|| Jai Sri Gurudev ||

CLINICAL PHARMACY NEWS LETTER

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DRUG INFOS- ONLINE DRUG INFORMATION CENTER EXT.NO.2115. docpinfo@gmail.com

Sri Adichunchanagiri College of Pharmacy is the premier educational institution in Pharmaceutical Sciences. The institution is under the aegis of Sri Adichunchanagiri Shikshana Trust, under the leadership of Sri Sri Sri Nirmalanandanatha Mahaswamiji, President, SAST(R). Now the institution is offering; D.Pharm, B.Pharm, M.Pharm, Pharm D, Pharm D (Post Baccalaureate) and Ph.d, courses, approved by AICTE, PCI & Affiliated to RGUHS Bangalore.

ZIKA VIRUS: A PHARMACIST NOTE

Zika virus is an emerging mosquito-borne virus that was first identified in Uganda in 1947 in rhesus monkeys through a monitoring network of sylvatic yellow fever. It was subsequently identified in humans in 1952 in Uganda and the United Republic of Tanzania. Zika virus disease outbreaks were reported for the first time from the Pacific in 2007 and 2013 (Yap and French Polynesia, respectively), and in 2015 from the Americas (Brazil and Colombia) and Africa (Cape Verde). In addition, more than 13 countries in the Americas have reported sporadic Zika virus infections indicating rapid geographic expansion of Zika virus.

Zika virus is transmitted to people through the bite of an infected mosquito from the Aedes genus, mainly Aedesaegypti in tropical regions. This is the same mosquito that transmits dengue, chikungunya and yellow fever. Zika virus infection is symptomatic in only about 1 out of every 5 cases. When symptomatic, Zika infection usually presents as an influenza-like syndrome, often mistaken for other arboviral infections like dengue or chikungunya. During large outbreaks in French Polynesia and Brazil in 2013 and 2015 respectively, national health authorities reported potential neurological and auto-immune complications of Zika virus disease. Recently in Brazil, local health authorities have observed an increase in Guillain-Barré syndrome which coincided with Zika virus infections in the general public, as well as an increase in babies born with microcephaly in northeast Brazil. Microcephaly is a condition where a baby's head is much smaller than expected. During pregnancy, a baby's head grows because the baby's brain grows. Microcephaly can occur because a baby's brain has not developed properly during pregnancy or has stopped growing after birth, which results in a smaller head size. On 1 February 2016 the World Health Organization (WHO) declared a Public Health Emergency of International Concern (PHEIC) regarding a recent cluster of microcephaly cases and other neurological disorders and the possible association of these illnesses with Zika virus infections. Additional international research is necessary and ongoing to determine the link between Zika virus and fetal damage.

Zika virus diagnosis can only be confirmed by laboratory testing for the presence of Zika virus RNA in the blood or other body fluids, such as urine or saliva. There is neither a vaccine, nor a drug to treat or prevent Zika infection. The key to avoiding the virus is to prevent mosquito bites using insect repellant, clothing that covers all body parts, and staying indoors where there are screens on doors and windows.

The Centers for Disease Control and Prevention (CDC) released interim guidelines for health care providers caring for pregnant women during this outbreak. Few recommendations pharmacists should know about are: Those who have traveled where the

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Zika virus is circulating, are showing 2 or more symptoms related to the infection during or within 2 weeks of travel, or have ultrasounds that point to fetal microcephaly should all be tested.The incubation period (the time from exposure to symptoms) for Zika virus disease is not known, but is likely to be a few days to a week. The symptoms of Zika are similar to those of dengue and chikungunya, diseases spread through the same mosquitoes that transmit Zika. The most common symptoms of Zika are fever, rash, joint pain, or conjunctivitis (red eyes). Other common symptoms include muscle pain and headache. In addition, some patients may develop Guillain-Barré syndrome following infection.Treatment may include rest, fluids, and use of analgesics and antipyretics. Travellers visiting countries where Zika virus is currently being transmitted should use personal preventive measures based on protection against mosquito bites indoors and outdoors.

Mosquitoes and their breeding sites pose a significant risk factor for Zika virus infection. Prevention and control relies on reducing mosquitoes through source reduction (removal and modification of breeding sites) and reducing contact between mosquitoes and people. This can be done by using insect repellent; wearing clothes (preferably light-coloured) that cover as much of the body as possible; using physical barriers such as screens, closed doors and windows; and sleeping under mosquito nets. It is also important to empty, clean or cover containers that can hold water such as buckets, flower pots or tyres, so that places where mosquitoes can breed are removed. Special attention and help should be given to those who may not be able to protect themselves adequately, such as young children, the sick or elderly. During outbreaks, health authorities may advise that spraying of insecticides be carried out. Insecticides recommended by the WHO Pesticide Evaluation Scheme may also be used as larvicides to treat relatively large water containers.

Compiled by : **Chava Narasimha Rao (Alumni)**
Pharm.D

US FDA approves MAC-ELISA test for Zika virus

The U.S Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the Centers for Disease Control and Prevention's (CDC) Zika IgM antibody capture ELISA (Zika MAC-ELISA) for the in vitro qualitative detection of human IgM antibodies to Zika virus.

Till Feb 2016 there were no FDA approved/ cleared tests available that can detect Zika virus in clinical specimens in the United States. Therefore, CDC has developed this test to detect evidence of Zika virus infections in human sera and CSF. Anti-Zika IgM is typically detectable starting near day 4 post onset of symptoms and is reliably detectable for approximately 12 weeks following infection.

As of February 20, 2016, serum is the priority specimen for collection and testing. Specimens should be collected with appropriate infection control precautions and according to the manufacturer's instructions for the specimen collection device. Sera should be collected in serum separator tubes and centrifuged after collection to reduce the likelihood of hemolysis.

The results should be used in conjunction with clinical signs and symptoms, epidemiological information, and travel history to diagnose recent Zika virus infection.

A positive test for Zika virus from the Zika MAC-ELISA indicates that anti-Zika IgM antibodies were detected in the sera or CSF of the patient. Confirmation of Zika MAC-ELISA positive or equivocal results requires additional testing by CDC or by qualified laboratories designated by CDC and in consultation with CDC, using the CDC-issued algorithm. A negative Zika MAC-ELISA result does not rule out Zika virus infection, particularly if testing is conducted less than 4 days after onset of symptoms (before IgM levels are expected to become detectable) or more than 12 weeks after the infection is thought to have occurred (as IgM levels are expected to drop).

Compiled by : **Mrs. Jamuna T R**
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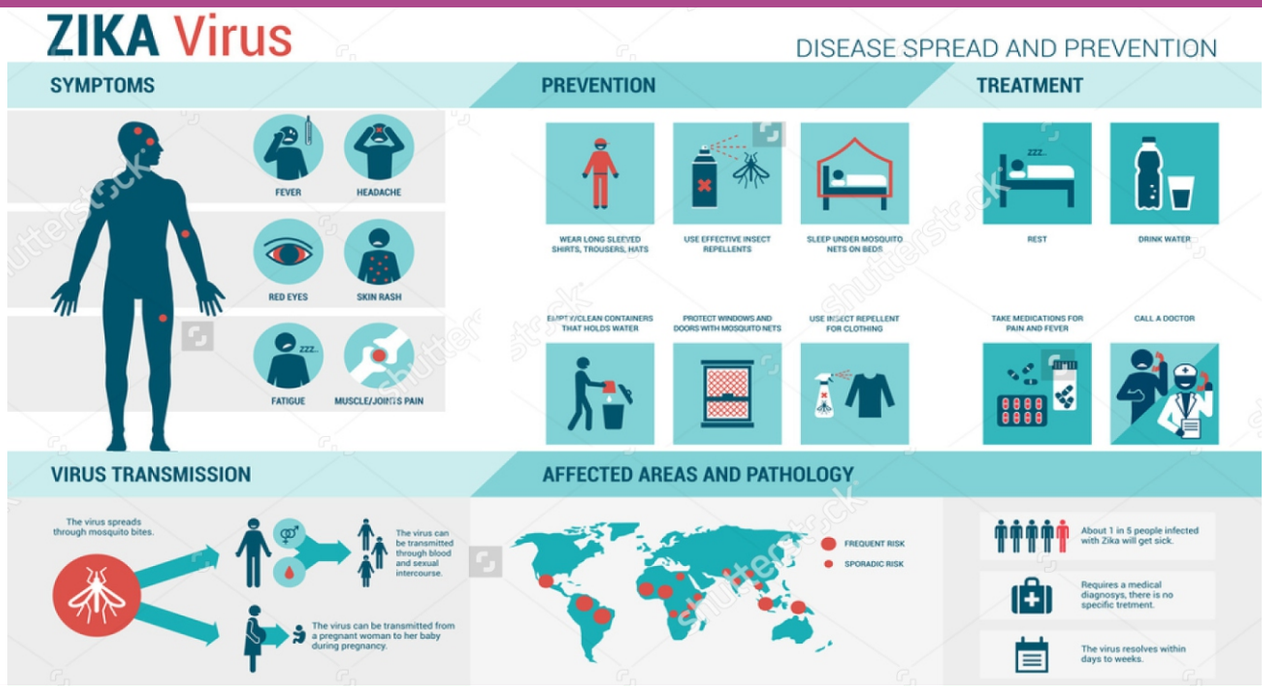
CLINICAL PHARMACY DEPARTMENT ACTIVITIES DURING DEC –2015 FEB - 2016

Sl.No	ACTIVITIES	NO.OF ACTIVITIES	CUMULATIVE TOTAL
1	PATIENT COUNSELLING	103	1160
2	MEDICATION HISTORY INTERVIEW	47	463
3	DRUG INTERACTION	52	460
4	ADVERSE DRUG REACTION	09	101
5	DRUG INFORMATION	53	485



NEW DRUG PROFILE:

MEPOLIZUMAB

Mepolizumab is an anti asthmatic interleukin-5 antagonist monoclonal antibody (IgG1kappa) is indicated for add-on maintenance treatment of patient with severe asthma and for patients (aged 12 year or older and with an eosinophilic phenotype) who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines.

Limitations for usage:

Not for treatment for other eosinophilic conditions and in relief of acute bronchospasam or status asthmaticus

Dosage and administration

100 mg should be administered only by subcutaneous (upper arm, thigh, or abdomen) once every 4 weeks since it is having longer half-life.

Mechanism of action

Mepolizumab is a IL-5 antagonist (IgG1 kappa) IL-5 is a major cytokine responsible for the growth and differentiation , recruitment , activation and survival of eosinophils. Mepolizumab binds to IL-5 with a dissociation constant of 100PM inhibiting bioactivity of IL-5 and thus reduces the eosinophil count and the allergic response.

Adverse Effects

- **Common (incidence > 5%)** Head ache, injection site reactions (pain, redness, swelling, itching or burning feeling at injection site) , back pain and weakness.
- Hypersensitivity reactions can occur within hours or days of being treated with Mepolizumab including swelling of face mouth and tongue. Herpes zoster virus infections have occurred in patients receiving Mepolizumab.

PHARMACOKINETICS

Absorption

The bioavailability of Mepolizumab was estimated to be approximately 80% following repeat SC administration once every 4 weeks, there was approximately a 2-fold accumulation at steady state.

Distribution

The population central volume of distribution of mepolizumab in patients with asthma is estimated to be 3.6L for a 70-kg individual.

Metabolism

Mepolizumab is a humanized IgG1 monoclonal antibody that is degraded by proteolytic enzymes widely distributed in the body and not restricted to hepatic tissue.

Elimination

Following SC administration of Mepolizumab, the mean terminal half-life (t1/2) ranged from 16 to 22 days. The population apparent systemic clearance of Mepolizumab in patients with asthma is estimated to be 0.28L/day for a 70-kg individual.

Renal Impairment : No clinical trials have been conducted to investigate the effect of renal impairment on the pharmacokinetics of Mepolizumab. Based on population pharmacokinetic analyses, Mepolizumab clearance was comparable between subjects with creatinine clearance values between 50 and 80mL/min and patients with normal renal function. There are Limited data available in subjects with creatinine

clearance values less than 50mL/min; however, Mepolizumab is not cleared renally.

Hepatic Impairment : No clinical trials have been conducted to investigate the effect of hepatic impairment on the pharmacokinetics of Mepolizumab. Since Mepolizumab is degraded by widely distributed proteolytic enzymes, not restricted to hepatic tissue, changes in hepatic function are unlikely to have any effect on the elimination of Mepolizumab.

USE IN SPECIFIC POPULATIONS

Pregnancy : The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as Mepolizumab, are transported across the placenta in a linear fashion as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy.

Pediatrics: Safety and efficacy in pediatric patients younger than 12 years have not been established.

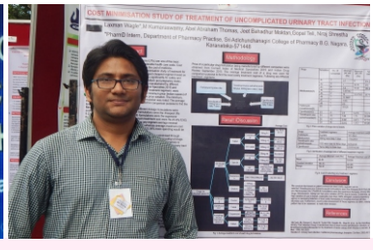
Benefits of Mepolizumab as add-on treatment in asthma.

Mepolizumab or placebo was administered to patients every 4 weeks as an add-on therapy. Compared to placebo patients with severe asthma receiving Mepolizumab had fewer exacerbations requiring hospitalizations and or emergency department visits and a longer time to first exacerbation. In addition patients with some severe asthma receiving Mepolizumab experienced greater reduction in their daily maintenance oral corticosteroids use, while maintaining asthma control compared with patients receiving placebo. However treatment with Mepolizumab did not result in significant improvement in lung function as measured by volume of air exhaled by patients in second.

Compiled by **: James Mathew Pharm D**
IV Pharm D.

DEPARTMENT NEWS

- Mr. K V Ramanath Associate Professor & Dr. Meenu Pandey Assistant professor participated the workshop on curriculum management for Pharm.D course in pharmacy practice clinical held during 4th and 5th February 2016 at RGUHS, Karnataka.
- Dr. Meenu Pandey Assistant professor attended the workshop on curriculum management for Pharm.D course in pharmacy practice clinical held during 8th and 9th February 2016 at SJM College of Pharmacy, Chitradurga.
- Dr. Meenu Pandey and 4th, 5th, 6th Pharm D and PG students of pharmacy practice attended and presented poster in 67th Indian pharmaceutical congress held during 19-21 December 2015 at Mysuru.
- Mr. K V Ramanath & Pharm D Students attended and presented poster in the International conference on evolving the role of Clinical pharmacist in a multi-disciplinary health care settings & Mr. K V Ramanath also worked as a resource person (poster evaluator) in the conference held on Jan 8-9 2016 at Manipal.
- Mr.Laxman wagle Pharm D intern attended Advance Academic training & Quality Improvement Programme On Oncology Pharmacy Practice During 8th To 20th Feb 2016 at Belgaum.



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To.