DOCTOR OF PHARMACY

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PharmawizNewsletter

Editorial desk...

It gives me immense pleasure to publish Pharmawiz Vol. 3, Issue 2. I believe newsletter is a platform to share ideas, and exchange experience of various personalities of pharmaceutical and medical field. Health is knowledge intensive sector where medicines/drugs play a key role. The safety, efficacy and strong regulations are vital aspects in providing and achieving rational drug therapy. Currently, the issue of availability of generics in India has come into focus, as pharmaceutical care through medicine has becomes a costly affair. Our country is the second largest producer of generics, but availability of quality generics in India is far behind reality as compared to what gets exported to US and Europe and other international markets. At least generics should be promoted in the management of cancer, diabetes, rheumatoid arthritis, osteoporosis, psychiatric disorders where drug has to be consumed for a prolonged period of time. Few of the state governments like Punjab, Orissa, Delhi, Haryana, Rajasthan have introduced generics in the healthcare sectors at various civil hospitals by supporting the opening of "***Jan Aushadhi Kendra***" outlets for the poor patients, but its success and existence in future is still questionable. Only a handful of states have come up with such programmes that are very limited in numbers and in few districts only. The drugs are made available at half the rates to poor patients but the effectiveness of these medicines has to be regulated and tested.

I would like to congratulate Mr. Mahesh Zagade, IAS, Commissioner, FDA Maharashtra,for controlling and regulating the dispensing of medicines through presence of qualified pharmacist only in various medicines retail outlets, which would at least promote rational drug dispensing and distribution. I would like to call upon all the pharmacy associations, community pharmacists and hospital pharmacists to come together to promote generics, just not in terms of cost but cost effective generics at every civil and primary health care centers.

Dr. Atmaram Pawar
Vice Principal & HOD
PharmD Programme

INSIDE THIS ISSUE:

Guest Column- What Makes Clinical Research Ethical

The violations of the rights of human subjects have lead to formulation of guidelines for research on human subjects that extends beyond the concept of informed consent. Most of the international guidelines were developed in response to specific crises. Thus, they do not present a general framework, but tend to focus on a single issue. These guidelines are among those recognized as world standards. However, because they tend to be developed in response to specific events and scandals, each emphasizes certain ethical requirements and ignores others. Based on the basic philosophies underlying major codes, declarations, and various ethical practices relevant to research with human subjects, 6 requirements are proposed that systematically elucidate a coherent framework for evaluating the ethics of clinical research studies:

(1)**Valuable scientific question**-enhancements of health or knowledge must be derived from the research; (2)**Valid scientific methodology**-the research must be methodologically rigorous;

(3)**Fair subject selection**-scientific objectives and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individual subjects;

(4)**Favorable risk-benefit evaluation**-within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5)**Informed consent**-individuals should be informed about the research and provide their voluntary consent; and (6)**Respect for enrolled subjects**-subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored.

Fulfilling all 6 requirements is necessary and sufficient to make clinical research ethical. These requirements are universal, although they must be adapted to the health, economic, cultural, and technological conditions in which clinical research plays vital role.

Mrs. Shilpa Kulkarni
(CTA,Reliance CRO,Mumbai)

WALKING IS THE BEST POSSIBLE EXERCISE. HABITUATE YOURSELF TO WALK VERY FAR. - THOMAS JEFFERSON

CITALOPRAM HYDROBROMIDE

DRUG ALERT

Ref- FDA Drug Safety Information

Currently, FDA has announced that higher doses of Citalopram can cause potential risk of QTc prolongation. So, it is recommended that citalopram should not be given at doses above 40 mg/day. It is recommended that citalopram should not be used in patients with congenital long QT syndrome, bradycardia, hypokalemia or hypomagnesemia, recent acute myocardial infarction, or uncompensated heart failure.

Electrolyte and/or ECG monitoring is recommended in certain circumstances. Patients being considered for citalopram treatment who are at risk for significant electrolyte disturbances should have baseline serum potassium and magnesium measurements with periodic monitoring.

NEWS STRIKE- Indian Medical Association is against the new directive of the MCI which mandates heads of medical colleges, hospitals and its state chapters prescribe medicines only in generic terms.

Evidence Based Drug Review [Student Corner]

Alogliptin: A review of its use in the management of type 2 diabetes mellitus.

Alogliptin is a dipeptidyl peptidase-4 inhibitor that is recently approved by FDA for the treatment of adult patients with type 2 diabetes mellitus that is inadequately controlled by diet and exercise alone or by diet plus treatment with an á-glucosidase inhibitor. Alogliptin plus diet and exercise is also approved for use in combination with a thiazolidinedione in patients with type 2 diabetes. In several large (n >250), double-blind, multinational trials of up to 26 weeks' duration, oral alogliptin as monotherapy or in combination with other oral antihyperglycaemic agents (metformin, glibenclamide orpioglitazone) or insulin therapy improved glycaemic control and was generally well tolerated in adult patients with inadequately controlled type 2 diabetes, including elderly patients.

Significant improvements in glycaemic control were evident from as early as 1 week in terms of improvements in mean fasting plasma glucose levels and from 4 weeks onwards for improvements in mean glycosylatedhaemoglobin levels. In general, the incidence of hypoglycaemia was similar to that seen in placebo groups and alogliptin treatment had neutral effects on bodyweight and lipid parameters. The long-term safety of alogliptin therapy remains to be established in clinical studies and with clinical experience. A planned clinical trial evaluating long-term clinical outcomes in patients with acute coronary syndromeand other planned or ongoing short-term trials will help to more definitively determine the position of alogliptin therapy in relation to other available antihyperglycaemic therapies. In the meantime, alogliptin is a promising new option for the treatment of patients with type 2 diabetes, including elderly patients.

BabluYadav, PharmD Intern

What is Evidence Based Practice???

The most common definition of EBP is taken from Dr. David Sackett, a pioneer in evidence-based practice. EBP is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research." (Sackett D, 1996)

EBP is the integration of clinical expertise, patient values, and the best research evidence into the decision making process for patient care. Clinical expertise refers to the clinician's cumulated experience, education and clinical skills. The patient brings to the encounter his or her own personal and unique concerns, expectations, and values. The best evidence is usually found in clinically relevant research that has been conducted using sound methodology. (Sackett D, 2002)

Drug Warning

Atypical femoral fracture have been reported rarely with bisphosphonate therapy, mainly in patients receving long-term treatment for osteoporosis. Discontinuation of bisphosphonate therapy in patients suspected to have an atypical femur fracture should be considered while they are evaluated, and should be based on an assessment of the benefits and risk of treatment.

The need to continue bisphosphonate treatment for osteoporosis should be re-evaluated periodically based on the benefits and potential risks of bisphosphonate therapy for individual patients, particularly after 5 or more years of use.

Pharmaw1z Quiz-

Q-1 What is the new maximum recommended dose of simvastatin when used with amlodipine or diltiazem? Why has this limitation been introduced?

Submit answer at:-

bvpcp.dic@gmail.com
www.bvupcp.edu.in
Till then
Happy Searching...

Drug Information "Helpline"And Paediatric Dose Division (PDD) Services

Drug Queries	Patients Counseled	PDD	Category of Drug Queries					
			Indication	ADR	Admn	Efficacy/ Safety	Poison	Others
14	50	14*	4	2	4	3	0	7

*Oxybutinin, enalpril meleate, lasilactone, lansoprazole, bosentan etc.

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3) GUIDE PUBLIC REGARDING FALSE CLAIM MADE IN AN ADVERTISEMENT A DRUG OR DISEASE CURE METHOD BY DRUGS.

4) DO NOT PROVIDE ANY INFORMATION RELATED TO SURGERIES, ALLIED MEDICAL TREATMENTS. ALWAYS CONSULT THE RESPECTIVE HEALTH CARE PROVIDER.

Drug Interaction- Recommendations on simvastatin interactions with amlodipine

Why has the simvastatin dosing guidance changed?

Myopathy is an adverse effect associated with statins. The risk of myopathy increases with higher plasma levels associated with high-dose therapy (simvastatin 80mg) or concurrent use of interacting drugs.

Key change: the maximum dose for simvastatin in conjunction with amlodipine is now 20mg daily.

What are the implications for patients taking amlodipine?

Reducing simvastatin dose to 20mgmost patients can be managed this way as the interaction with amlodipine leads to an increase in simvastatin exposure that is similar to taking simvastatin 40mg alone.

Staying on simvastatin 40mg discuss the risks and benefits of this 'off-label' option with the patient. Be aware that, due to the interaction with amlodipine, exposure to adverse effects is similar to that associated with simvastatin 80mg when given alone.

Change to an alternative statin Pravastatin, fluvastatin or rosuvastatin do not interact with amlodipine. Atorvastatin (20mg or 40mg daily) is an option if a more potent statin is needed. The risk of an interaction with amlodipine is much lower with atorvastatin than simvastatin.

Change to an alternative calcium channel blocker- do not change therapy in patients who are well controlled with amlodipine. Altering the calcium channel blocker is clinically less desirable.

Note-The maximum dose of simvastatin is also 20mg with verapamil and diltiazem.

Do other calcium channel blockers have similar effects on simvastatin?

Verapamil and diltiazem are known inhibitors of CYP3A4; the maximum dose of simvastatin is 20mg daily in patients taking these. Other calcium channel blockers do not interact with simvastatin.

What does NICE say about pharmacotherapy for lipid lowering?

Use 40mg simvastatin or drug of similar efficacy and acquisition cost.

Simvastatin 20mg has similar efficacy to simvastatin 40mg, when given in combination with amlodipine.

Ref- MHRA *Drug Safety Update* (August 2012)

Drug Safety Advice

Dibigatran is now contraindicated in patients with prosthetic heart valves requiring anti-coagulant treatment related to their valve surgery. This is regardless of the length of time elapsed since valve replacement took place. The contraindication is based on new clinical trial data in this population, which showed an increased frequency of thromboembolic and bleeding events in the group of patients treated with dabigatran compared with warfarin.

Ref- MHRA drug safety issue,Vol-5,Issue 12,July2012

Case Report- Proton pump inhibitors in long term use: reports of hypomagnesaemia

Ref-Drug Safety Update April 2012 vol 5, issue 9: A1.

Prolonged use of proton pump inhibitors (PPIs) has been associated with hypomagnesaemia. Healthcare professionals should consider measuring magnesium levels before starting PPI treatment and repeat measurements periodically during prolonged treatment, especially in those who will take a PPI concomitantly with digoxin or drugs that may cause hypomagnesaemia (eg, diuretics). Severe hypomagnesaemia has been reported infrequently in patients treated with PPIs, although the exact incidence is unknown.

A review of case reports described in the literature or reported to regulatory authorities in Europe suggests that PPIs may cause hypomagnesaemia. Some cases occurred after 3 months of PPI therapy, but most occurred after 1 year of treatment. Serious manifestations of hypomagnesaemia—fatigue, tetany, delirium, convulsions, dizziness, and ventricular arrhythmia—can occur, but they may begin insidiously and be overlooked. In most case reports, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI.

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Departmental News And Activities

Patient Education And Counseling Program

A Patient education and conseling program in association with Dept. Of Medicine, Bharati Medical College and Hospital, BVDU was held on 7th Feb 2013. Over 33 patients and there dignitaries from social ward department attended the session. Dr. Arundhati Diwan, HOD, Dept. Of Medicine highlighted the simple tips to maintain a normal blood pressure and educated about its complication. Dr. A.P. Pawar, HOD, Vice principal, PCP, BVDU emphasized on the availability of generic drugs, its importance in management of hypertension and provided simple tips on how to monitor its efficacy. Chetan Sonar, Kaveri Lokhande and Soamya Padma Pharm-D, students counseled the patients regarding management, drug administration and importance of compliance in HTN therapy. Most of patients reported very actively, as if they got what they expected.Sunita Pawar, Assistant Professor, Presided the complete program and concluded with the statement.

"ASK YOUR PHARMACIST"

Book Launch

IPA Pune Local Branch in association with Nirali Prakashan Pune organized open discussion on "Generic Drugs", where "Generic Aushade: Samaj-Gairsamaj" a marathi script book authored by Dr. Atmaram Pawar, President, IPA Pune Branch was released by Shri. Satej Patil Minister for State FDA Maharastra. Dr. Himadri Sen, Chairman, Pharmagroup Steer World, Mr Arun Kumar Khanna Executive Director,Emcure Pharma, Dr. Mrs Maya Tupule, President, IMA Pune branch were the eminent speakers present Hon. Minister felicitated Vijay Patil, President, MSPC Maharashtra, Dr. Pravin Choudhari, Dean, Pharmacy Pune University and Shridhar Joshi of JB Chemicals for their contribution in respective field. Mr. Sachin Itkar, Secretary IPA Pune was the convener and Dr. Neeraj Vyavhare was the coordinator of the program.

Guest Lecture:

Vinod V Nair, PharmD, MBA, Swiftwater, Pennsylvania addressed about scope of PharmD and pharmacy graduates in United States on 4th of January, 2013. He gave a spotlight on requirement of education, current trend of pharma market in US.

Dr. Jyoti Shetty, Professor and HOD of Psychiatry, Bharati Hospital on February 28, 2013. She centralized her talk about "Mood and Anxiety disorder and its Management. She also emphasized diagnostic parameter introduced globally.

Dr. Neelam Kardekar, (Manager, Clinical Research, Lupin) was invited to pinpoint a speech on "Drug Safety and Pharmacovigilance". She emphasized on the importance and scope of pharmacoviglance, along with up-to-date information on timelines for regulatory reporting.

Paper Presentations at International Conference:

1.Ms. Asawari Raut, Asst. Professor, presented a paper titled "**Severity and Preventability of ADR in geriatrics patients**" organized by SAC-ACCP IPA, Mumbai (21st-22nd April 2013.

2.Papers presented by PharmD Interns on "**Pattern of use and Pharmacoeconomic Impact of Antihypertensive Drugs in Hypertensive Disorder of Pregnancy"** at IPS Pharmacon-2013, Ahmedabad, Gujarat.

3.Papers presented by PharmD Interns at South Asian Chapter of American College of Clinical Pharmacology, Mumbai (India) 2013 on-

- ·Eclampsia- A Retrospective Study in a Tertiary Care Center.
- ·Prevalence of Drug Related Problem & Economic Analysis of Geriatric Patients in Tertiary Care teaching hospital.
- ·Cost of Dengue to Households: A Prospective Analysis.

To,

Book -Post