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CLINICAL PHARMACY NEWSLETTER

A Newsletter of Drug and Prescribing Information

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INSIDE THIS ISSUE

Vaccine Mismatch: What to Do After Dose 1 When Plans Change

Ideally, American COVID -19 patients receiving their Pfizer/BioNTech or Moderna COVID-19 vaccines both doses from the same manufacturer. They were tested for efficacy and safety, and it was results from those studies that led to emergency use authorization (EUA) being granted by the US Food and Drug Administration. But states and countries have struggled to keep up with the demand for vaccine, and more flexible vaccination schedules could help. Hence, researchers are exploring whether it is safe and effective to get the first and second doses from different manufacturers. And they are even wondering whether mixing doses from different manufacturers could increase effectiveness, particularly in light of emerging variants.

It's called the "interchangeability issue," for example, a patient recently asked about options for his father, who had gotten his first dose of the AstraZeneca vaccine in Ecuador, but had since moved to the United States, where that product has not been approved for use. Dr Gregory Poland, Vaccinologist from Mayo Clinic said to Medscape Medical News that he prefaces each answer with, "I've got no science for what I'm about to tell you." In this particular case, he recommended that the man's father talk with his doctor about his level of COVID-19 risk and consider whether he should gamble on the AstraZeneca vaccine getting approved in the United States soon, or whether he should ask for a second dose from one of the three vaccines currently approved.

AstraZeneca released positive results from its phase 3 trial, which will likely speed its path toward use in the United States. Although clinical trials have started to test combinations and boosters, there's currently no definitive evidence from human trials on mixing COVID vaccines. But a study of a mixed-vaccine regimen is currently underway in the United Kingdom. Participants in that 13-month trial will be given the Oxford/AstraZeneca and Pfizer/BioNTech vaccines in different combinations and at different intervals. The first results from that trial are expected this summer. And interim results from a trial combining Russia's Sputnik V and the AstraZeneca vaccines are expected in 2 months, according to a Reuters report.

Mix Only in "Exceptional Situations"

The Centers for Disease Control and Prevention (CDC) has been hesitant to open the door to mixing Pfizer and Moderna vaccinations, noting that the two "are not interchangeable." But CDC guidance has changed slightly. Now, instead of saying the two vaccines should not be mixed, CDC guidance says they can be mixed in "exceptional situations," and that the second dose can be administered up to 6 weeks after the first dose.

Further, Dr Poland expressed that although human trials have not proven; it is reasonable to assume that mixing COVID-19 vaccines that use the same platform such as the mRNA platform used by both the Pfizer and Moderna vaccines will be acceptable. However, it is unclear whether vaccines that use different platforms can be mixed. Can the first dose of an mRNA vaccine be followed by an adenovirus-based vaccine, like the Johnson & Johnson product or Novavax, if that vaccine is granted EUA?

Researcher Says Science Backs Mixing

Ross Kedl, a vaccine researcher and Professor of Immunology at the University of Colorado in Aurora, says that using the same vaccine platforms for both doses might not be the preferred strategy. He disagrees that there's a lack of science surrounding the issue, and says all signs point to mixing as not only a good option, but probably a better one. A mix of two different vaccine platforms likely enhances immunity. The heterologous prime-boost strategy has been used in animal studies for decades, and it is well known that this promotes a much better immune response than when immunizing with the same vaccine twice.

Each vaccine has a number of components in it that influence immunity in various ways, but between the two of them, they only have one component that is similar. In the case of the coronavirus vaccines, the one thing both have in common is the spike protein from SARS-CoV-2. In essence, this gives you two shots at generating immunity against the one thing in each vaccine you care most about, but only one shot for the other vaccine components in each platform, resulting in an amplified response against the common target.

In fact, the heterologous prime-boost vaccination strategy has proven to be effective in humans in early studies. For example, an Ebola regimen that consisted of an adenovirus vector, similar to the AstraZeneca COVID vaccine, and a modified vaccinia virus vector showed promise in a phase 1 study. And an HIV regimen that consisted of the combination of a DNA vaccine, similar to the Pfizer and Moderna mRNA vaccines, and another viral vector showed encouraging results in a proof-of-concept study. In both these cases, the heterologous prime-boost strategy was far better than single-vaccine prime-boost regimens and neither study reported any safety issues with the combinations. For now, it's best to stick with the same manufacturer for both shots, as the CDC guidance suggests, and more evidences are required to mix vaccines.

Reference:
https://www.medscape.com/viewarticle/948131

Aflibercept Won't Help Vision in Early Diabetic Retinopathy

Intravitreal injections with Aflibercept (Eylea) don't improve the visual acuity of people with non-proliferative diabetic retinopathy (NPDR). The treatments do reduce the risk for center-involved diabetic macular edema and proliferative diabetic retinopathy, however, some clinicians may decide to initiate preventative Eylea treatment for eyes with severe NPDR based on the reduction in anatomic complications, but some clinicians may choose to wait until disease worsens before initiating anti-VEGF [vascular endothelial growth factor] treatment.

The DRCR Retina Network Protocol W trial was published online in JAMA Ophthalmology, discussed that large randomized clinical trials showed that treatments with anti-VEGF intravitreal injections are effective in protecting and restoring vision for patients with diabetic macular edema and proliferative diabetic retinopathy. But it was uncertain whether these treatments would benefit patients in whose diabetic retinopathy had not led to such complications.

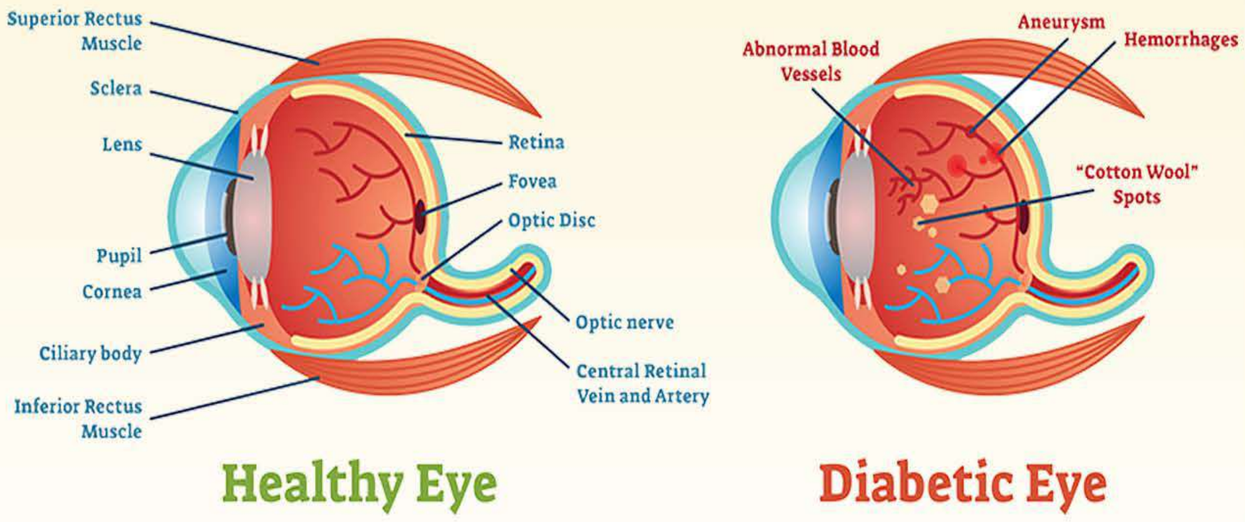
To address these issues, the study recruited adults with diabetes and moderate to severe NPDR. They randomly assigned 200 of them to receive intravitreal Aflibercept 2 mg and 199 to receive sham injections at baseline and at 1, 2, and 4 months, and then every 4 months for 2 years. The patients in both groups also received Aflibercept injections if they developed center-involved diabetic macular edema with vision loss or high-risk proliferative diabetic retinopathy. After 2 years, the mean number of Aflibercept injections in the Aflibercept group was 8.0; 7.7 of those were given for prevention alone. In the sham group, the mean number of Aflibercept injections was 1.1, and the mean number of sham injections was 7.4. After 2 years, significantly more patients in the sham group than in the Aflibercept group developed sight-threatening complications. The difference in the change in visual acuity was not significant between the two groups.

There were three cases of endophthalmitis in the Aflibercept group and none in the sham group. There was no difference between the groups in cardiovascular or cerebrovascular adverse events. On the basis of these results, doctors said that no need to administer anti-VEGF treatments as prophylaxis for NPDR patients. The burden of frequent intravitreal injections outweighs the benefit of preventing complications that could change if longer-term treatments, such as drug-eluting implants or gene therapy, become available. For now, the investigators closely monitors their patients with NPDR for complications, and published in Medscape Medical News that "If patients develop a complication, treat them early with anti-VEGF, and will not lose any sort of visual acuity benefit by waiting to treat them."

Protocol W is continuing for 2 more years, and it is possible that a difference in visual acuity will emerge between the two groups over that time because it can take that long for diabetic macular edema and proliferative diabetic retinopathy to affect vision. However, don’t expect that to happen because the design of the trial calls for the treatment of complications, and it appears possible to restore visual acuity once complications develop. The treatment is reassuring, and it really gives providers a lot of options to kind of tailor treatment depending on the patient.

The findings of Protocol W confirm those of the PANORAMA trial, which had a similar design but was sponsored by Regeneron, the maker of Eylea. While completing the 4-year results of Protocol W, the DRCR Retina Network is also studying the cholesterol-lowering drug Fenofibrate to see whether it can slow the progression of diabetic retinopathy.

OUTCOME	Aflibercept group	Sham group	P Value
Center-involved diabetic macular, % edema	4.1	14.8	.002
Proliferative diabetic retinopathy, %	13.5	33.5	.001
One or both of these complications, %	16.3	13.5	.001
Mean change in visual acuity, ETDRS letters	- .09	- 2.0	.47



Reference:
JAMA Ophthalmol. 2021 ; 139 (7) : 701 - 712. doi:10.1001/ jamaophthalmol . 2021. 0606

DRUG PROFILE

IBREXAFUNGERP

Class:
Triterpenoid antifungal

Indication:
Ibrexafungerp is indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC)

Mechanism of Action:
Ibrexafungerp is a triterpenoid antifungal agent which inhibits glucan synthase, an enzyme involved in the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall.

Anti-microbial activity:
Ibrexafungerp has been shown to be active against most isolates of the following microorganism
both in-vitro and clinical infections (Candida albicans, Candida auris, Candida dubliniensis, Candida glabrata, Candida guilliermondii, Candida keyfr, Candida krusei, Candida lusitaniae, Candida parapsilosis, Candida tropicalis).

Dosage form and Administration:
Ibrexafungerp is available in the form of 150 mg tablets which are purple, oval, biconvex shaped tablets debossed with 150 on one side and SCYX on the other side. Tablets are packaged in polyvinyl/polyvinylidene chloride child-resistant blister packs, four tablets per pack. Tablets can be stored at room temperature (20°C to 25°C).

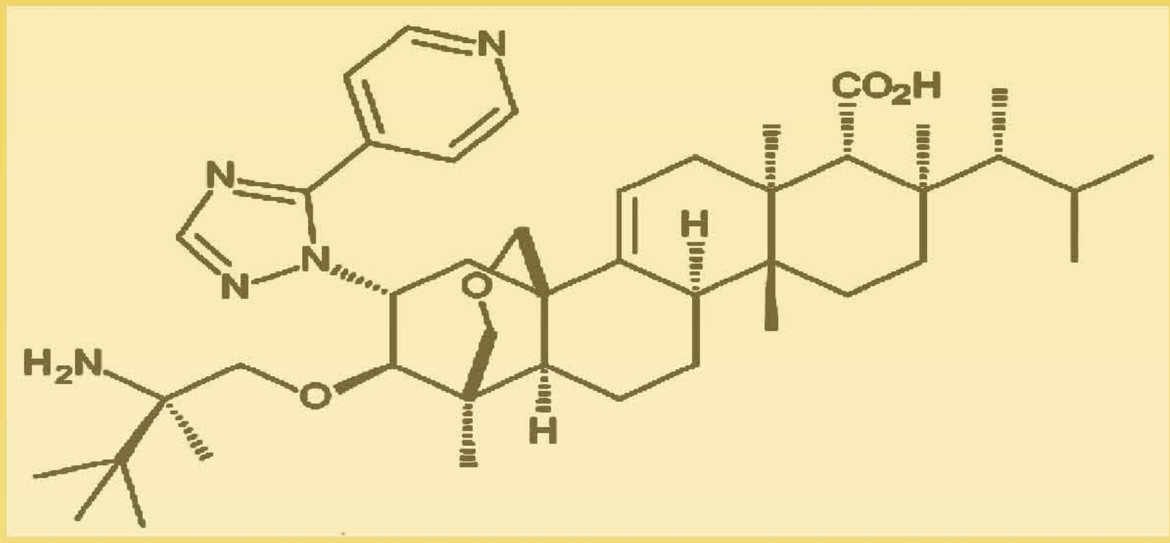
The recommended dosage of Ibrexafungerp in adult and post-menarchal pediatric females is 300 mg (two tablets of 150 mg) twice a day for one day, for a total treatment dosage of 600 mg. Tablets can be taken with or without food.

Dosing in Renal & Hepatic Impairment:
Information about dosage adjustment in hepatic and renal impaired patients is not available for Ibrexafungerp.

Pharmacokinetics:
After oral administration in healthy volunteers, Ibrexafungerp reaches maximum plasma concentrations 4 to 6 hours after single and multiple dosing. Ibrexafungerp area under the curve (AUC) and maximal concentration (Cmax) increased approximately dose-proportionally following single dose administration from 10 to 1600 mg (0.02 to 2.67 times the approved recommended daily dose) and multiple-dose administration from 300-800 mg (0.50 to 1.33 times the approved recommended daily dose).

Effect of Food:
Ibrexafungerp Cmax increased 32% and the AUC increased 38% with a high fat meal (800-1000 calories; 50% fat), compared to fasted conditions. This exposure change is not considered clinically significant.

The mean steady state volume of distribution (Vss) of Ibrexafungerp is approximately 600 L. Ibrexafungerp is highly protein bound (greater than 99%), predominantly to albumin. Drug is eliminated mainly via metabolism and biliary excretion. The elimination half-life is approximately 20 hours. studies show that Ibrexafungerp undergoes hydroxylation by CYP3A4, followed by glucuronidation and sulfation of a hydroxylated inactive metabolite. Following oral administration of radio-labeled Ibrexafungerp to healthy volunteers, a mean of 90% of the radioactive dose (51% as unchanged form) was recovered in feces and 1% was recovered in urine.



Adverse Reactions:
The most frequent adverse reactions (≥ 2%) reported with Ibrexafugerp treatment were diarrhea (16.7%), nausea (11.9%), abdominal pain (11.4%), dizziness (3.3%), and vomiting (2.0%).
The following adverse reactions occurred in < 2% of patients receiving Ibrexafungerp treatment: dysmenorrhoea, flatulence, back pain, elevated transaminases, vaginal bleeding and hypersensitivity reaction.

Contraindications:

Pregnancy: No adequate clinical data on exposed pregnancies are available for Ibrexafungerp. In animal reproduction studies, Ibrexafungerp administered orally to pregnant rabbits during organogenesis was associated with fetal malformations including absent forelimb(s), absent hindpaw, absent ear pinna, and thoracogastroschisis at dose exposures greater or equal to approximately 5 times the human exposure at the recommended human dose (RHD). Patients with severe hypersensitivity to Ibrexafungerp or to any of its excipients.

Precautions:

Ibrexafungerp is contraindicated in pregnancy. Hence, it is advised to do a pregnancy test before administering the drug.

The safety and effectiveness of Ibrexafungerp have not been established in pre-menarchal pediatric females.
Drug Interactions:

Ibrexafungerp is an inhibitor of CYP3A4, P-gp and OATP1B3 transporter. However, given the short treatment duration for VVC, the effect of Ibrexafungerp on the pharmacokinetics of substrates of CYP3A4, P-gp and OATP1B3 transporters is not considered to be clinically significant.

Concomitant use of strong CYP3A inhibitors: (Eg: Ketoconazole, Itraconazole) increases the plasma concentrations of Ibrexafungerp significantly. Hence, dosage reduction of Ibrexafungerp is suggested.

Concomitant administration of strong and moderate CYP3A inducers: (Eg: Rifampin, Carbamazepine, Phenytoin, St. John's wort, Long acting barbiturates, Bosentan, Efavirenz, Etravirine) may increase the plasma concentration of Ibrexafungerp. Hence, it is suggested to avoid concomitant administration of these drugs.

Reference:
Highlights of Prescribing information, from USFDA Website: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214900s000lbl.pdf

Scynexis website: https://www.scynexis.com/pipeline

Delta-Plus Variant: New COVID-19 variant of interest

All viruses, including SARS-CoV-2, the virus that causes COVID-19, change over time. Most changes have little to no impact on the virus' properties. However, some changes may affect the virus's properties, such as how easily it spreads, the associated disease severity, or the performance of vaccines, therapeutic medicines, diagnostic tools, or other public health and social measures.

World health organization, in collaboration with partners, expert networks, national authorities, institutions and researchers have been monitoring and assessing the evolution of SARS-CoV-2 since January 2020. During late 2020, the emergence of variants that posed an increased risk to global public health prompted the characterisation of specific Variants of Interest (VOIs) and Variants of Concern (VOCs), in order to prioritise global monitoring and research, and ultimately to inform the ongoing response to the COVID-19 pandemic.

WHO and its international networks of experts are monitoring changes to the virus so that if significant amino acid substitutions are identified, we can inform countries and the public about any changes that may be needed to respond to the variant, and prevent its spread. Globally, systems have been established and are being strengthened to detect "signals" of potential VOIs or VOCs and assess these based on the risk posed to global public health. National authorities may choose to designate other variants of local interest/concern.

Reducing transmission through established and proven disease control methods measures, as well as avoiding introductions into animal populations, are crucial aspects of the global strategy to reduce the occurrence of mutations that have negative public health implications.

Variants of Interest & Variants of Concern:
A SARS-CoV-2 variant that meets the definition of a VOI (see below) and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance:

Increase in transmissibility or detrimental change in COVID-19 epidemiology; OR Increase in virulence or change in clinical disease presentation; OR Decrease in effectiveness of public health and social measures or available diagnostics, vaccines, therapeutics.

Delta plus variant:
A novel SARS-CoV-2 variant, the delta plus variant, has been identified in over 10 countries. Researchers recently identified another variant, the delta plus variant also known as B.1.617.2.1 or AY.1. The delta plus variant is a sub lineage of the delta variant, with the only known difference being an additional mutation, K417N, in the virus' spike protein, the protein that allows it to infect healthy cells. The delta variant, also known as the B.1.617.2 lineage was first identified in India in December 2020 and quickly became the most common variant in the country. Health authorities are raising concerns that the delta-plus variant may have an increased ability to transmit, but they also note that this variant's transmissibility is likely similar to that of the pre-existing delta variant.

Furthermore, since India has labelled this variant a "variant of concern," the country's SARS-CoV-2 Consortium on Genomics (INSACOG), which is made up of 28 laboratories dedicated to whole genome sequencing of the SARS-CoV-2 virus and its evolving variants, continues to follow the evolution of delta plus. Also, INSACOG is currently studying the potential transmissibility/severity of the new variant.

Reference:
Tracking SARS-CoV-2 variants; World Health Organization. Available from: https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/
Delta plus variant of SARS-CoV-2: How does it compare with the delta variant? (Medical news today- Online) Available from: https://www.medicalnewstoday.com/articles/delta-plus-variant-of-sars-cov-2-how-does-it-compare-with-the-delta-variant
Delta Plus: Key things to know about new coronavirus variant. (The Economic Times-Online) Available from: https://economictimes.indiatimes.com/news/et-explains/delta-plus-key-things-to-know-about-new-coronavirus-variant-in-india/articleshow/83739996.cms?from=mdr

EVENT CORNER

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in 'National Webinar on Relevance of the shelf-life extension program' organized by Society of Pharmaceutical Sciences and Research on 4th April 2021.

Dr Aneena Suresh, Lecturer, Department of Pharmacy Practice participated in the First International e-conference on "Changing Waves in Healthcare Research: Focus on post-covid era" organized by National School of Pharmaceutical Technology, Adamas University, Kolkata on 5th & 6th April 2021.

Dr S Ponnusankar, Dr K P Arun, Dr. M Deepalakshmi, Dr Roopa B S, Dr. Sadgoban G K, Dr. Swathi Swaroopa B, Dr C Keerthana, Dr Aneena Suresh, Mr. Vishwas H N, Dr J Jeyaram Bharathi, Faculty, Department of Pharmacy Practice participated in the webinar 'Faculty Orientation Program on Scival and Funding Institutional, components of ELSEVIER' organized by Internal quality assurance cell, JSS Academy of Higher Education & Research, Mysuru on 8th April 2021.

Dr Roopa B S, Lecturer, Department of Pharmacy Practice participated in the national level webinar on 'The value of Cochrane Library' organized by National Research Marketing, Wiley Asia-Pacific on 14th April 2021.

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in webinar on 'Navigating your journey from research to patent & how patent and publication differ?' organized by Society of Pharmaceutical Sciences and Research on 18th April 2021.

Dr S Ponnusankar, Dr J Jeyaram Bharathi, Faculty, Department of Pharmacy Practice, participated inWebinar on 'Quality Management Systems' organized by Depatment of Health Systems Management Studies, JSS Academy of Higher Education & Research, Mysuru on 15th May 2021.

Dr M.Deepalakshmi, Lecturer, Department of Pharmacy Practice participated in Short Term Training Programme (STTP) "Approaches to teaching and self-efficacy beliefs" organized by Columbia Institute of Pharmacy, Near Vidhan Sabha, Raipur, with All India Council for Technical Education (AICTE), New Delhi, between 17th – 22nd May 2021.

Dr S Ponnusankar, Dr C Keerthana, Dr Aneena Suresh, Mr Vishwas H N, Faculty, Department of Pharmacy Practice, participated in the webinar on 'COVID 19 vaccination and Home isolation: Tips and tricks' organized by Department of Public Health Dentistry, JSS Dental College and Hospital, JSS Academy of Higher Education & Research, Mysuru on 18th May 2021.

EVENT CORNER

Dr Swathi Swaroopa B, Lecturer, Department of Pharmacy Practice participated in the webinar 'New Approaches in Teaching and Learning Pharmacy Calculations' organized by American Association of colleges of Pharmacy (AACP) on 20th May 2021.

Dr Aneena Suresh, Lecturer, Department of Pharmacy Practice, participated in international webinar "Overview of Community Pharmacy practice in the U.S." organized by Association of Community Pharmacists of India, in association with National Community Pharmacists Association, USA on 20th May 2021.

Dr Keerthana C, Dr Aneena Suresh, Faculty, Department of Pharmacy practice participated in 'Short Term Course on Scientific Writing & Communication' organized by National School of Pharmaceutical Sciences, Human Resource Development Center (HRDC), Lovely Professional University and Society of Pharmaceutical Education & Research (SPER) between 25th May – 1st June 2021.

Dr Aneena Suresh, Lecturer, Department of Pharmacy Practice participated in the sebinar on "From Vivarium to virtual room" organized by JSS College of Pharmacy, Mysuru on 28th May 2021.

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in the webinar on 'Professional excellence: an excel series' organized by JSS Dental College & Hospital, JSS Academy of Higher Education & Research, Mysuru on 27th -29th May 2021.

Dr Keerthana C, Clinical Resident, Department of Pharmacy Practice participated in webinar 'World No Tobacco Day Awareness Programme' organized by National Service Scheme Unit of Government College of Pharmacy, Bengaluru on 31st May 2021.

Dr Aneena Suresh, Lecturer, Department of Pharmacy Practice participated in webinar 'Vigyan se Vikash - Pradyogiki se Pragati' organized by Bio-NEST NIPER-Guwahati on 31st May 2021.

Dr M Deepalakshmi, Lecturer, Department of Pharmacy Practice acted as a Reviewer for two papers from Journal of Pharmacy Practice and Brazilian Journal of Pharmaceutical Sciences. (May 2021)

Dr Swathi Swaroopa B, Lecturer, Department of Pharmacy Practice acted as a Reviewer for one paper from Journal of Applied Pharmaceutical Science. (May 2021)

Dr Aneena Suresh, Lecturer, Department of Pharmacy Practice acted as a Reviewer for two papers from BMJ Open Journal and Cardiology and Angiology –An International Journal. (May 2021)

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in international webinar 'Appropriate management in the choice of medicine for self-care' organized by International Pharmaceutical Federation, The Netherlands on 2nd June 2021.

Dr S Ponnusankar, Dr C Keerthana, Dr J Jeyaram Bharathi, Faculty, Department of Pharmacy Practice participated in national level webinar 'Can artificial intelligence revolutionize Drug discovery?' organized by JSS College of Pharmacy, Mysuru on 3rd June 2021.

Dr K P Arun, Dr M Deepalakshmi, Dr Roopa B S, Dr Sadagoban G K, Dr Swathi Swaroopa B, Dr C Keerthana, Dr Aneena Suresh, Mr Vishwas H N, Dr J Jeyaram Bharathi, Faculty, Department of Pharmacy Practice participated in 'Three-day Leadership Webinar Series' organized by Internal Quality Assurance Cell, JSS Academy of Higher Education & Research Mysuru on 03rd - 05th June 2021.

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in webinar on 'Current international practices to conduct dental clinical trials' organized by JSS Dental College & Hospital, Mysuru on 5th June 2021.

Dr M Deepalakshmi, Lecturer, Department of Pharmacy Practice participated in webinar 'Pharmacist and NABH Accreditation of Hospitals Chapter 3. Management of Medication (MoM)' organized by Geetanjali Institute of Pharmacy, Geetanjali University, Udaipur, Rajasthan on 5th June, 2021.

Dr S Ponnusankar, Dr C Keerthana, Faculty, Department of Pharmacy Practice participated in webinar on 'Comprehensive management of mucormycosis and beyond – management of post COVID patients in dentistry' organized by JSS Dental College & Hospital, Mysuru on 10th June 2021.

Dr S Ponnusankar, Dr Sadagoban G K, Dr Swathi Swaroopa B, Dr C Keerthana, Dr Aneena Suresh, Dr J Jeyaram Bharathi, Faculty, Department of Pharmacy Practice participated in webinar on 'Beyond the Mind: Science and Spirituality' organized by JSS Dental College & Hospital, Mysuru on 11th June 2021.

Dr K P Arun, Dr M Deepalakshmi, Dr Sadabogan GK, Dr Swathi Swaroopa B, Dr C Keerthana, Dr Aneena Suresh, Faculty, Department of Pharmacy Practice participated in webinar 'SAMBAV-Health Professionals as mental health Facilitators' organized by JSS Medical College, Mysuru on 11th & 12th June 2021.

Ds S Ponnusankar, Dr M Deepalakshmi, Dr Sadagoban GK, Dr Swathi Swaroopa B, Dr C Keerthana, Dr Aneena Suresh, Mr Vishwas H N, Dr J Jeyaram Bharathi, Faculty, Department of Pharmacy Practice participated in webinar on 'Challenges and opportunities for practicing pharmacists during COVID-19 pandemic' organized by JSS College of Pharmacy, Mysuru 12th June 2021.

Dr Keerthana C, Resident, Department of Pharmacy Practice participated in webinar on 'Journal Citation Reports Certification series 2021' organized by Clarivate Webinars Between 15th -17th June 2021.

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in international webinar 'Delivering person-centered support for self-care: current and future pharmacy practice' organized by International Pharmaceutical Federation, The Netherlands on 16th June 2021.

Dr Roopa B S, Lecturer, Department of Pharmacy Practice participated in 'Web seminar: Journal Citation Reports (JCR) Training & Certification Program 2021 - Part 2' organized by Clarivate Webinars on 17th June 2021.

Dr K P Arun, Asst. Professor, Department of Pharmacy Practice acted as a Resource person and delivered a talk on 'Precision medicine- The way Forward' during 'The OEP-Live streaming classes for PG Diploma In Bioinformatics Program under eVBAB, MEA, INDIA' organized by Centre for Distance & Online Education, JSSAHER, Mysuru on 18th June 2021.

Dr Roopa B S, Lecturer, Department of Pharmacy Practice participated in international event "Introducing the FIP 'Transforming Vaccination Globally, Regionally and Nationally' 2021: Accelerating equity, access and sustainability through policy development and implementation" organized by FIP Digital Events on 18th June 2021.

EVENT CORNER

Dr S Ponnusankar, Dr M.Deepalakshmi, Dr Sadagoban GK, Dr Swathi Swaroopa B, Dr Aneena Suresh, Dr J Jeyaram Bharathi, Faculty, Department of Pharmacy Practice participated in international conference 'N-DECON: The international nursing diabetes and endocrine conference' organized by International Society of Endocrinology on 19th & 20th June 2021.

Dr Keerthana C, Clinical Resident, Department of Pharmacy Practice participated in online "Yoga Session on-Be with Yoga, Be at Home" organized by Department of Yoga & NSS, JSS Academy of Higher Education & Research, Mysuru on 21st June 2021.

Dr Swathi Swaroopa B, Lecturer, Department of Pharmacy Practice participated in international event 'FIP Digital Event FIP Development Goals 9: Continuing Professional Development Strategies' organized by International Pharmaceutical Federation on 23rd June 2021.

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in international webinar 'Pharmacy Practice Research Virtual Summer meeting for PhD students, Postdoctoral fellows and Supervisors' organized by International Pharmaceutical Federation, The Netherlands on 24th June 2021.

Dr M Deepalakshmi, Dr Aneena Suresh, Faculty, Department of Pharmacy Practice participated in webinar on 'From Good to Great Teacher' organized by Caritas College of Pharmacy, Kottayam on 25th June 2021.

Mr Vishwas H N, Lecturer, Department of Pharmacy Practice participated in 'National webinar on Challenges of Pharmaceutical care and Medication management: Need of the Hour in India' organized by BLDEA's SSM College of Pharmacy & Research Centre, Vijayapur, Karnataka-586103 on 26th June 2021.

Dr G K Sadagoban, Lecturer, Department of Pharmacy Practice acted as a Resource person and delivered a talk on 'Role of Clinical Pharmacist in Drug Safety and Pharmaceutical Care' during the event 'Comprehensive Prospects Of Pharm D: Drug Safety And Entrepreneurship' organized by Vijaya Institute of Pharmaceutical Sciences for Women, Vijayawada on 28th June 2021.

Dr S Ponnusankar, Professor & Head, Department of Pharmacy Practice participated in webinar 'World Elder Abuse Awareness 2021: Access to justice' organized by JSS Hospital, Mysuru on 30th June 2021.

Dr M Deepalakshmi, Dr K P Arun, S J Sajna published a book entitled 'KAP of Pharmacist & Physician Towards Generic Drug Use - A Cross Sectional Study' from Lambert Academic Publishing with ISBN Number: 9786203923278.

Dr Roopa BS, Lecturer, Department of Pharmacy Practice acted as a Reviewer for one paper from Journal of Pharmacy Practice. (June 2021).
Dr Aneena Suresh, Lecturer, Department of Pharmacy Practice acted as a Reviewer for one paper from Cardiology and Angiology –An International Journal. (June 2021).

PUBLICATIONS FROM THE DEPARTMENT OF PHARMACY PRACTICE
April - June 2021

Ravi R, Balasubramaniam V, Gowthamarajan K, Ponnusankar S. Current concepts and clinical importance of glycemic variability. Diabetes & Metabolic Syndrome: Clinical Research & Reviews.2021;15(2): 627-635.

Kartha GR, Babu DV, Tenzin Tsering S, Mani D. Comparison of Beers Criteria with START/STOPP Criteria for Detecting Potentially Inappropriate Medications in a Geriatric Setting. Annals of the Romanian Society for Cell Biology. 2021 Apr 7:224-230.

Roopa BS, Thomas E, Divya P, Ponnusankar S. Correlation of antenatal depression among the iron and s-25(OH)D Deficient Pregnant Women: An observational Study in a South Indian Population. International Journal of Pharmaceutical Research. 2021; 13(2): 3414-3420.

Roopa BS, Chris EV, Shruthi JS, Bhavya C, Sivasankaran P. Optimal Dosing of Lasmiditan in the Management of Acute Migraine Attack: A Systematic Review and Meta analysis. Annals of Indian Academy of Neurology 2021;24(2):155-163.

Sadagoban GK, Swathi SB, Arun KP. Humanistic outcome assessment of Type 2 Diabetes mellitus patients: A prospective study. International Journal of Pharmaceutical Research, 2021;13(02):790-794.

Asish KS, Aneena S, Thomas E, Niranjana N. Hydrosalpinx with Adhesion Colic: A Case Report Annals of the Romanian Society for Cell Biology.2021;25(4): 9489-9491.

Jyothikrishna P, Bhavatharini M, Zechariah BH, Nair N, James P, Viswanathan V, Babu B, Varghese J, Orathel SP, Arun KP. Simulation Approach for Dosage Optimization of Colistimethate Sodium in Critically Ill South Indian Patients-A Pilot Study. Annals of the Romanian Society for Cell Biology. 2021;25(6):4331-4335.

Deepalakshmi M, Kumar RS, Messiah MS, Raghavakrishna KR, Shalini S, Arun KP. A Comprehensive Review on Corticosteroids. Annals of the Romanian Society for Cell Biology. 2021;25(6):4219-4229.

Hyder KM, Mohan J, Varma V, Ponnusankar S, Raja D. Impact of prediabetes education program on Knowledge, attitude and practice among prediabetic population of south India. Preventive medicine reports. 2021; 23:101395.

WEAR A MASK
STOP THE SPREAD

ALUMNI INTERACTION SERIES

Bridging the gap - Connecting to the World

Speaker:
Dr Sneha Ramanujam
Senior Formulation Scientist
Plasticon Healthcare

Title of the presentation:
Contract Manufacturing of Over-The-Counter drug products, nutraceuticals and sterile product formulations

Alumni Interaction Series (AIS) is a new initiative of Dept. of Pharmacy Practice and Pharmacy Education Unit of JSS College of Pharmacy to connect the Pharm D students with the alumnus of our department with the quote *"Bridging the Gap- Connecting to the World"*.

This interaction series will provide an opportunity to the Pharm D and M Pharm (Pharmacy Practice) students to establish their professional connection with the alumnus of the institution and also understand the various topics dealt by the invitee. Further, this interaction will help the students to better appreciate the various requirement for the academic learning including the pharmacotherapy knowledge, clinical case understanding to serve as clinical pharmacists in diverse patient care settings. As patient care expert / specialist; our students have the responsibility to learn more from the working professionals which will help them to function as a member of a multidisciplinary health care team member and provide their services to the needy population.

With the aim, the first Alumni Interaction Series (AIS) was organized on the topic "Contract manufacturing of over-the-counter drug products, neutraceuticals and sterile product formulations" on 26.06.2021 for the benefit of our students.

Dr Sneha Soundharya started her presentation about the safe and effective way of using the OTC products and the importance of following the directions on the label and by health care professionals. The OTC medicine label has always contained important usage and safety information for consumers, but now that information will be more consistent and even easier to read and to understand. The U.S. Food and Drug Administration (FDA) has issued a regulation to make sure the labels on all OTC medicines (from a tube of fluoride toothpaste to a bottle of cough syrup) have information listed in the same order; are arranged in a simpler eye-catching, consistent style; and may contain easier to understand words.

"Nutraceutical" products are regulated as drugs, food ingredients and dietary supplements. Nutraceuticals, in contrast to pharmaceuticals, are substances, which usually have not patent protection. Both pharmaceutical and nutraceutical compounds might be used to cure or prevent diseases, but only pharmaceutical compounds have governmental sanction. A dietary supplement is considered as a product that bears or contains one or more of the following dietary ingredients: A mineral, a vitamin, an amino acid, a medical herb or other botanical, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.

Sterile product formulation development is more than just deciding which excipients to use with the given drug substance. The development of a sterile product requires that specific critical quality attributes be considered and evaluated, regardless of the route of delivery or the type of registration application.

Further, she also added the overview of ICH Q8 Pharmaceutical Development requirements and Health Authority Quality by Design expectations with regard to raw materials, packaging, and manufacturing process.

For clarifications/ feedback, write to:

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