Editors’ Desk

“Hydroxychloroquine or Chloroquine With or Without a Macrolide for Treatment of COVID-19: A Multinational Registry Analysis” published in The Lancet and “Cardiovascular Disease, Drug Therapy, and Mortality in COVID-19” published in The New England Journal of Medicine have been recently retracted raising serious concern on data validity and quality of publication at face value. Based on The Lancet publication, World Health Organization, had taken out the antimalarial drug from the SOLIDARITY clinical trial. Of course following retraction the drug is brought back for clinical trial. While neither retraction nor the questionable data are new to the scientific community, the concerns created by these publications at the time of pandemic COVID – 19 is definitely confuse on what is to believe and what is not to.

In the midst of COVID – 19, it is now apparent that we need to live along with this invisible and little known corona virus as there is neither any medicine nor any vaccine. Our Prime Minister has given a call for “Self Reliant India”. Though we are not only self-reliant on finished pharmaceutical products but also meeting the need of many other countries, we still largely dependent on Active Pharmaceutical Ingredients in China. China has already started increasing the price by around 20% compared to pre-covid era posing a serious challenge. In an attempt to improve our API production in the country the Government has already announced Rupees 7000 crore scheme. This is a welcome move and is a strategy towards self-reliance and achieving medicine security.

We believe that after successfully editing this ‘Medicine Information Newsletter’ for more than five years leaving a legacy on our superannuation from regular service in the University. This has been possible because of your love, encouragement and support. Our colleagues would continue to publish, may be in better way, and we request your continuing patronage.

Happy Reading! Stay Safe and Healthy!

- Prabal Kumar Manna and Guru Prasad Mohanta
Dietary Guidelines for Pre-diabetics [The Purple Book, 2019]

**Foods to Eat**
- Whole grains, millets, pulses and legumes, sprouts.
- All fresh vegetables, salads and fruits.
- Egg, fish and chicken – lean pieces.
- Low fat milk and its products like paneer, curd.
- Soy and its products.

**Foods to Avoid**
- White rice, refined flours (breads, bakery items).
- Potato, sago, processed fruits and fruit juices.
- Red meat, organ meat, fried meat, processed, canned and frozen fishes, processed and frozen meat.
- Butter, cream, cheese, mayonnaise.
- Junk food, bakery products, fried foods, salted foods, packaged foods, roadside foods, foods containing artificial colours and sweeteners.

The National Institutional Ranking Framework (NIRF), Ministry of Human Resources, Government of India, ranks the institutions across the country based on parameters: “Teaching, Learning and Resources,” “Research and Professional Practices,” “Graduation Outcomes,” “Outreach and Inclusivity,” and “Perception.” Under NIRF 2020, the Department of Pharmacy of Annamalai University is ranked at 12th position in All India basis among the Pharmacy Institutions.

**NEWS**

**Generic Version of AstraZeneca’s Faryiga (dapagliflozin) launched:** The Natco Pharma has launched the generic version of the patented Faryiga, anti-diabetic drug, at two strength: 5 mg and 10 mg. Natco has named its product, Dapnat (branded generic), and is selling these products at Rs 15/- and Rs 19.50 respectively against the AstraZeneca's price of Rs 49/- and Rs 57/- for each tablet.

**USFDA authorised the emergency use of Remdesivir:** The USFDA has authorised the emergency use of Remdesivir for the treatment of hospitalised COVID – 19 patients in a life threatening situation. It is a direct acting antiviral drug that inhibits viral RNA synthesis. It is an investigational drug developed by Gilead Science, Inc. It is to be administered in an inpatient hospital setting via intravenous infusion.

**Plasma Therapy for COVID Patients:** The Government of India has approved the clinical trial of convalescent plasma therapy for COVID – 19 patients. As per protocol, the plasma is extracted from the whole blood donated by recovered individuals after 28 days of symptoms free period. The clinical trial is in progress in many states like Kerala, Delhi, and Maharashtra. USFDA has already approved this therapy.

**Several Companies signed agreement to make Remdesivir:** Several Indian companies: Zydus Cadila, Cipla, Jubilant Sciences and Hetero Labs, have signed agreements with Gilead Sciences, the patent holder of the experimental prospective Remdesivir to manufacture and sell in India. The drug is already approved in USA, India and South Korea for emergency use for severely ill COVID – 19 patients in hospital.

**Wearing Masks**

Wearing a mask and keeping a distance of two metres from others are the most effective ways of stopping the spread of COVID -19. Masks are not a replacement of physical distancing, hand hygiene and other public health measures.

- Everyone should wear a three layered fabric or non-medical mask in public to prevent the spread of COVID – 19.
- People of above 60 years or with other health problems should wear medical mask when social distancing is difficult. Others should wear three layered fabric mask.
- Cloth mask should have three layered fabric mask made of absorbent cotton closest to the face, followed by polypropylene layer and then a synthetic layer.
- Repeatedly taking it off and putting it on and use of contaminated hand to adjust the mask increase the risk of infection.
Websites of Interest

**National Centre of Excellence and Advanced Research on Diets (NCEARD):** The National Centre of Excellence and Advanced Research on Diets (NCEARD) established in 2018 within the Department of Food and Nutrition at Lady Irwin College, New Delhi. It is a technical assistance resource centre to the Ministry of Health and Family Welfare, Government of India, on research and policy formulation for women's nutrition. The centre is the designated lead for development and testing of guidelines on strengthening maternal nutrition services at antenatal care at facility and community level; guiding consensus driven policy needs on maternal nutrition; act as an apex laboratory for development and standardisation of local food products; design and conduct capsular training programmes; and undertake research and nutrition awareness activities. One can access the centre at: [http://www.nceardladyirwin.in/Home.aspx](http://www.nceardladyirwin.in/Home.aspx)

**International Society for Infectious Diseases (ISID):** ISID aims to support health professionals, non-government organizations, and governments around the world in their work to prevent, investigate, and manage infectious disease outbreaks when they occur. ISID has a particular focus in countries that have limited resources and which disproportionately bear the burden of infectious diseases. The Society is dedicated to developing partnerships and to finding solutions to the problems of infectious diseases across the globe and encourages the collaborative efforts of human health, veterinary health, and environmental health communities working locally, nationally, and globally for best control and management of infectious diseases. More details can be found at: [https://isid.org/about/](https://isid.org/about/)

**Medicines We Can Trust:** Launched in 2018, Medicines We Can Trust is a global movement to: raise awareness about the scope and impact of poor quality medicines; inspire collective action by illustrating effective solutions; showcase personal stories of those affected by and working to address poor quality medicines and provide a platform for advocates to access resources and mobilize policy changes. The website can be accessed at: [https://medswecantrust.org/](https://medswecantrust.org/)

**Did You Know?**

In a pandemic COVID – 19 with no specific medicines, several therapies are under investigation including convalescent plasma transfusion. The hypothesis behind the plasma therapy is the presence of virus specific antibodies in the donors' plasma that may help in clearance of virus and improvement of symptoms in the transfused patients. The credit of this principle goes to **German Doctor Emil von Behring, known as father of serum therapy**. He was the first Nobel Prize Awardee in Physiology and Medicine in 1901 for his work on serum therapy and especially on its use against diphtheria.

**Conferences**

**MyDispense Global Symposium:** MyDispense Symposium is conducted every alternate year by Monash University of Australia. The 2020 event is cancelled due to COVID – 19 pandemic and is now rescheduled to 4-7th July 2021. The event will be held at the Monash Prato Centre nestled in the heart of Tuscany in Italy. This provides an opportunity to be part of growing international community, committed to working together to improve pharmacy education. More details are available at: [https://info.mydispense.monash.edu/community/symposium/?ct=t(PES_email_November_1_20168_31_2016_COPY_04)](https://info.mydispense.monash.edu/community/symposium/?ct=t(PES_email_November_1_20168_31_2016_COPY_04)

**Monash Education Symposium 2022-Better Together:** The 11th Monash University Pharmacy Education Symposium scheduled to take place in July 2021 is now rescheduled to 10-13th July 2022. Better Together presents a unique opportunity to explore how enhanced coordination, collaboration and communication can lead to better pharmacy education and patient care. More details are available at: [https://www.monash.edu/pharm/about/events/education-symposium?ct=t(PES_email_November_1_20168_31_2016_COPY_04)](https://www.monash.edu/pharm/about/events/education-symposium?ct=t(PES_email_November_1_20168_31_2016_COPY_04)

**FIP Seville 2021:** 80th FIP World Congress of Pharmacy and Pharmaceutical Sciences is scheduled during 12-16th September 2021 at Seville, Spain. More details are available at: [https://seville2021.fip.org/](https://seville2021.fip.org/)

**Important Health Days**

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<tr>
<th>Month</th>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>July</td>
<td>1</td>
<td>Doctors Day (In India)</td>
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<td>11</td>
<td>World Population Day</td>
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<td>29</td>
<td>ORS Day</td>
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<td>August</td>
<td>1-7</td>
<td>World Breast Feeding Week</td>
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<td>25th Aug – 8th Sept.</td>
<td>Eye Donation Fortnight</td>
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<td>September</td>
<td>1-7</td>
<td>National Nutrition week</td>
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<td>4-11</td>
<td>World Pharmacy Week</td>
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<td>12</td>
<td>World Oral Health Day</td>
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<td>21</td>
<td>World Alzheimer’s Day</td>
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<td>25</td>
<td>World Pharmacists Day</td>
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<td></td>
<td>26</td>
<td>World Day of the Deaf</td>
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<tr>
<td></td>
<td>28</td>
<td>World Heart Day I World Rabies Day</td>
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Alerts

**Box Warning for Montelukast:** Montelukast, a leukotriene receptor antagonist, is used for the prophylaxis and chronic treatment of asthma. USFDA has recently recommended for updated labelling for Montelukast to include a box warning related to serious neuropsychiatric events. The doctors are advised to discuss with patients / care givers the benefit and risk of the treatment. The drug should be immediately discontinued if the patient develop neuropsychiatric symptoms appear.

**Fluoroquinolone with risk of aortic aneurysm:** The TGA, Australian Drugs Regulatory Authority, has announced the inclusion of risk of aortic aneurysm and dissection in product information of fluoroquinolone antibiotics.

**Lorcaserin with risk of cancer:** The USFDA has requested the manufacturers to voluntarily withdraw lorcaserin, a weight reducing agent, from US market due to an increased risk of cancer.

**Ulipristal acetate with risk of hepatic injury:** The European Medicine Agency has recommended to stop use of Ulipristal acetate for the treatment of uterine fibroids. While the review on risk of liver injury in progress, it is advised not to start treatment with this drug in new patients.

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**Update on COVID - 19**


- **Signs and Symptoms:**
  - Fever
  - Cough
  - Fatigue
  - Shortness of Breath
  - Expectoration
  - Myalgia
  - Rhinorrhea, Sore Throat and Diarrhoea
  - Loss of smell (anosmia) or loss of taste (ageusia)

- **Hydroxychloroquine** – should be used as early in the disease course as possible to achieve any meaningful effects and should be avoided in patients with severe disease. An ECG should ideally be done before prescribing the drug to measure QTc interval (and HCQ avoided if QTc is >500 ms). Dose: 400 mg BD on day 1 followed by 400mg daily for next 4 days.

- The use of azithromycin in combination with Hydroxychloroquine is discontinued.

- **Remdesivir** – is recommended in patients with moderate stage of COVID – 19 requiring oxygen support. It is not recommended for those with severe renal impairment and high level of liver enzymes, pregnant and lactating women and those below 12 years. Dose: 200 mg on day one followed by 100 mg daily for five days.

- **Convalescent Plasma Therapy** (Off Label Use) – it may be considered for patients with moderate illness with no improvement in conditions despite the use of steroids. Dose is variable ranging from 4 to 13 ml/kg (usually 200 ml single dose given slowly over not less than 2 hours.

- **Tocilizumab** (Off Label Use) – may be considered in patients with moderate illness with progressively increasing in oxygen requirement and in mechanically ventilated patients not improving despite the use of steroids. Patients should be carefully monitored. Dose: 8mg/kg (maximum 800 mg at one time) given slowly in 100 ml NS over 1 hour; dose can be repeated once after 12 to 24 hours if needed.

- **New Diagnostic Kit:** The new kit, Standard Q COVID – 19 Ag, is a rapid low cost and reliable antigen based tool. The testing kit will allow infected patients to be diagnosed within 30 minutes at a cost of around 500 rupees.
Resources

**Australia's Therapeutic Guidelines (TG):** The Therapeutic Guidelines Limited (TGL) is an Australian not-for-profit organisation that exists to support the work of healthcare practitioners. However, at this time of unprecedented crisis caused by COVID-19, TGL would like to ensure everyone who needs it can access eTG complete. Complimentary access is now available for those that do not have a current subscription, and includes use of eTG complete online and the eTG complete app (for Apple and Android devices). A free subscription will be available until 31-July-2020. Details regarding complimentary access to eTG are available from https://www.tg.org.au/complimentary-access/

**Improving early childhood development (WHO guideline):** Enabling young children to achieve their full developmental potential is a human right and an essential requisite for sustainable development. Given the critical importance of enabling children to make the best start in life, the health sector, among other sectors, has an important role and responsibility to support nurturing care for early childhood development. The WHO has developed the guideline which provides direction for strengthening policies and programmes to better address early childhood development. The resource can be accessed and downloaded from: https://www.who.int/publications-detail/improving-early-childhood-development-who-guideline

**Global Guide to Patent Linkage:** The patent linkage is a complex issue as it merges the protection of Intellectual Property (IP) governed by IP laws with the remit of drug regulators and varies from country to country. The global guide to patent linkage is a comprehensive resource that explores which legal regimes adopt patent linkage doctrines and what enforcement options are open to drug patent rights holders to protect their assets. The guide can be accessed at: https://f.datasrvr.com/fr1/019/56376/Global_Guide_to_Patent_Linkage_Handbook_21_November_2019.pdf

**Fair Pricing Series of Articles:** The World Health Organization has published a series that was proposed by the WHO and commissioned by The BMJ on the issue of Achieving Fair Pricing. The link to each of the articles can be found at: https://www.bmj.com/fair-pricing

**Purple Book on Diets for Diseases:** It is a handbook on diets for diseases for general dietary recommendations and advice on diets for diseases. This is developed by Food Safety and Standards Authority of India and is intended for hospitals, clinics and medical treatment centres that do not have access to professional dieticians and nutritionists. The handbook can be downloaded from: https://fssai.gov.in/book-details.php?bkid=343

**Guide for clinical care management and infection prevention and control during a measles outbreak:** The World Health Organization has developed this guideline to reduce the high morbidity and mortality seen in some of the current outbreaks of measles. The guide is intended for front line clinicians and healthcare workers who care for clinically suspected or confirmed measles in any healthcare setting. This can be freely downloaded from: https://apps.who.int/iris/bitstream/handle/10665/331599/9789240002869-eng.pdf?ua=1

**New WHO Guide to help countries expand access to essential medicines:** A careful selection of essential medicines is the first step in ensuring a population can obtain the quality-assured medicines it needs at an affordable price. Countries need to do more to ensure that all people and communities can access highly effective medicines. WHO's new manual is a resource to do just that. This can be freely downloaded from: https://www.who.int/publications-detail/selection-of-essential-medicines-at-country-level

**WHO guideline on clinical management of COVID -19:** This guidance document is intended for clinicians caring for COVID-19 patients during all phases of their disease (i.e. screening to discharge). This update has been expanded to meet the needs of front-line clinicians and promotes a multi-disciplinary approach to care for patients with COVID-19, including those with mild, moderate, severe, and critical disease. The updated publication can be obtained from: https://www.who.int/publications-detail/clinical-management-of-covid-19
Inspiring Change - Creating impact with evidence based implementation: The Centre for Implementation offers a free mini course providing a high level overview on how to create impact with evidence based implementation. The mini course intends to help understanding what evidence based implementation is to simple tips and tricks which can be used for success. The details are available at: https://thecenterforimplementation.com/courses

OpenWHO: This is the WHO’s new, interactive, web-based platform that offers online courses to provide information on various topics to people preparing to work in epidemics, pandemics and health emergencies or current frontline responders and decision-makers. The OpenWHO platform delivers WHO’s and partners’ expertise closer to where it is needed and provides information in user-friendly formats for frontline responders and decision-makers. More details can be accessed at: https://openwho.org/

E – Learning Course in Pharmacovigilance: Uppsala Monitoring Centre has developed free online e-learning courses covering different aspects of science of medicine safety to meet the global need for training in Pharmacovigilance. More details are available at: https://courses.who-umc.org/

Courses

### Webinars

Following Webinars conducted by Department of Pharmacy

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<tr>
<th>S.No.</th>
<th>International Webinar Title</th>
<th>Resource Person</th>
<th>Youtube Link</th>
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<tbody>
<tr>
<td>1.</td>
<td>Combating COVID 19: Where are we now?</td>
<td>Dr. Sirajudeen, M. Pharm, PhD&lt;br&gt;Department of Clinical Pharmacy, King Khalid University, Abha, KSA</td>
<td>t.ly/rwVw</td>
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<td>2.</td>
<td>Drug Product Development: USFDA Regulatory Approach</td>
<td>Dr. Bhaskara Rao Rayini, PhD&lt;br&gt;Research Fellow, Perrigo, USA</td>
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<td>3.</td>
<td>Pharmacy Evaluation in Post Covid Era</td>
<td>Dr. Noohu Abdulla Khan&lt;br&gt;Department of Clinical Pharmacy, King Khalid University, Abha, KSA</td>
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<td>4.</td>
<td>Qualitative Research Methods: Insights in to Medication Taking Behaviour among Type-II Diabetes Patients</td>
<td>Dr. Akram Ahmad&lt;br&gt;Research Scholar, School of Pharmacy, University of Sydney, New South Wales, Australia</td>
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<td>5.</td>
<td>Team Based Learning in Pharmaceutical Education: Possible Approaches</td>
<td>Dr. Vetriselvan Subramaniam&lt;br&gt;Associate Professor of Pharmacology&lt;br&gt;Faculty of Medicine, MAHSA University, Malaysia</td>
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<td>6.</td>
<td>Secret of Achieving Success in Pharma Career</td>
<td>Dr. Venkat R. Kota, Ph.D.&lt;br&gt;COO, Lupin Pharma, USA</td>
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<td>7.</td>
<td>Validating Ayurvedism with the Current Therapeutic Concepts for the Management of Movement and Mental Disorders</td>
<td>Dr. Muralikrishnan Dhanasekaran&lt;br&gt;Professor, Harrison School of Pharmacy&lt;br&gt;Auburn University, USA</td>
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<td>8.</td>
<td>Innovation in Transdermal Drug Delivery - Key Considerations</td>
<td>Dr. Haranath Kumar Vaddi&lt;br&gt;CATALENT Pharma Solutions, USA</td>
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(L to R): **Dr. S. Madhusudhan**, Associate Professor & **Dr. V. P. Maheshkumar**, Assistant Professor, had participated and presented papers in the Oral Session of First ISIUM Conference held at Bangkok, Thailand, during January 26–28, 2020. The theme of the Conference was “People Improving the Use of Medicines: What we know and don't know”.

**DISCLAIMER:**

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the University shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.