DOCTOR OF PHARMACY

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BVDU-PCP

Pharmawiz Newsletter

Editorial desk...

It has been a glorious year for Dept. Of Clinical Pharmacy in achieving excellent outputs in the various areas of research paper publications, community activities, company collaborations. The faculty and students has immensly contributed in various community awareness programs like schizophrenia awareness in association with Schizophrenia Awareness Association (SAA), conducted cancer and osteoarthritis screening camps jointly with IRSHA, occupational hazard screening in Katraj bus depot etc. Department succeeded in getting six publications in various international and national journals. Our dynamic students bagged Runners Championship Trophy in general category for 52nd National Pharmacy Week (2013-14). Apart from all these achievements, our students are completely placed in various areas of pharmaceutical sectors such as pharmacovigilance, clinical data management, hospital clinical pharmacist, clinical trials in reputed industries such as TCS, Cognizant, Sciformix, Sahayadri Hospitals etc. Eminent guests from Jubilant Pharma, Sciformix, Cognizant visited department and guided students for the future.

Dr. Atmaram Pawar
Vice Principal & HOD
PharmD Programme

INSIDE THIS ISSUE:

GUEST COLUMN

Dr. Priya Pallewar
Trainer,CTA,
Cognizant, Mumbai

What Makes Clinical Research Ethical ?

The recent amendments in schedule Y are

- Introduction of Rule 122DAB - Specifying the procedures for payment of compensation to the subjects of the trial in cases of injury or death
- Introduction of Rule 122DAC Specifying various conditions for conduct and inspection of clinical trials
- Introduction of Rule 122DD - Specifying the detailed guidelines for registration of Ethics Committee
- Drugs and Cosmetics (Amendment) Bill 2013. Yet to be introduced

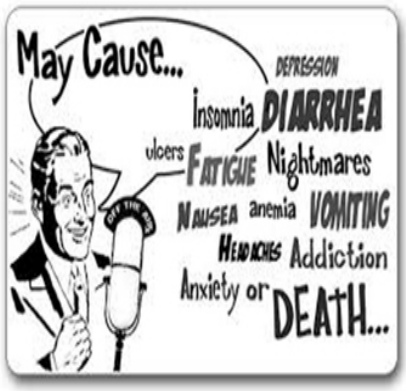
As per Appendix XII the Investigator shall report all serious and unexpected adverse events to the CDSCO, the Sponsor or his representative whosoever had obtained permission from the CDSCO for conduct of the clinical trial and the Ethics Committee, within twenty four hours of their occurrence.

In case of serious adverse events of death, the reports shall be examined by an independent Expert Committee constituted by DCG(I) to determine if the cause of death is due to following reasons, which are considered as clinical trial related death and gives its recommendation to CDSCO. In case of clinical trial related death the committee shall also recommend the quantum of compensation to be paid by the sponsor or his representative, to CDSCO.

a) adverse effect of investigational product(s);
b) violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the investigator;
c) failure of investigational product to provide intended therapeutic effect;
d) use of placebo in a placebo-controlled trial;
e) adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;
f) for injury to a child inutero because of the participation of parent in clinical trial;
g) any clinical trial procedures involved in the study clinical trial;

CDSCO shall consider the recommendations of the Expert Committee and shall determine the cause of death and also the quantum of compensation in case of clinical trial related death within three months of receiving the report of SAE of death.

A miracle drug is any drug that will do what the label says it will do. ~Eric Hodgins



METHYSERGIDE: SERIOUS FIBROTIC REACTIONS

DRUG ALERT

Reference: Drug Safety Update March 2014 vol 7, issue 8: A1.

A Europe-wide review concluded that there is a risk of fibrosis (mainly retroperitoneal fibrosis) associated with Methysergide treatment. This side effect may be serious and in some cases irreversible or fatal.

NEWS STRIKE

25 July 2014 - On World Hepatitis Day, 28 July, WHO welcomes new progress in tackling one of the world's most serious diseases. Viral hepatitis a group of infectious diseases known as hepatitis A, B, C, D, and E affects millions of people worldwide, causing acute and chronic liver disease and killing close to 1.4 million people every year.

EVIDENCE BASED DRUG REVIEW

RIZATRIPTAN: AN UPDATE OF ITS USE IN THE MANAGEMENT OF MIGRAINE.

RIZATRIPTAN is a 5-HT1 agonist,second generation- Triptan used for the treatment of migraine headaches. It is available in strengths of 5 and 10 mg as tablets and orally disintegrating tablets (Maxalt-MLT).The 5-$HT_{1B/1D}$ receptor agonist Rizatriptan constricts intracranial, extracerebral blood vessels, inhibits neurogenic vasodilation and extravasation in the meninges and is effective clinically against migraine.Rizatriptan is an effective therapy for acute, moderate or severe migraine headaches, as demonstrated by multiple randomized double-blind placebo-controlled studies. Rizatriptan in most studies shows quite a good consistency of effect, in the range of 70% to 80% of attacks. There does not seem to be any tolerance or loss of efficacy with repeated use. Studies also indicate that Rizatriptan is generally preferred over other Triptans and nontriptan medications for acute migraine headaches. The majority of the studies on patient preference however were open-label and therefore unblinded.

Oral Rizatriptan 5 and 10mg have shown greater efficacy than placebo in providing pain relief, an absence of pain, relief from associated symptoms, normal functional ability and an improvement in patient quality of life. Earlier results showed that Rizatriptan provides faster freedom from pain and reduces nausea to a greater extent than oral sumatriptan. More recent studies have shown that Rizatriptan 10mg provides faster pain relief and a higher percentage of patients with an absence of pain and normal functional ability at 2 hours than Naratriptan 2.5mg or Zolmitriptan 2.5mg. The efficacy of Rizatriptan is retained when used in the long term and the drug is generally well tolerated. Although well designed studies comparing Rizatriptan with Almotriptan, Eletriptan and Frovatriptan would further define the position of Rizatriptan, current data suggest Rizatriptan should be considered as a first-line treatment option in the management of migraine.

The two principal treatment goals for patients with migraine are to (a) decrease the frequency of migraine attacks and (b) decrease the duration and intensity of attacks when they do occur. With acute therapy, the ultimate objective is to eliminate the headache as quickly as possible, with no recurrence of the pain. The results of our meta-analysis indicate that there are differences in the ability of individual oral Triptans to completely relieve Migraine pain within two hours in spite of the fact that Triptans are generally considered to be equally effective.

References:

1. Wellington K,1,. Plosker G, L,. Rizatriptan: an update of its use in the management of migraine. Drugs. 2002; 62(10): 1539-74.
2. T felt-Hansen P, Ryan R E Jr Department of Neurology, Glostrup Hospital, University of Copenhagen, Denmark. Neurology [2000, 55(9 Suppl 2):S19-24].

Drug Warning

RISK OF CORTICOSTEROID INJECTIONS INTO THE EPIDURAL SPACE OF THE SPINE.

Injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments.

References: Drug Safety Communication April 2014, U. S FDA

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

Drug Queries	Patients Counseled	PDD	Category of Drug Queries					
			Indication	ADR	Admn	Efficacy/ Safety	Interactions	Others
34	18	59*	10	5	5	6	5	3

*Oxybutinin, enalpril meleate, lasilactone, 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) 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 SAFETY ADVICE

ORLISTAT THEORETICAL INTERACTION WITH ANTIRETROVIRAL HIV MEDICINES

Orlistat may theoretically reduce the absorption of antiretroviral HIV medicines. Initiate orlistat treatment only after careful consideration of the possible impact on efficacy of antiretroviral HIV medicines. People who take antiretroviral HIV medicines should consult their doctor before taking non-prescription 60 mg orlistat. Orlistat is indicated for weight loss in combination with a low-calorie, low-fat diet. It is available as 120 mg capsules under the brand name Xenical and as 60 mg capsules under the brand name Alli. Xenical is only available with a prescription, whereas Alliis available without a prescription under the supervision of a pharmacist. Orlistat is a potent, specific, and long-acting inhibitor of gastrointestinal lipases which decreases the amount of fat absorbed from the diet. On the basis of reports from literature1,2 and data obtained after licensing, orlistat may theoretically reduce the absorption of antiretroviral HIV medicines. This may be due to retention of lipophilic medicines in the gastrointestinal tract or reduced gastrointestinal tract transit time. This interaction could negatively affect the efficacy of antiretroviral HIV medications. Reports have been received of suspected interactions between orlistatand efavirenz, and between orlistat and lopinavir. However, the theoreticalinteraction mechanism described above could also apply to other antiretroviral medicines.

Reference: Drug Safety Update March 2014 vol 7, issue 8: A1.

MY EXPERIENCE IN CYTOTOXIC DEPARTMENT

Cytotoxic Reconstitution Services (CRS) have been developed in hospital pharmacies throughout the world. I had undergone one month training in department of cytotoxic admixture, Aditya Birla Memorial Hospital (ABMH), Pune. Centralized safe chemotherapy practices was running in a pharmacy under the direction of a suitably trained and experienced pharmacist and medical oncologist. Medical oncologist was prescribing cytotoxic medications. Prescription order contained information regarding complete drug and the patient details which was sent by concerned nurse to cytotoxic admixture department one hour before administration to the patient. After reviewing the complete prescription order and the patient file, the pharmacist arrange equipments used for preparing drugs (preparing drugs should incorporate a closed system, where possible, and also reduce the potential for generating high pressure). Reconstitution of admixture of anticancer agents was performed by the pharmacist following a SOP, in a minimum Class II Type B Biological Safety Cabinet (BSC) that maintains an ISO Class 5 environment which includes dilution with protective clothing (boots and overshoes, head covering, masks, safety glasses). This prevents contamination of clothes and subsequently the skin. Safe work policies and practices were developed and implemented by the hospital for those who are involved in managing spills and waste management segregation. Reconstituted drug carried and stored at 2-8°c /RT stable for at least 24 hrs. Finally Nurses follow the instruction for administration of the admixed medication at right time, right patient at right infusion rate with all precautions.

BY: ARUN GAJRE (PHARM.D INTERN)

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Department endeavour

Drug information query
ADR monitoring
Paediatrics Dose Divison
Patient counseling

Prepared By
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DEPARTMENTAL NEWS AND ACTIVITIES

Schizophrenia Awareness Programme (8th Feb 2014)

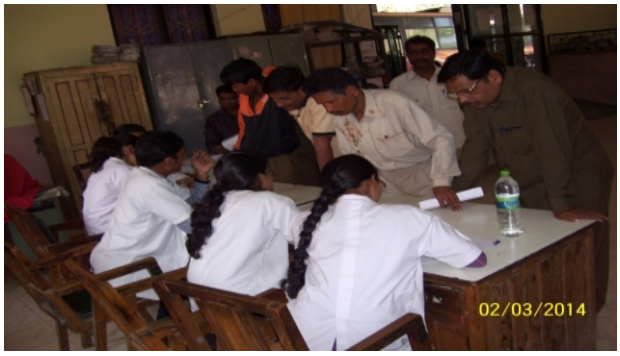
Following students i.e Amrita, Sumit, Harsh and Naveen from fifth year made a presentation on Schizophrenia awareness with main emphasis on medications; its importance, adherence aspects and solution for non adherence at Schizophrenia Awareness Association at Singhagadh Road, Pune. They also administered pre and post questionnaires to the patient's care givers, about 20 participants were present. Following students of fourth year were Marathi translators as an when required: Isha, Shashikant More and Aditi Padke(They were equally and amazingly excellent in their work) In the feedback the participants told that they were aware of the general aspects of the Schizophrenia but most of the technical information and specially related to medication aspect, they really gained a good know ledge after the presentation. They would like to have more such programmes in future from us and have welcomed us back to their institute.

The challenging part was that all the participants were highly educated, experts in the knowledge of schizophrenia and were experienced enough. They asked lot of questions to students and they were very logically answered by our students. This was highly appreciated by all.Dr.Bakshi the president of SAA who said that this was a first kind of presentation at their institute and of all the students till date who came to them ours were the best in their efforts and excellence. They all got a very good praising applauds from the president's secretary and the participants for their excellent and convincing presentation

Survey on occupation related health problems among PMT employees in Pune city

Dept of Pharmacy Practice, Bharati Vidyapeeth University, Poona College of Pharmacy

The Dept. of Pharmacy Practice, PCP, BVDU, conducted a medical survey of the PMC staff on 3rd February, 2014. It was a good initiative taken by the Final year Pharm. D (Doctor of Pharmacy) students in the field of public health care. A group of six students accompanied by two members of the faculty; Mr. Bijoy Panda and Mrs. Manjusha Sajith, carried out the Occupational Screening Program at Katraj Depot. Around one hundred and thirty PMC employees including conductors, drivers, workers and administrative staff were screened for respiratory diseases and musculoskeletal disorders. Afterwards, in collaboration with Dept. Of Pulmonay, Bharati Hospital, a health screening on 26 Feb 2014 was conducted.



PUBLICATIONS

1. Manjusha Sajith, Madhu Pankaj, Atmaram Pawar, Amit Modi, Ronak Sumariya. Medication Adherence to Antidiabetic Therapy in Patients with Type 2 Diabetes Mellitus. Int J Pharm Pharm Sciences 2014; 6; Suppl 2, 564-570.
2. Manjusha Sajith, Soumya Padma, Kaveri Lokhande, A P Pawar. Prevalance Of Various Skin Disorders And Prescribing Pattern Of Antihistamines In Tertiary Care Hospital, Pune IJPSR 2014; 5 (3),73-77.
3. Manjusha Sajith, Vandana Nimbargi, Amit Modi, Ronak Sumariya, A P Pawar. A Study on Incidence and management of Preeclampsia in a Tertiary Care Hospital. IJPER 2014; 48 (2), 70-76.
4. Manjusha Sajith, Vandana Nimbargi, Amit Modi, Ronak Sumariya, Atmaram Pawar. Incidence of Pregnancy Induced Hypertension and drug prescribing pattern of hypertensive drugs in pregnancy. IJPSR 2014; 5 (4), 163-170.
5. Sunita Pawar, Kaveri Lokhande, Soumya Padma, Arundhati Diwan. Effect of Pharmacist mediated patient counseling in hypertensive patients in terms of knowledge, compliance and lifestyle modifications. IJPPS 2014; 6 (4), 277-281.
6. .Manjusha S, Amit M, Ronak S. A Study on Prescribing Pattern and Potential Drug-drug Interactions in Type 2 Diabetes Mellitus inpatients. IJOPP 2014; 7(1), 7-12.

PAPER AND POSTER PRESENTATIONS AT INTERNATIONAL CONFERENCE

1. Poster presented by Kaveri Lokande (Pharm D intern) titled "The impact of patient counseling in hypertension Patients in terms Of Knowledge,Compliance and lifestyle modification".
2. Paper was presented by Jyothi Gautam (Pharm D intern) titled "Nosocomial infections in university hospital ICU".
3. Poster presented by Sankeerthana Vydiam,TanmayPore (5th year Pharm.D)titled "Drug related problems and pharmacist intervention in geriatric patients"
4. Poster presented by K.Sri.Nikitha, Divya Jacob (5th year Pharm.D)titled "Survey on occupation related health problems among bus conductors and drivers in Pune city".