JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
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CLINICAL PHARMACY NEWSLETTER

A Newsletter of Drug and Prescribing Information

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(A Unit of Department of Pharmacy Practice, JSS College of Pharmacy, Ooty)

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INSIDE THIS ISSUE

COVID-19 Vaccination for Children aged 12-14 years in India: An Update

India has decided to expand its Covid-19 vaccination drive to include children in the 12 to 14 year age group starting 16th March 2022. The children will be administered Corbevax vaccine manufactured by Hyderabad-based Biological E.

Corbevax is India's first indigenously developed RBD-protein subunit vaccine. Unlike any other vaccine, it uses a recombinant protein platform that targets spike protein on the virus. The vaccine injects a volume of cloned spike proteins, instead of instructing cells to replicate it. It reduces the virus' ability to cause any serious diseases. While Biological E will produce the vaccine in India, it was developed by Texas Children's Hospital Center for Vaccine Development and Baylor College of Medicine in Houston, Texas and Dynavax technologies based in Emeryville, California, USA.

Contents of the Vaccine: The vaccine consists of a receptor binding domain (RBD) of the SARS-CoV-2 spike protein together with the adjuvants, aluminium hydroxide gel and CpG 1018. The protein is produced by the yeast Pichia pastoris.

Dosage and safety: Children will be administered with two doses at an interval of 28 days – four weeks after the first dose. The vaccine is stored at 2 to 8 degrees Celsius.

Regulatory information: A phase I clinical trial was carried out to evaluate the safety and immunogenicity of the vaccine candidate in about 360 participants. The phase II concluded in April 2021 and the Drugs Controller General of India permitted the vaccine candidate to start phase III clinical trials. A total of 1,268 healthy participants between the age of 18 and 80 years to be selected from 15 sites across India for the trial and intended to be part of a larger global Phase III study. As of December 2021, Biological E announced positive results.

Under the Revised Guidelines, Government of India has procured vaccines being produced by the manufacturers in the country and provided it free of cost to States/UTs. Government has also provided States/UTs advance information of vaccine doses to be supplied to them. States and union territories are expected similarly, to further allocate doses well in advance to districts and vaccination centres. States and union territories are instructed to put in the public domain the information about the above availability at district and vaccination centre level, and widely disseminate it among the local population, maximizing the visibility and convenience of citizens. All citizens irrespective of their income status have all along been entitled to free vaccination. Those who have the ability to pay are encouraged to use private hospital's vaccination centres. The CoWIN platform provides every citizen the facility of conveniently and safely prebooking vaccination appointments.

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- https://www.hindustantimes.com/india-news/corbevax-vaccine-for-kids-all-you-need-to-know-about-this-indigenous-jab-101647430058379.html
- https://www.livemint.com/news/india/biological-e-completes-phase-2-covid-vaccine-trial-gets-sec-nod-for-phase3-11619261685348.html
- http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=56379
- https://www.mohfw.gov.in/pdf/GuidelinesforCOVID19VaccinationofChildrenbetween15to18yearsandPrecautionDosetoHCWsFLWs&60populationwithcomorbidities.pdf

National Vaccination Day

On 16th March every year, National Vaccination Day is observed in India which is also known as National Immunisation Day. It was first observed on 16th March 1995 when the first dose of Oral Polio Vaccine was given. It is an attempt to increase awareness for the eradication of polio from the planet earth.

Dupilumab Reduces Corticosteroid Use in Severe Asthma

Dupilumab, a parenterally administered interleukin (IL)-4 receptor alpha antagonist, was first approved for the treatment of adults with moderate-to-severe atopic dermatitis by USFDA 0n March 28, 2017. On October 20, 2021, the USFDA has approved Dupixent® as an add-on maintenance treatment of patients aged 6-11 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma. Dupilumab is developed by Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi Genzyme.

The FDA approval is based on data from a Phase 3 randomized, double-blind, placebo-controlled trial that evaluated the efficacy and safety of Dupilumab combined with standard-of-care asthma therapy in children with uncontrolled moderate-to-severe asthma. More than 90% of children in the trial had at least one concurrent type 2 inflammatory condition. Dupilumab substantially reduced rate of severe asthma attacks, with a 65% average reduction over one year compared to placebo. Dupilumab is the only biologic medicine to improve lung function in children aged 6 to 11 years observed as early as two weeks and sustained for up to 52 weeks, measured by percent predicted pre-bronchodilator FEV1.

Despite available treatments, moderate-to-severe asthma can severely impact children's developing airways, causing sleepless nights, persistent coughing and wheezing, and potentially life-threatening exacerbations that require the use of systemic steroids that can negatively affect growth. Dupilumab brings new hope for such children who may be suffering from life-threatening asthma attacks and poor lung function, affecting their ability to breathe, potentially into adulthood.

Mechanism of action: Dupilumab inhibits the overactive signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key proteins that contribute to the Type 2 inflammation that may underlie moderate-to-severe asthma. This effect is associated with the reduction of inflammatory biomarkers including fractional exhaled nitric oxide (FeNO), immunoglobulin E (IgE) and eotaxin-3 (CCL26).

Dosage and Administration:
Dosage in adults and adolescents 12 years and older (pre-filled pen)

Initial Loading Dose	Subsequent Loading Dose
400 mg (two 200 mg injections)	200 mg every 2 weeks (Q2W)
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)

Dosage in Pediatric Patients (6 to 11 Years of Age) (pre-filled syringe)

Body weight	Subsequent Loading Dose
15 to less than 30 kg	100 mg every other week (Q2W) or 300 mg every four weeks (Q4W)
≥30 kg	200 mg every other week (Q2W)

Dupilumab can be administered by a healthcare professional or self-administered at home. In children below 12 years it should not be self-administered.

Adverse effects:
- Serious side effects include allergic reactions (hypersensitivity), including anaphylaxis. Inflammation in blood vessels, joint aches and pain
- Common side effects include injection site reaction, pain in the throat (oropharyngeal pain) and cold sores in mouth or on lips, eosinophilia), and parasitic (helminth) infections. Eye and eyelid inflammation, including redness, swelling and itching have been seen in patients who have atopic dermatitis.

Warnings and Precautions
- Do not use if allergic to Dupilumab or to any of the ingredients in DUPIXENT®.
- Before using Dupilumab, discuss with healthcare provider about all medical conditions, including if :
  - o have a parasitic (helminth) infection
  - o are scheduled to receive any vaccinations. You should not receive a "live vaccine" right before and during treatment with Dupilumab.
  - o are pregnant or plan to become pregnant. It is not known whether Dupilumab will harm your unborn baby.
  - o are breastfeeding or plan to breastfeed. It is not known whether Dupilumab passes into breast milk.

Dupilumab is currently approved for moderate-to-severe asthma in several other countries, including Japan, China and in the European Union (EU).

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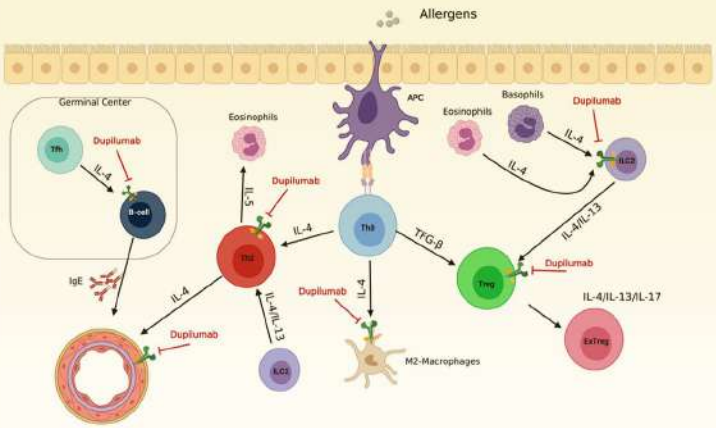
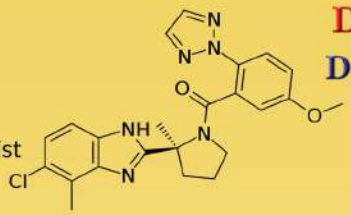
- https://www.dupixent.com/asthma#:~:text=DUPIXENT%20helps%20prevent%20severe%20asthma,to%20treat%20sudden%20breathing%20problems.
- https://www.sanofi.com/en/media-room/press-releases/2021/2021-10-20-23-30-00-2317854



Potential sites of action of Dupilumab in inhibiting allergic inflammation. Dupilumab can act to inhibit TH2 cell differentiation, the transformation of Treg cells into ex-Treg cells in the context of allergic inflammation, and IgE production by B cells, driven by T follicular helper (TFH)- derived IL-4. It can also prevent IL-4-related vascular endothelium dysfunction. Furthermore, it can inhibit ILC2 induction via eosinophils and basophils

THE THREAT IS THE VIRUS,
NOT THE PEOPLE
#MASKINDIA

DRUG PROFILE
DARIDOREXANT



Class:
Orexin receptor antagonist

Indication:
Daridorexant is indicated for insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Mechanism of Action:
Daridorexant is an orexin receptor antagonist. The mechanism of action of Daridorexant in the treatment of insomnia is presumed to be through antagonism of orexin receptors. The orexin neuropeptide signaling system plays a role in wakefulness. Blocking the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R is thought to suppress wake drive.

Dosage form and Administration:
Daridorexant is available in the form of film-coated tablets of 25 mg and 50 mg. 25 mg tablet is light purple, arc-triangle shaped, tablet debossed with "25" on one side and "i" (Idorsia logo) on the other side, containing 25 mg Daridorexant. 50 mg tablet is light orange, arc-triangle shaped, film-coated tablet debossed with "50" on one side and "i" (Idorsia logo) on the other side, containing 50 mg Daridorexant The recommended dosage range of Daridorexant is 25 mg to 50 mg of Daridorexant taken orally no more than once per night within 30 minutes of going to bed (with at least 7 hours remaining prior to planned awakening). Time to sleep onset may be delayed if taken with or soon after a meal.

Dosing in Renal & Hepatic Impairment:
The maximum recommended dosage of Daridorexant in patients with moderate hepatic impairment (Child-Pugh score 7–9) is 25 mg not more than once per night. Drug is not recommended in patients with severe hepatic impairment (Child-Pugh score ≥ 10).
No dose adjustments are necessary for patients with mild, moderate, or severe renal impairment.

Pharmacokinetics:
Daridorexant plasma exposure is dose proportional from 25 mg to 50 mg. The Daridorexant pharmacokinetic profile is similar following multiple-dose and single-dose administration with no accumulation. Daridorexant reaches peak plasma concentrations within 1–2 hours (Tmax). Daridorexant has an absolute bioavailability of 62%. Daridorexant has a volume of distribution of 31 L. Daridorexant is 99.7% bound to plasma proteins. The blood to plasma ratio is 0.64. The elimination half-life of Daridorexant is approximately 8 hours. Daridorexant undergoes extensive metabolism and is primarily metabolized by CYP3A4 (89%). Other CYP enzymes individually contribute to less than 3% of metabolic clearance of Daridorexant. The primary route of Daridorexant excretion is via feces (approximately 57%), followed by urine (approximately 28%), primarily as metabolites. Trace amounts of parent drug were found in feces and urine. Age, sex, race (White, Black, Asian), body size, and mild to severe renal impairment (Cockcroft-Gault < 30 mL/min, not on dialysis) did not have a clinically significant effect on the pharmacokinetics of Daridorexant. The effect of severe hepatic impairment (Child-Pugh score ≥ 10) on the pharmacokinetics of Daridorexant has not been studied.

Adverse Reactions:
1-10%: Headache (6-7%), Somnolence or fatigue (5-6%), Dizziness (2-3%), Nausea (3%)
<1%: Hypnagogic and hypnopompic hallucinations (0.6%), Sleep paralysis (0.3-0.5%)

Contraindications:
- *Daridorexant is contraindicated in patients with narcolepsy*
- *The safety and effectiveness of Daridorexant have not been established in pediatric patients*

Precautions:
- Daridorexant is a central nervous system (CNS) depressant that can impair daytime wakefulness even when used as prescribed. CNS-depressant effects may persist in some patients for up to several days after discontinuing drug. Prescribers should advise patients about the potential for next-day somnolence.
- Driving ability was impaired in some subjects taking Daridorexant 50 mg. The risk of daytime impairment is increased if drug is taken with less than a full night of sleep remaining or if a higher than recommended dose is taken. If Daridorexant is taken in these circumstances, patients should be cautioned against driving and other activities requiring complete mental alertness.
- Co-administration with other CNS depressants (e.g., benzodiazepines, opioids, tricyclic antidepressants, alcohol) increases the risk of CNS depression, which can cause daytime impairment. Dosage adjustments of Daridorexant and of concomitant CNS depressants may be necessary when administered together because of potentially additive effects.
- Concomitant use of Daridorexant with other drugs to treat insomnia is not recommended.
- Patients should be advised not to consume alcohol in combination with Daridorexant because co-administration with alcohol resulted in additive effects on psychomotor performance.
- Like many other hypnotics, Daridorexant should be administered with caution in patients exhibiting symptoms of depression. Monitoring of suicide risk and protective measures may be required.
- Sleep paralysis, an inability to move or speak for up to several minutes during sleep-wake transitions, and hypnagogic/hypnopompic hallucinations, including vivid and disturbing perceptions, can occur with the use of Daridorexant. Prescribers should explain the nature of these events to patients when prescribing the drug.
- Complex sleep behaviours, including sleepwalking, sleep-driving, and engaging in other activities while not fully awake (e.g., preparing and eating food, making phone calls, having sex), have been reported to occur with the use of hypnotics, including orexin receptor antagonists such as Daridorexant. Drug should be discontinued immediately if a patient experiences a complex sleep behaviour.

Drug Interactions:
- Concomitant use with a strong or moderate CYP3A4 inhibitor increases exposure to Daridorexant, which may increase the risk of Daridorexant adverse reactions. (Ex: Clarithromycin, Erythromycin, Diltiazem, Itraconazole, Ketoconazole, Ritonavir, Verapamil, Phenobarbital, Phenytoin, Rifampicin, St. John's Wort, Glucocorticoids.)
- Concomitant use with a strong or moderate CYP3A4 inducer decreases exposure to Daridorexant. Concomitant usage of these drugs are not recommended.
- Concomitant use of alcohol or other CNS depressants with Daridorexant may lead to additive impairment of psychomotor performance and risk of CNS depression. Patients should be advised to avoid alcohol when taking Daridorexant.

REFERENCES:

- United states food & drug administration website. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214985s000lbl.pdf
- Idorsia website with information regarding Daridorexant. Available from: https://www.idorsia.com/media/news-details?newsId=2665386

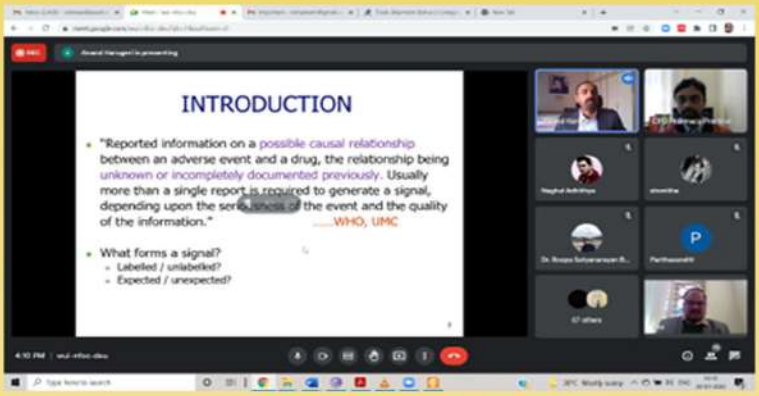
EVENT CORNER

- Dr Mohsina Hyder, Lecturer, Department of Pharmacy Practice participated in webinar entitled 'Mitochondrial Metabolic Reprogramming in Cancer' organized by Caritas College of Pharmacy, Ettumanoor, Kottayam, Kerala on 6th January 2022.
- Dr B Swathi Swaroopa, Asst. Professor, Department of Pharmacy Practice got identified as 'Reviewer of manuscript' for 'Journal of Pharmacy Practice' on 21st January 2022.
- Dr. Roopa B S, Asst. Professor, Department of Pharmacy Practice got identified as 'Reviewer of manuscript' for 'PLOS ONE' journal on 24th January 2022
- Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice participated in webinar entitled 'Pharmacotherapy of Dementia-Herbal hopes' organized by Department of Pharmacognosy, JSS College of pharmacy, Ooty on 28th January 2022.
- Ashna Chackochan, Sherin Mary Shaji, Bhavatharini PA, Keerthana Chandrasekar from Department of Pharmacy Practice published a book chapter entitled 'COVID 19 Induced Respiratory Infection' in the book 'Advances in Health and Disease' published by Nova Science Publishers in January 2022. (ISBN -978-1-68507-504-0).
- Dr. S Ponnusankar, Dr M Deepalakshmi, Dr Aneena Suresh, Dr Keerthana C, Dr Jeyaram Bharathi, Mr Vishwas H N Staff, Department of Pharmacy Practice participated in webinar entitled 'Enhancing Consciousness, Cognition and Compassion - Mission and Vision– Sadhguru Center for a Conscious Planet' organized by Special Interest Group in Patient Care Management (SIGPCM), JSS Medical College, JSS Academy of Higher Education & Research, Mysuru on 01st February 2022.
- Dr G K Sadagoban, Asst. Professor, Department of Pharmacy Practice acted as resource person and delivered a talk on 'Cost Effectiveness Analysis in Relevance to Pharmacoeconomic Studies' in the CPE Program - Health economics and outcome research organized by Department of Pharmacy Practice, Vignan Pharmacy College, Vadlamudi, Guntur, Andhra Pradesh on 1st February 2022.
- Dr KP Arun, Dr M Deepalakshmi, Staff, Department of Pharmacy Practice participated in FDP on "Research Writing and Publishing" organized by St. Paul College of Pharmacy in association with Climed Research Solutions. Hyderabad, India between 5th to 18th February 2022.
- Dr J Jeyaram Bharathi, Clinical Resident, Department of Pharmacy Practice participated in webinar entitled 'New Designer Drugs and its Impact on Healthcare' organized by Indian Pharmacy Graduates' Association in Coordination with Alwar Pharmacy College, Rajasthan on 05th February 2022.
- Mr Vishwas H Nparticipated in DBT-CTEP Sponsored seminar on 'Recent advances in the use of biomaterials for the treatment of chronic wounds: An multidisciplinary approach, current trends and future prospects' organized by Department of Pharmaceutics, JSS College of Pharmacy, Ooty on 4th & 5th February 2022.
- Dr C Keerthana, Mr Vishwas H N, Staff, Department of Pharmacy Practice participated in webinar entitled 'Prevention, detection & treatment of Cancer' organized by JSS Academy of Higher Education & Research, Mauritius & International Indian Welfare Association, Mauritius on 19th February 2022.
- Mr Vishwas H N, Lecturer, Department of Pharmacy Practice participated in International Workshop on Gender Issues in Water Management in Developing Countries and Sustainable Development organized by Department of Water & Health-Faculty of Life Sciences, JSSAHER, Mysuru on 22nd and 23rd February 2022.
- Dr J JeyaramBharathi, Clinical Resident, Department of Pharmacy Practice acted as resource person and delivered a talk on 'Know your Medicines' in the event DST STUTI "Communicating Science to Students" organized by JSS College of Pharmacy, Ooty at Panchayat Union Middle School, Bagyanagar, Kagguchi on 25th February 2022.
- Dr B Swathi Swaroopa, Asst. Professor, Department of Pharmacy Practice got identified as 'Reviewer of manuscript' for 'Journal of Clinical Pharmacy & Therapeutics' during February 2022.
- Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice participated in Refresher Course on "Research project writing, bioethics and scientific communications". Organized by Department of Pharmacology, PSG College of Pharmacy, Coimbatore between 7th to 12th March 2022.
- Dr M Deepalakshmi, Asst. Professor, Department of Pharmacy Practice participated in AICTE Sponsored Quality Improvement Program on "Emerging Trends in Clinical Research and Development organized by Department of Pharmacy Practice, KLE College of Pharmacy Belagavi between 9th to15th March 2022.
- Dr M Deepalakshmi, Dr C Keerthana, Staff, Department of Pharmacy Practice participated in Two days Virtual International Conference of Clinical Pharmacy Practice and Research organized by Department of Pharmacy Practice, School of Pharmaceutical Sciences, VISTAS, Chennai on 18th and 19th March 2022.
- Dr. Keerthana C, Dr Mohsina Hyder, Staff, Department of Pharmacy practice participated in webinar entitled 'Implications of Endocrine Disorders on Dental Treatment' organized by SIG Medical Problems & Medical Emergencies in Dental Practice, JSS Dental College & Hospital on 24th March 2022.
- Dr J Jeyaram Bharathi, Clinical Resident, Department of Pharmacy Practice participated in webinar entitled 'National Intellectual property awareness mission' organized by Intellectual Property Office, India on 16th March 2022.
- Dr M Deepalakshmi presented a paper entitled 'Pharmacometric Approach using Modeling and Simulation' and won 'Best Oral Presentation Award' during Two days Virtual International Conference of Clinical Pharmacy Practice and Research Virtual International Conference organized by Department of Pharmacy Practice, School of Pharmaceutical Sciences, VISTAS, Chennai during 18th & 19th March 2022.
- Mr Vishwas H N, Lecturer, Department of Pharmacy Practice acted as a resource person and delivered a talk on 'Importance of Statistics in clinical pharmacy research' during the Webinar on 'Importance of statistics in clinical pharmacy research'-Invited guest lecture organized by Department of Pharmacy Practice, KLE College of Pharmacy, Vidyanagar, Hubballi on 21st March 2022.
- DR S Ponnusankar acted as 'Session Chair' during the event 'CSIR sponsored 1st National Congress on Herbal Medicine and Nano Technology inspired novel formulations: an emerging therapeutic target for cancer and neurodegenerative disorders' on 25th & 26th March 2022.

Industrial Expert Interaction series – Lecture I

Enhancing interpersonal and professional skills

With an objective of enhancing interpersonal and professional skills of the students, Department of Pharmacy Practice in association with Pharmacy Education Unit, JSS College of Pharmacy, Ooty has planned to conduct Industrial Expert Interaction series. Industry expert interactions series provides a platform for budding Pharmacists to be aware of the skills required to enter profession and what Industry expects from the young graduates.



Speaker:
Dr. Anand B Harugeri
Director, Service Operations
PV Project Leadership and Strategic Solutions,
Lifecycle Safety, IQVIA, Bangalore

Title of the presentation:
Signal Detection in Vaccinovigilance

Date of Presentation: *20.01.2022*

Dr Anand started on the discussion with Introduction to signals and their importance in Pharmacovigilance industry. He explained about the important terminologies used by WHO, Hauben & Aronson definition and GVP Module IX terminologies of signal. Further, he elaborated about the importance of signal detection for vaccines. Dr Anand explained in detail about the various steps involved in signal detection for vaccines which involves steps like detection, selection, strengthening, assessment, follow-up, action.

Further, he also detailed about the favouring situations for signal generation along with sources of signals. He elaborated on the various data mining techniques for signal detection along with few methods utilized for analysis. He explained the methods like Bayesian approach, Proportional reporting ratio, Chi-square analysis, Bayesian confidence propagation neural network (BCPNN) and Du Mouchel method (Multiitem Gamma Poisson shrinking). Further, he explained about the stratification of signals and how software help in the process. Further, he explained about the utilization of Log-likelihood ratios in spontaneous reporting data. He further explained about signal strengthening and follow-up. Finally, Dr Anand summarized the quantitative and qualitative aspects related to signal assessment. He further elaborated about the regulatory actions taken if a signal or a potential signal is identified. He further explained about the process of signal detection at Uppsala Monitoring Centre, Sweden.

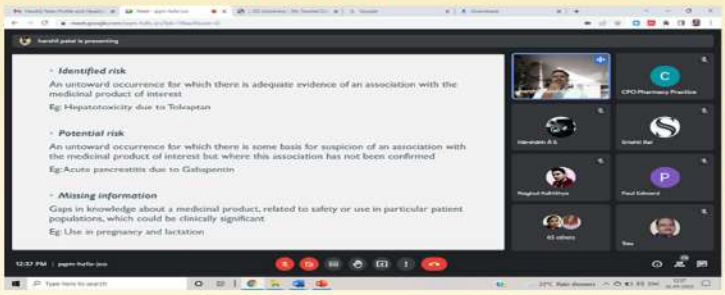
He even showed few outputs, sector maps from automated software used for signal identification. Dr Anand spoke about recent updates in the pharmacovigilance industry like Vigirank, Signal impact assessment tool, Signal detection assessment using change point analysis, Impact of age stratification, GVP-Module IX, Control vocabulary-based ADR signal dictionary, Double fast discovery rate method for signal detection analysis and many other automated tools available with the industry today. Finally, there was a question-and-answer session where few staff and students clarified their doubts related to pharmacovigilance.

Industrial Expert Interaction series – Lecture II

Speaker:
Mr. Harshil V Patel
Global RMP Manager,
Novartis, India

Title of the presentation:
Risk Management Planning in Pharmacovigilance

Date of Presentation: *26.03.2022*



Mr. Harshil started on the discussion with basics of Pharmacovigilance with the examples of 'Thalidomide, Rofecoxib, Valproate & Fluoroquinolones public hearing. He further explained about the importance of healthcare professionals in risk reduction and risk management. He further elaborated about the purpose of risk management and importance of risk management plan in clinical trials. Mr. Harshil elaborately discussed the various 'risk minimization measures' utilized by Pharma companies. He further discussed the various safety specifications for identified/potential risks.

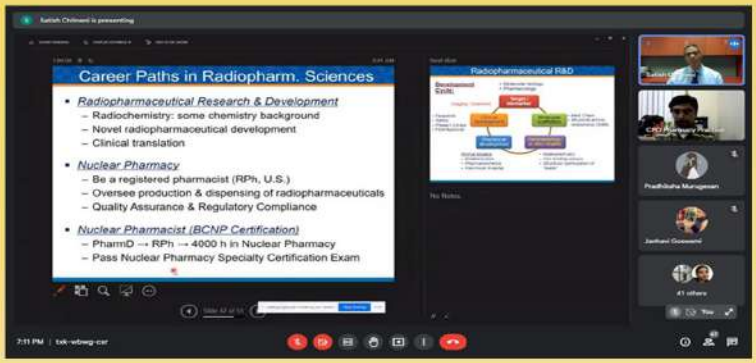
Mr. Harshil further discussed about the 'Factors to be considered for risk minimization tool selection' namely, risk identification, objective of risk minimization and audience for risk minimization intervention. Mr. Harshil explained risk minimization plans implemented for paracetamol and carbamazepine. He further spoke about few regulations related to risk management (DIRECTIVE 2001/83/EC, COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012 and FDA Amendments act 2007). He further spoke about risk minimization plans implemented in Asia-pacific region / Latin America and Gulf countries. Finally, he elaborated the Role of pharmacists in risk management in relation to practice perspectives, research perspectives and industrial perspectives.

After the presentation, staff, scholars, PG and Pharm D Students were encouraged to interact through question-and-answer session. Mr Harshil clarified few doubts regarding Pharmacovigilance and risk minimization. The event was coordinated by Dr S Ponnusankar and Mr Vishwas H N, Department of Pharmacy Practice. About 105 participants comprising of students and staff from Department of Pharmacy Practice attended the event.

Alumni Interaction Series

Bridging the gap: Connecting to the world

Alumni Interaction Series (AIS) is a new initiative of Dept. of Pharmacy Practice and Pharmacy Education Unit of JSS College of Pharmacy, Ooty 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, etc.



Speaker:
Dr Satish K Chitneni
Associate Professor of Radiology
Director, Translational
PET/CT molecular imaging Ctr
DUKE University, USA

Title of the presentation:
Radiopharmaceuticals: What are they and how are they relevant to healthcare?

Date of Presentation: *23.10.2021*

Dr Satish started his presentation with classic definition of the term radiopharmaceuticals are "a class of pharmaceuticals consisting of radioactive elements and used for diagnosis or treatment of diseases". The science of incorporating a suitable radionuclide into a pharmaceutical or other biologically active molecule. The resulting radiopharmaceuticals are used for diagnosis and/or treatment of diseases.

Nuclear medicine is a specialized area of radiology that uses very small amounts of radioactive materials, or radiopharmaceuticals, to examine organ function and structure. A radioactive tracer, radiotracer, or radioactive label, is a chemical compound in which one or more atoms have been replaced by a radionuclide so by virtue of its radioactive decay it can be used to explore the mechanism of chemical reactions by tracing the path that the radioisotope follows from reactants to products. Therapeutic Radionuclides: Radionuclides that decay by emitting beta or alpha particles. Cause significant damage as they traverse through the tissue, e.g., cancer. Induce DNA strand breaks (single, double), oxidize water molecules – free radicals. A number of radionuclides, such as iodine-131 (131I), phosphorous-32 (32P), strontium-90 (90Sr), and yttrium-90 (90Y), have been used successfully for the treatment of many benign and malignant disorders. Recently, the rapid growth of this branch of nuclear medicine has been stimulated by the introduction of a number of new radionuclides and radiopharmaceuticals for the treatment of metastatic bone pain and neuroendocrine and other malignant or non-malignant tumours.

After the introduction of the basics, he also added the details about the nuclear imaging using SPECT / CT and the use of SPECT radionuclides over the use of PET/ CT. Further he narrated about the conventional imaging techniques. Radiopharmaceutical production: More than 100 radiopharmaceuticals have been developed, using radioisotopes that were either produced by nuclear research reactors or cyclotrons. The production of radiopharmaceuticals involves the handling of large quantities of radioactive substances and chemical processing. Further, he added the various therapeutic radionutraceuticals used in the treatment of various cancer, bone pain etc.

Academic Expert Interaction series

Speaker:
Dr. Manas Mandal
Associate Professor of Pharmaceutical Sciences
Roseman University of Health Sciences College of Pharmacy, Henderson, Nevada
United States of America

Title of the presentation:
Immunotherapeutics for Autoimmune disorders

Date of Presentation: *20.01.2022*

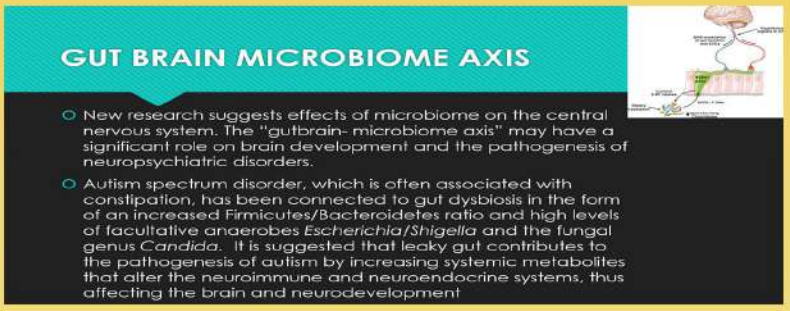
Dr Mandal discussed about the commonly observed autoimmune diseases and the basic mechanisms. He explained about the basic inflammatory response triggered by injury, infection, stress and nutrition. Dr Mandal further explained about the various mechanisms for development of autoimmune disorders namely, breakdown of tolerance, generation of autoantibodies, generation of auto reactive T cells, complement activation, inflammation and further hypersensitivity followed by chronic tissue damage. He even explained about the various autoimmune diseases which affect humans like Rheumatoid arthritis, Type-I diabetes, Grave's disease, Myasthenia gravis, Thrombocytopenia and Systemic lupus erythematosus. Dr Mandal further elaborated about detection of autoimmune disorders. He elaborated few diagnostic tests utilized for identification of autoimmune disorders. He further discussed about the various drug options available for treating the same. Dr Mandal discussed about the treatment modalities like cytotoxic drugs, DMARD's, Corticosteroids, NSAIDs and Biologicals. Dr Mandal also explained in-detail about various biologicals used in autoimmune disorders.

He spoke about the various technologies used for production of these biologicals. He further explained about how cytokine balance is brought by biological agents. He explained in detail about the mechanisms of action for monoclonal antibodies like Rituximab, Alemtuzumab, Belimumab, Adalimumab, Infliximab and Tocilizumab. He spoke about the common precautions to be taken while administering these drugs and how to dose the biological agents for few disease conditions. Finally, he discussed two case studies related to autoimmune disorders and its management. There was a question-and-answer session where few staff and students clarified their doubts related to biological agents. A total of 85 participants were present in the session.

Academic Expert Interaction series

Speaker:
Dr. Asha Hegde
Unit Head, DR TMA Pai Rotary Hospital
Karkala, Karnataka

Title of the presentation:
GUT Microbiome: The Pharmacy in Your Gut



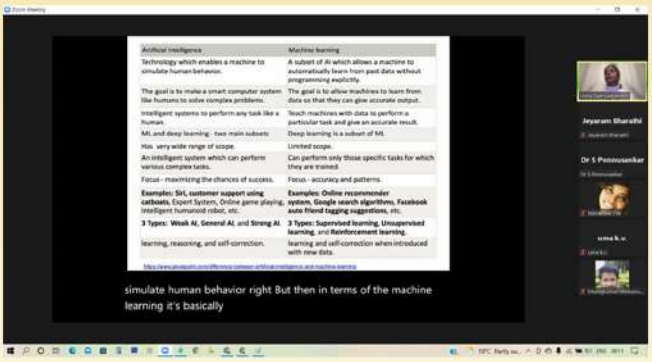
Date of Presentation: *27.01.2022*

Dr Asha Hegde started her presentation with the basic introduction to Gut and Gut microbes as approximately 100 trillion micro-organisms (most of them bacteria, but also viruses, fungi, and protozoa) exist in the human gastrointestinal tract—the microbiome is now best thought of as a virtual organ of the body. Gut microbes are key to many aspects of human health including immune, metabolic and neuro behavioural traits. The human genome consists of about 23000 genes, whereas the microbiome encodes over three million genes producing thousands of metabolites, which replace many of the functions of the host, consequently influencing the host's fitness, phenotype, and health. Although there is a heritable component to gut microbiota, environmental factors related to diet, drugs, and anthropometric measures are larger determinants of microbiota composition.

Microbiome refers to the collective genomes of the micro-organisms in a particular environment, and microbiota is the community of micro-organisms themselves. Microbiota diversity—a measure of how many different species and, how evenly distributed they are in the community. Dysbiosis -Lower diversity is considered a marker of dysbiosis (microbial imbalance) in the gut and has been found in autoimmune diseases and obesity and cardiometabolic conditions, as well as in elderly people. Further, she also described about the various/ common organisms present in stomach/duodenum; colon; jejunum and ileum. She further explained about the impacting factors on gut microbiome such as: Diet, Pharmaceuticals, Stress (exercise, metabolic, psychological), Infant feeding method, Birthing process, Lifecycle stages and Geography.

Pharmacomicrobiomics (effects of food and drugs on the gut microbiota): Specific foods and dietary patterns can all influence the abundance of different types of bacteria in the gut, which in turn can affect health. The interaction between gut microbes and commonly used non-antibiotic drugs is complex and bidirectional. Gut microbiome composition can be influenced by drugs, but, vice versa, the gut microbiome can also influence an individual's response to a drug by enzymatically transforming the drug's structure and altering its bioavailability, bioactivity or toxicity (Pharmacomicrobiomics). The gut microbiome can also indirectly impact an individual's response to immunotherapy in cancer treatment.

Academic Expert Interaction series



Speaker:
Dr. Usha Sambamoorthi
Professor of Pharmacotherapy
Associate Dean for Health Outcomes Research
University of Texas
USA

Title of the presentation:
Health Services / Health Economics / Health Outcome Research :& Artificial Intelligence and Machine Learning

Date of Presentation: *14.03.2022*

Dr Usha started her presentation with the basic introduction to health economics, health outcomes research using the machine learning approach. Outcomes Research is the cornerstone of health technology assessment (HTA), which decision-makers use to inform the adoption of new health technologies. However, the generation of outcomes that are used in OR typically requires a period of data collection and analysis that may take months or years to complete, which in turn increases the amount of time taken to finalize HTAs and thus delays adoption by decision-makers. Artificial Intelligence (AI) has the potential to accelerate and contribute additional accuracy and quality studies to the evidence base and thus facilitate the decision-making process.

Artificial intelligence, a branch of computer science, is intelligence demonstrated by machine that mimics human intelligence, such as reasoning, recognition, and problem solving. One of the benefits of AI is the ability to create many plausible analytic models with minimum work effort and to analyze large amounts of data. There have been studies assessing how AI could help with hospital or health system planning with a focus on how AI-informed support systems could lead to efficiency gains in resource utilization. The use of AI in medical research has focused on several areas including radiology and imaging, pathology, ophthalmology, dermatology, genetics, oncology, neurology, endocrinology, mental health, and critical care. The most mature applications are in radiology and imaging, and pathology, which reflects the fact that AI is able to detect complex and previously unknown patterns in immense amounts of data used to inform the diagnosis of various diseases.

Despite the huge promise of AI in health care, experts caution that its potential is currently limited by data quality issues and a lack of defined evidence standards. A major barrier to greater adoption of AI is the level of confidence of decision-makers in the appropriateness of the algorithms used. Further, she also added various examples of algorithms used in decision making of health care. And added the challenges with AI / ML in HEOR/ HSOR.

Publications from Department of Pharmacy Practice

(January-March 2022)

- Som S, Antony J, Dhanabal SP, Ponnusankar S. Neuroprotective role of Diosgenin, a NGF stimulator, against Aβ (1–42) induced neurotoxicity in animal model of Alzheimer's disease. Metabolic Brain Disease. 2022; 37(1): 359-372.
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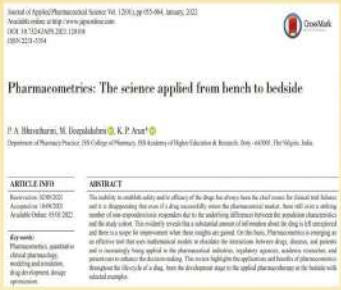
- Aswathy V, Pillai S, Chandra KR, Jyothikrishna P, Arun KP. Dosage optimization of clopidogrel via a precision medicine approach: the way forward. Pharmacogenomics. 2021;23(3):195-206.
- Shaji SM, Sadagoban GK, Swathi Swaroopa B. Mucormycosis in COVID-19: modifiable risk factors and its mitigation in India. Italian Journal of Mycology. 2022;51:11-22.
- Mustafa NH, Sekar M, Shivkanya Fuloria, Yasmin Begum M, Gan SH, Nur Rani N, Subban Ravi, Kumarappan C, Subramaniyan V, Sathasivam KV, Jeyabalan S, Uthirapathy S, Ponnusankar S, Lum PT, Vijay Bhalla, Neeraj Kumar F Chemistry, biosynthesis and pharmacology of Sarsasapogenin: a potential natural steroid molecule for new drug design, development and therapy. Molecules. 2022; 27: 2032.
- Ponnusankar S, Vishwas HN, Manoj S, Balasubramaniam V Assessment of the attitude and knowledge about abortion and its consequences in women attending Obstetrics unit at a public hospital: a prospective, descriptive survey based study. Eurasian Journal of Family Medicine. 2022; 11(1): 52-59.
- Roopa BS, Chauhan BS. A cross-sectional study investigating the association of serum iron concentration and platelet count as a risk biomarker among the pregnancy-induced hypertensive women in the highlands Western ghats of Nilgiris. Indian Journal of Community Medicine. 2022; 47:125-9.
- Sadagoban GK, Shaji JR, Premnath B, Siby AR, Swathi Swaroopa B, Ayilya M, Arun KP. Cost-effectiveness analysis of Dapagliflozin versus Canagliflozin in treatment of type 2 diabetes mellitus. Journal of Applied Pharmaceutical Sciences, 2022; 12(03): 171–178.
- Sumathi K, Bencer WB, Keerthana C. Common infectious disease conditions and antibiotic resistance in pediatric population. Journal of Medical Pharmaceutical and Allied Sciences. 2022, 11(2):4503-4506.


Neuroprotective role of Diosgenin, a NGF stimulator, against Aβ (1–42) induced neurotoxicity in animal model of Alzheimer's disease


Pharmacometrics: The science applied from bench to bedside


Dosage optimization of clopidogrel via a precision medicine approach: the way forward


Mucormycosis in COVID-19: modifiable risk factors and its mitigation in India


Chemistry, Biosynthesis and Pharmacology of Sarsasapogenin: A Potential Natural Steroid Molecule for New Drug Design, Development and Therapy


Assessment of the Attitude and Knowledge About Abortion and Its Consequences in Women Attending Obstetrics Unit at A Public Hospital: A Prospective, Descriptive Survey-Based Study


A Cross-Sectional Study Investigating the Association of Serum Iron Concentration and Platelet Count as a Risk Biomarker among the Pregnancy-Induced Hypertensive Women in the Highlands Western Ghats of Nilgiris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For clarifications/ feedback, write to:

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