



Medicine Information NEWSLETTER

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Message from Vice Chancellor

I am happy to know that the Department of Pharmacy is publishing 'Medicine Information Newsletter' for the benefit of all stake holders from physicians to patients.

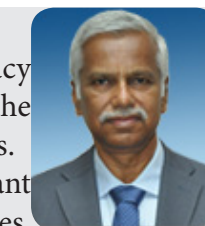
Medicines are undoubtedly the most important weapons of the mankind to fight illness and diseases.

Their safe and effective use is of paramount importance to avoid harming the patients and prevent economic loss. Inappropriate use of medicines is a global issue and all around efforts are necessary.

Availability of reliable and unbiased medicine information from prescribers to the patients is crucial to derive the maximum benefits from medicine use. The healthcare professionals mostly receive information on medicines from the pharmaceutical companies and other web sources which may be biased, misleading and even outdated. The information from independent sources are often inaccessible.

The laudable initiative of the Department of Pharmacy to publish Medicine Information Newsletter to provide adequate and updated independent information is a welcome move. Hope this may be useful to promote rational use of medicines both in the healthcare facilities and community.

I wish them all the best in their ventures.



-Dr. S. Manian

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The desire to take medicine is perhaps the greatest feature which distinguishes man from animals.

- William Osler

From Editors' Desk

We have the great pleasure in presenting the SECOND ISSUE of our quarterly electronic publication 'Medicine Information Newsletter' with the message of our new Vice Chancellor.

WHO's warning "MERS-CoV posed a threat to the entire world" in May 2013 continues to be alarming even today. Middle East Respiratory Syndrome (MERS) is reported to have infected over 1300 persons spreaded globally covering over 25 countries. It has already killed 37% of the infected cases. Early symptoms of MERS are similar to nonspecific febrile respiratory tract infection with potential to progress rapidly leading to respiratory failure. Public health measures like infection prevention and control, isolation, contact tracing and quarantine; and improved hand hygiene in community and health settings are proven useful measures combating MERS.

This issue focuses on Bedaquiline for treatment of MDR TB, safety alert on antidiabetic and cardiology medicines; open access to Global Safety Data Base and the usual features: website of interest, forthcoming courses. Additionally, the current issue contains the list of important health days falling in the next quarter (July to September) as a ready reference for observation and celebration.

We wish our readers happy reading and look forward their constructive feedback for improving the contents as well as usefulness. One can reach us through e.mail: dicpharmd@gmail.com.

Merck Manual On-Line

The Merck Manual which has been one of the important sources of health and drug related information is now available on line at www.merckmanuals.com. The site features two options: one for the healthcare professionals (physicians, pharmacists and nurses) and the other for common man (patients, care givers or parents). It is free.

Medicines to Avoid [Rev Prescriber February 2015]

These medicines are more harmful than beneficial and alternatives are available. In this issue we have included the medicines related to cardiology.

Aliskiren, an antihypertensive rennin inhibitor, has not been shown to prevent cardiovascular events. On the contrary, a trial in diabetic patients showed that the drug was associated with an excess of cardiovascular events and renal failure. It is more prudent to choose one of the many

tried and tested antihypertensive drugs such as a diuretic or an angiotensin – converting enzyme (ACE) inhibitor.

Fenofibrate, Bezafibrate, and Ciprofibrate are cholesterol lowering drugs with no proven efficacy in the prevention of cardiovascular events (beyond the placebo effects). They have many adverse effects including cutaneous, haematological and renal disorders. When a fibrate is considered, Gemfibrozil is the only one that has been shown to prevent cardiovascular complications of hypercholesterolaemia, although it must be used with care.

Ivabradine, an inhibitor of cardiac I_f current, can cause visual disturbances, cardiovascular disorders including MI, potentially severe bradycardia and other cardiac arrhythmias. It has no advantage in angina or heart failure. Treatments shown to be effective in angina include beta-blockers and calcium channel blockers Amlodipine and Verapamil. There are also far better options for heart failure: one is to refrain from adding another drug to an optimized treatment regimen; another is to use a beta-blocker with a proven impact on mortality.

Nicorandil, vasodilator with solely symptomatic efficacy in the prevention of effort angina, can cause severe mucocutaneous ulceration. It is more prudent to use a nitrate to prevent effort angina.

Olmesartan, an angiotensin II antagonist (sartan), is not more effective than other sartans in arterial hypertension. This can cause bowel inflammation with chronic diarrhoea (potentially severe) and weight loss and possibly an increased risk of cardiovascular mortality. It is better to choose another of several available sartans, such as Losartan and Valsartan, which do not appear to have these adverse effects.

Trimetazidine, a drug with uncertain properties, is used in angina despite its only modest symptomatic efficacy (shown mainly in stress tests). It can cause parkinsonian syndrome; hallucinations and thrombocytopenia. It is far more prudent to choose better known treatments for angina, such as certain beta-blockers or the calcium channel blockers Amlodipine and Verapamil.

Topical NSAIDs for acute pain in adults

A recent Cochrane review confirmed the effectiveness of topical non-steroidal anti-inflammatory drugs (NSAIDs) is similar to that of orally administered ones. The study compared the effects of NSAIDs in the form of gel, spray, or cream. Formulations of topical diclofenac, ibuprofen, ketoprofen, piroxicam, and indomethacin demonstrated significantly higher rates of clinical success than matching topical placebo. Benzydamine did not. Gel formulations of diclofenac (as Emugel®), ibuprofen, and ketoprofen, and some diclofenac patches, provided the best effects. The adverse events reported were very minimal. Local skin reactions were mild and transient and similar to placebos.

[<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007402.pub3/abstract>]

Open Access to WHO Global Medicine Safety Database : VigiAccess

The World Health Organization's suspected adverse drug reactions database maintained by the Uppsala Monitoring Centre (UMC) is now open for everyone. It allows everyone to browse and view data at

<http://www.vigiaccess.org>

Deadly Camel Virus at Doorstep

The World Health Organization (WHO) has urged India to 'enhance surveillance for severe acute respiratory infection, focus on early diagnosis, and step up infection prevention and control procedures in health care facilities'. A new virus, 'camel virus' is now on the way to India from Seoul, capital of South Korea. The virus is technically called the Middle East Respiratory Syndrome Corona Virus or MERS has taken a huge toll on the confidence of the South Koreans. The original host of MERS CoV virus was camel and hence the name as camel virus. The new virus seems to have reached Seoul on May 22, 2015 and by one month it has infected more than 160 cases and killed at least 24 persons. Though the virus has not yet arrived India, it is likely to get access through travellers who come to India from affected areas.

Since the MERS virus's first appearance in 2012, more than 1300 cases have been reported worldwide. More than 500 persons died. The virus has very high mortality rate killing almost 37% of the infected persons. The common symptoms of the infection are like a cough, has fever, and a shortness of breath with a sensation of vomiting and in severe cases it causes a pneumonia and kidney failure. Medical and travel case history are crucial in diagnosis.

New, Free Maternal Infections Online Training Course

Maternal Infections is a free, online, open access training course developed by the Nuffield Department of Obstetrics & Gynaecology at the University of Oxford, Harvard Maternal Health Taskforce, The Global Health Network and the Geneva Foundation for Medical Education and Research. The course has 6 modules: Overview of maternal infections, HIV in Pregnancy, Urinary Tract Infections in Pregnancy, Maternal Sepsis, Syphilis in pregnancy, Malaria in Pregnancy. On completion of the modules, there is final quiz. More details can be seen at: <https://globalhealthtrainingcentre.tghn.org/maternal-health-infections>

Revision of Essential Medicine List

The World Health Organization has recently revised the Essential Medicine List. The WHO has been revising the model list every two year since the first edition released in 1977. The concept of essential medicine list for public health facilities has been widely accepted as important public health intervention. The 19th WHO Model List of Essential Medicines (April 2015) can be accessed at http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf and 5th WHO Model List of Essential Medicines for Children (April 2015) can be accessed at http://www.who.int/medicines/publications/essentialmedicines/EMLc2015_8-May-15.pdf.

The Government of India is now in the process of revising its list. National Essential Medicine List has wide significant to our public health as the prices of these medicines are controlled under the Drug Price Control Order to make them affordable.

Dietary Potassium - Beneficial in Hypertension

Study has shown that large increases in dietary potassium (above the generally inadequate amounts currently consumed) can significantly lower blood pressure and reduce the occurrence of hypertension and one of its most serious consequences: strokes. An increase in population dietary potassium intake of 1.5 gm/day could avert over one million deaths from stroke per year on a worldwide scale and is expected to produce overall health benefits by reducing the impact of consequent disabilities. Modest dietary salt restriction



„Potassium Lowers Blood Pressure.“

with increasing potassium intake serves as broad spectrum strategy to prevent or control hypertension and decrease cardiovascular morbidity and mortality. Salt intake higher than 8 g/day is considered as a risk factor for hypertension. Dietary potassium intake is recognized as essential public health effort to reduce the rates of hypertension and to prevent kidney disease, stroke and cardiovascular disease. Fruits (Banana, Orange etc.), vegetables (Potatoes, Tomatoes, Beet, Soybeans, Spinach etc.) and milk are rich sources of potassium.

Important Health Days

July 1: Doctors Day
July 11: World Population Day
July 29: ORS Day
August 1-8: World Breast Feeding Week
August 25 – September 8: Eye Donation Fortnight
September 1-7: National Nutrition Week
September 12: World Oral Health Day
September 21: World Alzheimer Day
September 25: World Pharmacists Day
September 26: World Day of Deaf
September 28: World Heart Day / World Rabies Day

COURSES

1. 3rd International Course on Rational Use of Medicines with Added Focus on HIV&AIDS, TB and Malaria, scheduled to be held at the IIHMR University, Jaipur, India, from August 17 to 28, 2015. More details are available at <https://iihmr.edu.in/Training-Program/training-detail.aspx>.
2. Online Rational Medicines Use Module will be offered by the University of the Western Cape Schools of Public Health and Pharmacy, in collaboration with the SIAPS, Richard Laing (BUSPH and ex-WHO) and other partners. Further details can be seen at: <http://www.uwc.ac.za/Faculties/CHS/soph/News/Pages/NEW-Online-Rational-Medicines-Use-Module.aspx>

Government restricted the advertisement of medicines

The Government of India in a recent notification restricted the advertisement of medicines. The notification says “No advertisement of the drugs specified in Schedule H, Schedule H1 and Schedule X shall be made except with previous sanction of the Central Government”. The restriction of advertisement is made in public interest as the advertisements are likely to influence self medication leading to often harming individual’s health.

Schedule H contains medicines which are to be sold on the prescription of registered medical practitioners only. The Schedule H1 is curved out of Schedule H whose sells are more restricted. The Schedule H1 contains third and fourth generation antibiotics, anti-tubercular medicines and habit forming medicines. The chemists while selling these medicines on prescription of registered medical practitioners require proper documentation of records. The Schedule X has Narcotics and Psychotropic Substances and the chemists require preserving the copy of the prescription.

ALERT ON DIABETIC MEDICINES

Recently the US FDA issued warning on three new antidiabetic medicines used in type 2 diabetes: canagliflozin, dapagliflozin, and empagliflozin “may cause acidosis leading to hospitalization”. These medicines belong to the category sodium-glucose cotransporter-2 inhibitors (SGLT2 inhibitors) which work by removing sugar with urine through kidney. Till a regulatory decision is made the doctors should evaluate the presence of acidosis in patients for safe medications. The doctors and the pharmacists should educate the patients to keep a watch for signs of ketoacidosis such as difficulty in breathing, nausea, vomiting, abdominal pain, confusion, and unusual fatigue or sleepiness and seek medical attention. These two: canagliflozin and dapagliflozin medicines are available in India.

USFDA advises the prescribers to discontinue SGLT2 inhibitors if acidosis is confirmed and initiate appropriate measures to correct the acidosis while managing blood glucose level.

[Source: <http://www.fda.gov/drugs/drugsafety/ucm446845.htm>]

Website of Interest

International Association for Public Health Logisticians (IAPHL):

The International Association of Public Health Logisticians (IAPHL) is a professional association dedicated to improving public health supply chain management by promoting the professional development of those who work with health supplies, including nurses, pharmacists, and others carrying out logistics tasks. IAPHL supports supply chain professionals by providing them with access to resources, job listings, and facilitated listserv discussions related to public health supply chain management. The membership to the association is free. The more details can be accessed at: <http://iaphl.org>

Bedaquiline 100 mg Tablet [for MDR-TB]

Bedaquiline is recently approved by the Government of India for use as part of combination therapy of pulmonary tuberculosis due to multi-drug resistant *Mycobacterium tuberculosis*. This should be used when an effective treatment cannot be provided. US FDA has approved this drug in December 2012 on fast track basis. This is the only US FDA approved tuberculosis drug in last 40 years.

Having limited data on safety and efficacy of the drug, the World Health Organization (WHO) has the following interim recommendations:

- To be added to only WHO recommended regimen in adult MDR – TB patients;
- Treatment should be offered under closely monitored conditions;
- Treatment is meant only for adults (18 years and above). Special precaution for persons of 65 years or older and adults with HIV;
- Use in pregnant women and children is not advisable;
- Should be used with caution in patients with co-morbidities (diabetes), or persons with alcohol or substance of abuse;
- There is need of clinical monitoring and management of co-morbidities (especially cardiac and liver diseases);
- To be used for a maximum duration of 6 months and at suggested dosing (400 mg daily for the first 2 weeks, followed by 200 mg three times per week for the remaining 22 weeks);
- There should be system to ensure early detection and timely reporting of adverse events using active pharmacovigilance methods (cohort event monitoring);
- Must not be added alone to a failing regimen
- Resistance to the drug should be monitored; and
- Duly informed decision making process by the patients should be followed.

Adverse events (AE): The most frequently reported are nausea, arthralgia, headache, hyperuricaemia, and vomiting. Additional AEs, in order of frequency, are dizziness, increased transaminases, myalgia, diarrhoea and QT prolongation on electrocardiogram (ECG) and hepatic disorder. Limited clinical trial data showed higher incidences of deaths compared to placebo groups.

Efficacy: The proportion of subjects defined as cured at 120 weeks was 57.6 % in the bedaquiline arm versus 31.8% in the placebo arm.

[Source: The use of bedaquiline in the treatment of multi-drug resistant tuberculosis, Interim Policy Guidance, WHO, 2013]

DISCLAIMER

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