the Department of Clinical Pharmacy during Jan – August 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	Hypersensitivity vasculitis
Co-trimoxazole	Pancytopenia
Cyclosporine	Hypertrichosis
Dexamethasone	Hypereosinophilia
Hydroxyurea	Lichenoid drug reaction
Insulin	Lipodystrophy
Itolizumab	Desaturation associated with chills
Itraconazole	Burping
Lanzoprazole	Maculopapular rash
Pantoprazole	Blisters
Propofol	Bronchospasm
Quetiapine	Somnolence
Risperidone	Xerostomia
Tenofovir disoproxil fumarate	Avascular necrosis of femoral head
Valproic acid	Vesicular rash

### **Aceclofenac induced hypersensitivity vasculitis**

Aceclofenac induced hypersensitivity vasculitis is a rare reaction. It is also referred to as leucocytoclastic vasculitis, is thought to be an immunopathogenic disease resulting from the deposition of immune complexes, mainly in the small vessels. The precipitating antigen can be endogenous (in the context of connective tissue disorders or other chronic diseases) or exogenous (drugs or infections). In its most benign form, the skin is the most commonly involved organ, mainly as a palpable purpura, usually in the lower limbs. However, any organ can be affected. Antibiotics and non-steroidal anti-inflammatory drugs are the drugs most commonly associated with this reaction.

### **Co-trimoxazole induced pancytopenia**

Co-trimoxazole induced acute pancytopenia is a rare reaction and generally caused due to severe megaloblastosis with arrest of maturation in the erythroid, granulocyte series and marked decrease of megakaryocytes. Haematological reactions have been estimated to occur in 0.86% of patients who were receiving co-trimoxazole. The most common reactions have been neutropenia (including agranulocytosis) and thrombocytopenia. Also, Co-trimoxazole is the drug most commonly related to the occurrence of agranulocytosis.

### **Pantoprazole induced blisters**

Pantoprazole induced blister is a serious skin reaction known to induce Type I hypersensitivity reactions. However, severe delayed type hypersensitivity reactions (DHR) induced by PPI, such as Stevens Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), or drug rash with eosinophilia and systemic symptoms (DRESS) are rarely reported. Patients developed cross hypersensitivity reactions to alternative structurally similar PPIs. It also inhibits acid secretion and attenuate bleeding. The rash may be red or purple and then turn into blisters or peeling of the skin.

**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 CDSCO, INDIA

The following are the drugs that are approved by the Central Drugs Standard Control Organization (CDSCO) during the period May–August 2020.

Details of Drug	INDICATION
Centhaquine citrate bulk and Centhaquine citrate injection 1.0mg/vial	Add on resuscitative agent for hypovolemic shock
Hydrogen peroxide 0.5% w/w spray	Cleans, disinfects and deodorizes hard non- porous inanimate environmental surfaces
Remdesivir Injection 5 mg/mL and Remdesivir lyophilised powder for Injection 100 mg	For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with severe disease, in light of Covid 19 outbreak, for restricted emergency use in the country
Lymphoseek 50mcg kit (each kit contains :Tilmanocept 50mcg, Glycine 0.1mg, Sodium ascorbate 0.1mg, Trehalose dihydrate 16mg, stannous chloride dihydrate 0.015mg, sodium hydroxide q.s, hydrochloric acid q.s, Nitrogen q.s, water for injection q.s)	Indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma or localized squamous cell carcinoma of the oral cavity. This medicinal product is for diagnostic purpose only
Favipiravir bulk and Favipiravir film coated tablet 200mg	For the treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak, for restricted emergency use in the country
Remdesivir bulk drug	
Propylene glycol 0.6% lubricant eye drops	Dry eye therapy for the temporary relief of burning and irritation due to dryness of the eye
Pretomanid bulk and Pretomanid tablets 200mg	Indicated as part of a combination regimen with Bedaquiline and Linezolid, in adults for the treatment of pulmonary extensively drug resistant (XDR), or treatment intolerant or nonresponsive multidrug-resistant tuberculosis (MDR-TB)
Favipiravir film coated tablet 400mg	For the treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak for restricted emergency use in the country
n-alkyl dimethyl benzyl ammonium chloride 0.105% w/w spray	Cleans, disinfects, deodorizes hard, non- porous inanimate environmental surfaces
Dofetilide bulk and Dofetilide capsules 125mcg, 250mcg, 500mcg	<p><b>Maintenance of Normal Sinus Rhythm (Delay in AF/AFL Recurrence)</b></p> <p>Dofetilide is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AF/AFL]) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have been converted to normal sinus rhythm. Because Dofetilide can cause life threatening ventricular arrhythmias, it should be reserved for patients in whom atrial fibrillation/atrial flutter is highly symptomatic</p> <p>In general, antiarrhythmic therapy for atrial fibrillation/atrial flutter aims to prolong the time in normal sinus rhythm. Recurrence is expected in some patients</p> <p><b>Conversion of Atrial Fibrillation/Flutter</b> Dofetilide is indicated for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm</p> <p>Dofetilide has not been shown to be effective in patients with paroxysmal atrial fibrillation</p>
Octyl decyl dimethyl ammonium chloride 6.670% spray	Cleans, disinfects, deodorizes hard, non- porous inanimate environmental surfaces

**Reference:** List of new drugs approved in the year 2020 till date. [internet] Aug 2020 [cited Sep 3, 2020]. Available from:

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NjM4Mg==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjM4Mg==)



## Mifepristone Plus Misoprostol More Effectively Treats Miscarriage Than Misoprostol Alone

A Multicenter, double-blind, placebo-controlled, randomized trial (MifeMiso) was conducted in 28 hospitals in United Kingdom. Women aged 16 years and older, diagnosed with a missed miscarriage by pelvic ultrasound scan in the first 14 weeks of pregnancy, chose to have medical management of miscarriage were enrolled into the study. The study participants were randomly assigned (1:1) to a single dose of oral mifepristone 200 mg or an oral placebo tablet, both followed by a single dose of vaginal, oral, or sublingual misoprostol 800 µg 2 days later. The randomization was done through a secure web-based randomization program, with minimization to balance study group assignments according to maternal age (<30 years vs ≥30 years), body-mass index (<35 kg/m<sup>2</sup> vs ≥35 kg/m<sup>2</sup>), previous parity (nulliparous women vs parous women), gestational age (<70 days vs ≥70 days) and amount of bleeding (Pictorial Blood Assessment Chart score; ≤2 vs ≥3). The study participants, clinicians, pharmacists, trial nurses, and midwives were masked to study group assignment throughout the study. The primary outcome was failure to spontaneously pass the gestational sac within 7 days after random assignment. Primary analyses were done according to intention-to-treat principles. The study is registered with the ISRCTN registry, ISRCTN1740502

Over 22 months study period, 2595 women were identified as being eligible for the MifeMiso trial. 711 women were

randomly assigned to receive either mifepristone and misoprostol (357 women) or placebo and misoprostol (354 women). 696 (98%) of 711 women had available data for the primary outcome. 59 (17%) of 348 women in the mifepristone plus misoprostol group did not pass the gestational sac spontaneously within 7 days versus 82 (24%) of 348 women in the placebo plus misoprostol group (risk ratio [RR] 0.73, 95% CI 0.54–0.99; p=0.043). 62 (17%) of 355 women in the mifepristone plus misoprostol group required surgical intervention to complete the miscarriage versus 87 (25%) of 353 women in the placebo plus misoprostol group (0.71, 0.53–0.95; p=0.021). They found no difference in incidence of adverse events between the study groups.

The treatment with mifepristone plus misoprostol was more effective than misoprostol alone in the management of missed miscarriage. Women with missed miscarriage should be offered mifepristone pre-treatment before misoprostol to increase the chance of successful miscarriage management, while reducing the need for miscarriage surgery

**Reference:** Chu JJ, Devall AJ, Beeson LE, Hardy P, Cheed V, Sun Y, et al. Mifepristone Plus Misoprostol More Effectively Treats Miscarriage Than Misoprostol Alone. *The Lancet*. Published online August 24, 2020  
[https://doi.org/10.1016/S0140-6736\(20\)31788-8](https://doi.org/10.1016/S0140-6736(20)31788-8)

## Limited Evidence Supports Escalation of Therapy for Acute Asthma Exacerbations in Kids

A cochrane review was published on 5<sup>th</sup> August, 2020 evaluating the effectiveness and safety of treatment options available for children with acute asthma who do not improve with standard first-line treatment. The review included 13 Cochrane Systematic Reviews on various treatment options, including inhaled medication, intravenous medications, and other therapies. This overview provides the most up-to-date evidence from systematic reviews with meta-analyses of randomised controlled trials on acute severe asthma in children.

### Key results of the review

- ✓ Intravenous magnesium sulfate (a bronchodilator given through a vein) appears to reduce the length of time spent in hospital;
- ✓ No evidence suggests that any treatment reduced the risk of being admitted to intensive care;
- ✓ Some treatments appeared to reduce the risk of hospital admission. These included adding a second type of inhaled bronchodilator treatment (anticholinergic medication such as ipratropium bromide) to standard inhaled treatment (beta-agonist such as salbutamol), giving intravenous magnesium sulfate, and breathing a mixture of helium and oxygen;

- ✓ Serious adverse events may be reduced by inhaled magnesium sulfate;
- ✓ Nausea and/or vomiting is more common with aminophylline (another bronchodilator medication given through a vein); and
- ✓ Adding a second type of inhaled bronchodilator treatment (anticholinergic medication such as Ipratropium bromide) reduces the risk of nausea and tremor but not vomiting.

### Recommendations for future research

One of the major problems with existing research is that a small number of patients is included in each study, likely because severe acute asthma in children is relatively uncommon. To work out whether or not a treatment is effective and/or to tell the difference between treatments, a research study must include enough patients receiving each treatment. Therefore, high-quality research into severe acute asthma in children requires multi-centric studies that include many hospitals.

**Reference:** Craig SS, Dalziel SR, Powell CVE, Graudins A, Babl FE, Lun C. Interventions for escalation of therapy for acute exacerbations of asthma in children: an overview of Cochrane Reviews. Version published: 05 August 2020.  
<https://doi.org/10.1002/14651858.CD012977.pub2>

## Department Activities

A series of webinars were organized by the Department during July and August 2020 for the benefit of faculty and students of second year M Pharm, fifth, and sixth year Pharm D. The webinars were themed on challenges and opportunities during the COVID19 Pandemic. The details are provided below.

### Webinar on Challenges During COVID-19 Pandemic: Pharmacists' Perspectives

The Department of Pharmacy Practice, JSS College of Pharmacy (JSSCP), JSS Academy of Higher Education & Research (JSS AHER), Mysuru organised a Webinar on "Challenges During COVID-19 Pandemic: Pharmacists' Perspectives" in association with the Pharmaceutical Society of Srilanka on 2<sup>nd</sup> July 2020 between 4.00 PM and 6:00 PM. The webinar was conducted with the objectives: (1) To understand the new



Guests and resource persons of the webinar

normal for pharmacists post-pandemic; (2) To assess the shortfalls of pandemic and preparations to overcome; (3) To motivate the practicing pharmacists to adopt the new normal.

More than 150 pharmacists participated in the webinar. Pharmacist provided an excellent feedback on this webinar and they expressed that the content delivered through this webinar were need based topics and benefited them.

### Webinar on "Catalysing Opportunities to Strengthen Pharmacovigilance During COVID-19 Pandemic

Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Mysuru conducted a webinar on the topic "Catalysing opportunities to strengthen pharmacovigilance during COVID 19 pandemic" on 7<sup>th</sup> August 2020 for the benefit of PharmD and M. Pharm 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 the COVID-19 pandemic and to promote & disseminate pharmacovigilance research among the students of health professions education programs.



During the webinar

### Webinar on Utilising COVID-19 Pandemic to Strengthen the Dialogue of Access to Essential Medicines and Vaccines

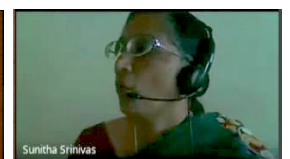
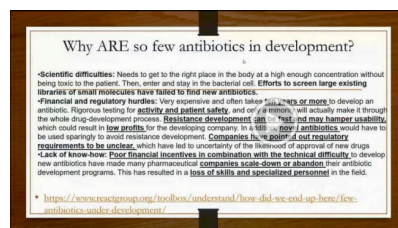


During the Webinar

Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Mysuru conducted a webinar on the topic 'Utilising COVID-19 Pandemic to Strengthen the Dialogue of Access to Essential Medicines and Vaccines' on 12<sup>th</sup> August 2020 for the benefit of PharmD and M. Pharm 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 of identifying the need for and the importance of access to essential medicines during this COVID-19 pandemic.

### Webinar on Managing the Double-Edged Sword: Antimicrobial Resistance and COVID

Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Mysuru conducted a webinar on the topic "Managing the Double-Edged Sword – Antimicrobial Resistance and COVID" on 19<sup>th</sup> August 2020 for the benefit of PharmD and M. Pharm 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 of enhancing the understanding on potential implications of some of the



Dr. Sunitha Srinivas during the webinar

current management practices and practicalities of managing the novel coronavirus outbreak in relation to antimicrobial resistance (AMR).



## Guest Lecture Series on Case Based Learning

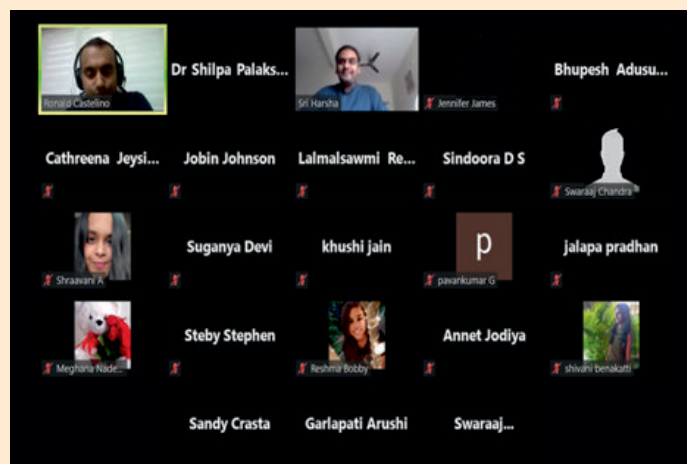
The Department of Pharmacy Practice organized a guest lecture series on case based learning during July 2020. **Dr. Ronald Castelino**, Senior Lecturer in Pharmacology & Clinical Pharmacy, Faculty of Medicine and Health, University of Sydney, Australia delivered the lectures. Case details and activity worksheets along with case questions were provided to the students a week in advance. Students were required to perform the activities and be prepared with answers to case questions before the discussion. The following four guest lectures (one per week) were planned and executed on a cloud-based video communication platform (zoom).

### Lecture on Chronic Kidney Disease held on July 9, 2020:

**Dr. Ronaldo** briefed students about the pharmacological management of chronic kidney disease and also tutored them on certain practical considerations that should be exercised while managing the chronic kidney injury patients. Also, the speaker interacted with participants discussing on pattern of management adopted at their hospital settings. Ms. Shilpa Palaksha facilitated the session. A total of 78 students of fifth & sixth year PharmD and II M. Pharm Pharmacy Practice students attended the guest lecture. Students were provided the opportunity to interact with speaker and ask questions related to chronic kidney disease and get their doubts clarified. As it was an interactive session, students actively participated in the discussion.

related to acute kidney disease, which the speaker answered. A total of 80 students of fifth & sixth year PharmD and II M. Pharm Pharmacy Practice students attended the guest lecture.

### Lecture on Cardiovascular Diseases held on July 23, 2020



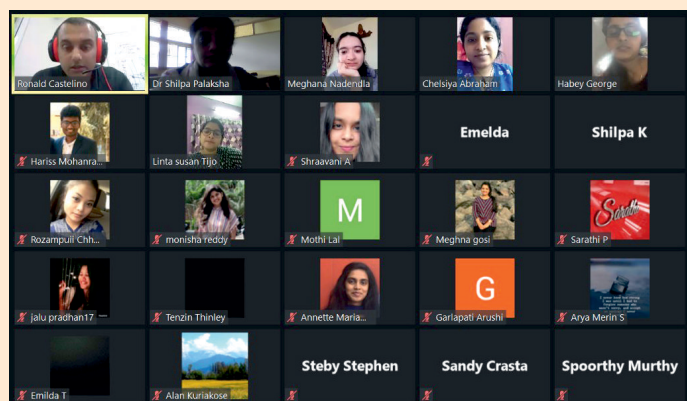
### During guest lecture

**Dr. Ronald**, during his talk, emphasized on the role of clinical pharmacist in the management of cardiovascular diseases and briefed the students on certain practical considerations that should be exercised while managing the patient. Dr. Harsha Chalasani interacted with the speaker and assisted in the discussion. A total of 75 students of fifth & sixth year PharmD and II M. Pharm Pharmacy Practice students attended the guest lecture. Students were provided the opportunity to ask questions related to cardiovascular disease management, which speaker answered enthusiastically. The participants expressed that the session was beneficial as it provided synergistic discussions and ensured active participation of them.

### Lecture on Diabetes Mellitus held on July 30, 2020

In this lecture, **Dr. Ronaldo** adopted the flipped class method for the discussion. To facilitate the discussion, the relevant information was provided to the students earlier. The speaker interacted with the students and allowed them to discuss the case given to them. He encouraged students to provide their views, along with which he added his expert comments. Students were very excited as they had an opportunity to discuss and learn. The session was facilitated by Dr. Siddarth. A total of 85 students of fifth & sixth year PharmD and II M. Pharm Pharmacy Practice students attended the guest lecture.

Overall, the series of case discussions were advantageous for students, especially during the Covid-19 lockdown period, as they were kept engaged and provided with ample opportunities to hone their acquired skills in a virtually provided practice environment.



### Participants of guest lecture

### Lecture on Acute Kidney Injury held on July 16, 2020

**Dr. Ronaldo**, in his talk, briefed about the pharmacological management of acute kidney disease. He then invited students to answer the case questions and discussed the appropriateness of therapy in the patient and the pros and cons of other treatment options. Specifically, he emphasized on dose calculations, adjustment of doses based on ideal body weight, and harmful consequences of errors in dosing. Mrs. Savitha R S who facilitated the session interacted with the speaker and discussed on the therapeutic approach at practice sites in Mysore. Students were provided the opportunity to ask questions

## Research Work Related to COVID -19

### *Impact of COVID-19 Pandemic on Psychological Responses of The General Population in India: A Nationwide Survey.*

Juny Sebastian, Amal Anand, Rithika Vakkalaganti Rajesh, Jisha Myalil Lucca, Royes Joseph.

**Background:** Any pandemic can influence the mental health of the general population, as it may restrict activities, change normal routine, affect social and economic wellbeing of them.

**Aims:** This study was aimed to assess the impact of COVID-19 pandemic on mental health of the general public in India

**Methodology:** A cross-sectional web-based study was conducted for a period of 20 days among general population of India. The study used PHQ-4 and IES-6 scales to measure depression/anxiety and distress respectively. Multiple binary logistic regression was used for exploring the relationship of the personal characteristics with the prevalence of psychiatric illness.

**Results:** The study enrolled a total of 1257 individuals with representation from 29 states of India with a mean (SD) age of 29.3 (9.7). Based on the combined PHQ-4 scale, 13.9% (n=174) had reported a moderate-severe level of anxiety or depression. Regarding distress, nearly three-quarters (n=942) had exhibited clinical concern for distress and more than a half (n=670) met the threshold for probable diagnosis of distress. The study found individuals who lived alone, lived in shared

accommodation, or who did not have chronic illness were reported a higher prevalence of anxiety or depression, and accommodation type was associated with the distress level in comparison with their counterparts.

**Conclusion:** Our findings may be used to assist various a healthcare professionals and Government advisors to strategize targeted interventions as required for fighting this pandemic in India and across the globe, as COVID-19 posing a higher risk for a possible pandemic psychological illness.

**For Further Reading:** Sebastian J, Anand A, Rithika VR, Lucca JM, Joseph R. Impact Of COVID-19 Pandemic On Psychological Responses Of The General Population In India: A Nationwide Survey. *International Journal of Pharmaceutical Research* 2020; 12 (Supple 1): 2349-2357. Available from <https://doi.org/10.31838/ijpr/2020.SP1.340>

*To facilitate the Spontaneous reporting of Adverse Drug Reactions (ADRs), an electronic reporting system was developed and integrated into the electronic Hospital Information System (HIS). All the healthcare professionals of JSS Hospital, Mysuru are requested to use this facility for reporting Suspected Adverse Drug Reactions (SADRs).*

### Accolades



**Dr. M. Ramesh**, Professor & Head, Dept. of Pharmacy Practice, JSS College of Pharmacy, JSSAHER, Mysuru was Nominated as **Member of Core Training Panel (CTP) AND Member of Signal Review Panel (SRP)** under Pharmacovigilance Program of India (PvPI), National Coordination Centre, Indian Pharmacopoeia Commission, Ghaziabad.

### The Drug & Poison Information Service

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