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BVDU-PCP

Pharmawiz Newsletter

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Editorial desk

Dear Readers,

Greetings for the New year.

Pharmacy Council of India announced to observe 25th September as "PHARMACIST DAY"to recognize and honor pharmacist in healthcare sector and encouraged every State Pharmacy Councils, Institutions and association to celebrate this occasion. PCP-BVDU celebrated "WORLD PHARMACIST DAY" in collaboration with Chemist Association of Pune District (CAPD). Mr. BR Masal, Joint Commissioner (Drugs), FDA, Pune, Dr. K R Mahadik, Principal (PCP), Mr. Santosh Khiwansara, CAPD President, Mr. Vijay Changediya, CAPD Secretary chaired the function. Sudhakar Jadhav Ex-Asst. Commissioner, FDA,Pradip Supekar, Community Pharmacist and Arun Gandhi, Ex-Manager Nulife Pharma, Pune were felicitated on this occasion for their relentless contribution in various aspect to establish a healthy society.

Students and faculty members of PCP are constantly involved in providing social services such as, Organizing Camps with Medical allies, providing unbiased drug information to professionals and public, assisting in Pediatric Dose Division, conducting education and counselling programs in community etc. I hope the newsletter unlocks all my readers about medicines and updates in pharmaceutical field.

Dr. A P Pawar, HOD & Vice Principal, PCP-BVDU

Five Ideas to Make a Research Site more Subject Friendly (Guest Column)

The main objective of this column is to clear some page breaks that have spotted by the Clinical Research volunteers in making their research participation more familiar. Below are the five points which proves that the research participation is friendlier towards subject.

1.Making contact points perfectly clear: There are two main key points where research subjects interact with research centre:

The research centre / waiting room in research centre must be clearly visible.

The research centre should have an independent communication system in order to keep the onboard volunteers in contact.

2. Make front desk experience informative

The clinical research front desk should be well organized and regularly updated about the schedule of the doctors and their appointments. A blank sign-in-sheet is commonly observed in all the investigation sites to maintain a record of all the visitors on that particular day which is collected by a sponsor to know about the visits. This can be advanced by generating a list of all the appointments including name of visitor, scheduled appointment time and the duration of appointment and circulate it among the site team.

3. Mark the visit, make sure everyone is on same page

Most of the Research centers follow a study schematic protocol to view the study details statistically. The visit numbers are entered in columns and the study procedures are entered in rows which make the document easily understandable and eye catching. This makes the subject be aware of the study procedure at that particular visit and also allows the subject to prepare for the visit.

4. Personal touch of the PI

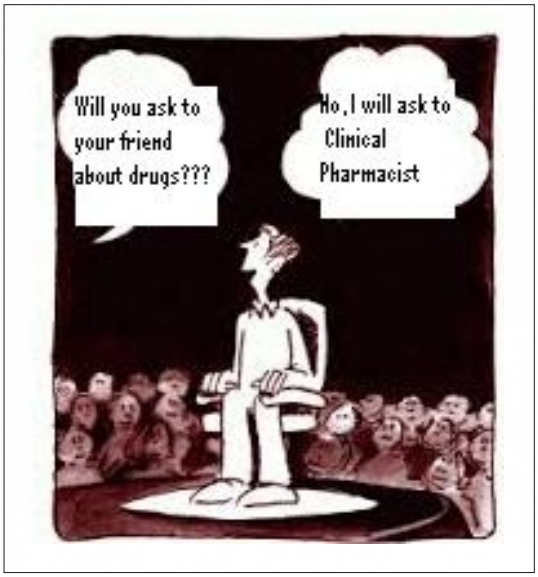
Past surveys indicate that Principal Investigators (PI) enforce most of the study visits to be conducted by the study coordinators in Phase III clinical trial and the PI may be present only at the time of physical examination protocol. However, PI remains the obligation to supervise the clinical trial personally and to take charge at any adverse event that might occur. Though the study procedures are routine and can be delegated to trained staff, the presence of PI moralizes the subject. A timed visit by the MD may not only moralizes the subject but also adds in improving the accuracy of the data provided by the investigate site team.

5. Scramble drill for busy times

Its quite often that there may be a delay or absence to the shift by any staff member due to late or illness, which makes the subjects to stay in the waiting arena for longer time. This can be avoided by making a "subject friendly site organization "whose major objective is to not place the burden of time delays on the shoulders of the subjects. The working of the subject friendly site organization is to implement a logical solution for the backup of each position in every shifts. A honest communication of letting the subject be aware of the reason for time delay and how long will it affect their appointment.

Mr. Sandeep Kaul (Project Manager,Jubilant Clinsys Ltd.,Mumbai)

HE WHO TAKES MEDICINE & NEGLECTS TO DIET WASTES THE SKILL OF HIS DOCTORS - CHINESE PROVERB



Fluoroquinolone

Ref- *FDA Drug Safety Information*

The risk of peripheral neuropathy occurs with approved fluoroquinolones (levofloxacin, ciprofloxacin, moxifloxacin, norfloxacin, ofloxacin and gemifloxacin) that are taken by mouth or by injection. If a patient develops symptoms of peripheral neuropathy, the fluoroquinolone should be stopped, and the patient should be switched to non-fluoroquinolone antibacterial drug, unless the benefits outweigh the risk. Peripheral neuropathy can occur at any time during treatment with fluoroquinolones and can last for months to years after the drug is stopped or be permanent. Patients who develop symptoms like numbness and tingling in feet and hands, unusual sweating, muscle weakness using fluoroquinolones should immediately consult their doctor.

NEWS STRIKE- 1st December 2013 survey: The rate of HIV infection is declining Worldwide, 2.3 million people became newly infected with HIV in 2012, down from 3.4 million in 2001.

Evidence Based Drug Review

[Student Corner]

Racecadotril: A Review of its use in management of diarrhoea in adults and children

Racecadotril is a novel antidiarrhoeal agent indicated in the treatment of acute diarrhoea. Racecadotril (acetorphan) is an antisecretory drug that exerts its antidiarrhoeal effects by inhibiting intestinal enkephalinase. Racecadotril reduces hypersecretion of water and electrolytes into the intestinal lumen by preventing the degradation of endogenous enkephalins. Racecadotril (1.5 mg/kg 3 times daily) as adjuvant therapy to oral rehydration solution significantly reduced mean stool output in 2 randomised, double-blind studies in paediatric patients (aged 2 months to 4 years) with severe acute diarrhea compared with placebo recepients. Racecadotril significantly reduced the incidence and duration of diarrhoea and the number of diarrhoea-related symptoms compared with placebo in a double-blind trial (n=193) in adult patients with acute diarrhoea of infectious origin. Compared with placebo, the incidence of diarrhoea was reduced by 30% and the duration of diarrhoea by 1 day. In addition, diarrhoea-associated symptoms including abdominal pain, anal burning, anorexia and nausea were significantly reduced compared with placebo. Racecadotril appeared to have similar efficacy to loperamide for the treatment of adults and children with acute diarrhoea in several double-blind comparative trials. Both racecadotril (1.5 mg/kg 3 times daily) and loperamide (0.03 mg/kg 3 times daily) resulted in resolution of acute diarrhoea within 1 to 2 days of initiation of treatment in double-blind trials carried out in 102 children aged 2 to 10 years and in 147 adults with acute diarrhoea. Racecadotril treatment resulted in fewer adverse events, particularly constipation, than loperamide in adults compared to chlidren. It is significantly more effective than placebo and shows similar or slightly reduced efficacy compared with loperamide. However, racecadotril appears to be better tolerated than loperamide resulting in lower instances of post-treatment constipation and abdominal distension. The good tolerability profile in children less than 4 years of age is particularly important since loperamide is not recommended for use in infants and young children. Further work is required to establish the efficacy of this drug in diarrhoea caused by other specific enteropathogens.

Ref: Wang HH, Shieh MJ, Liao KF. A blind, randomized comparison of racecadotril and loperamide for stopping acute diarrhea in adults. World J Gastroenterol 2005; 11(10): 1540-1543.

Drug Warning

FDA has approved label changes and added a new Medication Guide to address the safety issues related to ketoconazole oral tablets including limited drug usage and warning that it can cause liver injury, which may potentially result in liver transplantation or death. It may cause adrenal insufficiency by decreasing the body's production of corticosteroids and advising that it can lead to harmful drug interactions with other medications. It can be used for the treatment of certain fungal infections like endemic mycosis only when alternative antifungal therapies are not available or tolerated. Liver status like serum ALT levels and Adrenal function in patients with adrenal insufficiency or with borderline adrenal function should be assessed during treatment.

Pharmaw1z Quiz-1

Q-1 When is codeine considered to be used in children? Why it has restricted use in children?

Submit answer at:-

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

Drug Information "Helpline" service/Paediatric Dose Division(PDD)

Drug Queries	Patients Counseled	PDD	Category of Drug Queries					
			Indication	ADR	Admn	Efficacy/ Safety	Poison	Others
38	15	53*	10	9	4	5	6	4

*Hydrochlorothiazide, Diazoxide, Sildenafil, Acetazolamide, Cisapride, Indomethacin, Bosentan, lansoprazole etc.

We can help you with any questions you might have on the use of drugs or any information regarding the drugs . We assist you with any drug related problems you face in your daily practice.

Phone : (020) 24368227/40555555 Ext. 308 **E-mail: bvpcp.dic@gmail.com**

1) WE DO NOT PRESCRIBE OR ADVISE TO TREAT ANY DISEASES. IT IS THE ROLE OF PHYSICIANS.

2) WE PURELY PROVIDE INFORMATION ON HOW A PRESCRIBED DRUG WORKS, DRUGS ADMINISTRATION TECHNIQUES, SIDE-EFFECTS, INTERACTION WITH OTHER DRUGS AND FOOD, COUNSEL ON DRUG PROBLEMS AND HEALTH PROBLEMS.

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.

5) WE DO NOT ASSIST IN EMERGENCY TREATMENTS.

Drug Interaction- Recommendations on Macrolide antibiotics interaction with CCBs

Why montoring is required when macrolide antibiotics co-administered with CCBS?

Coadministration of CCBs with certain macrolide antibiotics may increase concentrations and effects of CCBs. The proposed mechanism is macrolide inhibit isoenzyme CYP450-3A4 which is responsible for metabolism of CCBs. Hence, concentration of CCBs increase which may lead to hypotension, bradycardia, atrio-ventricular block.

What are the precautions for patients taking verapamil and clarithromycin concurrently?

The dose of verapamil should be reduced to 40mg/TDS from its normal adult dose (80-120mg TDS) as the concurrent use of verapamil with clarithromycin increases the effect of CCBs.

Change to an alternative Macrolide?

Azithromycin and Dirithromycin are generally believed to have little effect on CYP 450-3A4. So, Azithromycin and Dirithromycin are safer drugs compared to other macrolide antibiotics when co-administered with verapamil.

Change to an alternative CCBs?

Most of CCBs interact with macrolide antibiotics in the same way like verapamil. Hence, changing to another CCBs is less advisable.

Ref: Alissa et al.The risk of hypetension following co-prescription of macrolide antibiotic and CCBs. CMAJ.22Feb 2011;183(3):303-307.

FDA drug Safety Update NITROFURANTOIN

Contraindication

Use of nitrofurantoin for Urinary tract infections is contraindicated in patients with <60 mL/min creatinine clearance. The reason is, antibacterial efficacy in this infection depends on the the renal secretion of nitrofurantoin into the urinary tract. In patients with renal impairment, renal secretion of nitrofuranoin is reduced, which can result in treatment failure.

Ref- FDA Drug Safety Update December 2013 Vol 7, Issue 1; A3.

Drug Safety Advice

valproate sodium is indicated for prevention of migraine headaches. It is contraindicated and should not be taken by pregnant women as it can cause decreased IQ in children. Based on information from a recent study, there is evidence that it can cause decreased IQ scores in children whose mothers are exposed to drug, when they are pregnant. It should be used in pregnant women with epilepsy/bipolar disorder only if other treatments have failed to provide adequate symptom control or are otherwise unacceptable. valproate pregnancy category for migraine use will be changed from "D" to "X".

Ref- FDA drug safety Communication,5June2012

Case series- Clopidogrel: Risk of acquired hemophilia

Ref-Drug Safety Update December 2013 Vol 7, Issue 5; A2.

Reports of acquired hemophilia have been received in association with clopidogrel. Acquired hemophilia is a very rare condition that affects between 1-4 men or women per million per year; it generally occurs in elderly. Morbidity and mortality associated with acquired hemophilia are high. The condition tends to cause bleeding into the skin and soft tissues.

A total of 11 cases of acquired hemophilia A and 1 case of acquired hemophilia B have been received worldwide by the license holder in association with clopidogrel, 4 of which were published case reports. The case reports described patients aged between 6581 years, with no previous history of abnormal haemostasis. In 6 cases, it was reported that symptoms of acquired hemophilia resolved after stopping clopidogrel and corrective treatment (including steroids). Although no cases had a fatal outcome, 2 were considered life- threatening. Although these events are very rare, it is important to be aware of the possibility that a patient may develop acquired hemophilia as distinct from the risk of bleeding associated with clopidogrel.

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Department Endeavour

Drug information query
ADR monitoring
Paediatrics Dose Divison
Patient counseling
Scientific Publication

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Departmental News And Activities

Pharmacist Day-25th September 2013

On the occasion of pharmacist day on 25th September 2013, the department of clinical pharmacy organized a patient cum pharmacist awareness programme about pharmacy profession and its responsibilities towards society at different pharmacies in Kothrud, Pune. Simultaneously the patients who visited the pharmacy were instructed regarding their prescribed medications and were emphasized on the concept of "ASK YOUR PHARMACIST".

Patient counselling: Community Awareness Programme

The staff and Pharm. D interns of clinical pharmacy department has conducted a community awareness programme on 27th November 2013 regarding hypertension at the "Primary Health Care Center" of Ambawade, Bhor Taluka, Pune district. There were about 200 patients of hypertension who were educated about disease, causes, signs/ symptoms, its complications, treatment and precautions.

Patient Information Leaflets for hypertension and general medication instructions sheets were also distributed to the participants. Apart from patients, Doctor, Nurses, Pharmacist, Social workers and Attendants also participated.

The outcome of the programme was very satisfactory which was reflected in the feedback received from patients, their family members and the staff of PHC. They wanted such kind of awareness programme for chronic diseases like diabetes mellitus, asthma, rheumatoid arthritis etc. in future.

Osteoarthritis Camp

Pharm. D Interns and staff of clinical pharmacy department participated in Osteoarthritis Camp organized by Dr. Dalal, an Orthopedic surgeon and his team from BVDU Ayurvedic Medical College collaborated with Interactive Research School for Health Affairs (IRSHA) on 22 December 2013, in Harjivan Hospital, Nasarapur, District: Pune. The purpose of the camp was screening of Osteoarthritis patients with the objective of 'Knee Help'.106 Patients visited the camp. 55 potential patients were screened for signs, symptoms and abnormality in various joint architectures. Assessment of severity of pain was conducted in 12 patients using pain assessment scale, further screened patients were sent to orthopedic surgeons for medical intervention.

Guest Lectures

Sandeep Kaul (Project Manager, Jubilant Clinsys Limited) addressed regarding **"Overview of Clinical Research Operations"** on 21st September 2013.He emphasized on Source Data Verification, Monitoring Visit Reports and Success factors for managing a Clinical Trial.

Dr. Deepali Pawar (Assistant Manager Pharmacovigilance in TCS, Mumbai) addressed a brief speech on "**Job Opportunities and Challenges in Pharmacovigilance and Clinical Data Management**" on 7th December 2013. She informed the students about the real time scenario and practical aspects data management of PV data and various data software used.

Prashanth Vardhan (Senior Drug Safety Analyst in Sciformix Technologies Pvt Ltd) addressed regarding **"Case Processing in Pharmacovigilance"** on 21st December 2013 . He gave information on case processing in Pharmacovigilance, ADR reporting and Various safety reports.

Paper and Poster Presentations at National Conference

1.Poster presented by Pharm.D Interns titled **"Medication Adherence in Patients with Type II Diabetes Mellitus" organized by ABMH-PHARMACON-2013** (21st-22nd Sep)
1st Prize Winner. *(Ronak Sumariya and Amit Modi)*

2.Papers presented by PharmD Interns at Aditya Birla Memorial Hospital PHARMACON- 2013,Pune - India (21st-22nd Sep) on:

1. A Prospective Study of Adverse Drug Reactions in an Indian Tertiary Care Hospital. *(B. Rojarani)*
2. Surveillance of Device Associated Infections and its Management in ICU.*(Arun Gajure)*
3. An Effect of Patient Counselling in Hypertensive Patients.*(Soumya Padma)*

To,

Book-Post