



NATIONAL PHARMACOVIGILANCE PROGRAMME

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NPVP was started in our Department in October 2005 onwards and we are regularly sending ADR reports to regional centre at Lady Hardinge Medical College, New Delhi.

From October 2005 to September 2006, 210 ADR forms were sent with average of 17 per month. Most of ADR reporting were of outdoor patients.



Maximum response was obtained from RMO's, emergency officers, general physicians and Post Graduate Students



Funds (Rs. 15,000/-) from Ministry to cover expenses were received on 24th January 2006 and till date only Rs. 698/- has been utilized.

Percentage distribution of common medications causing ADRs.

Non steroidal anti inflammatory drugs	-	53
Fluoroquinolones	-	32
Cephalosporins	-	31
Macrolides (Azithromycin)	-	16
Chloroquine (other anti malarials)	-	14
Co-trimoxazole	-	11
Antiemetics	-	07
Amoxycillin	-	05
Antipsychotics	-	05
ATT	-	04
Phenytoin	-	03
Anti-spasmodics (Meftal)	-	03
Lignocaine	-	04
Oral hypoglycemics	-	02
Antioxidants	-	02
Steroids	-	02
Miscellaneous	-	16

Incidence of different types of ADR

General Pruritis	36%
Rashes	29%
Diarrhea	18%
G.I. Disturbance	14%
Oral Ulcer / Stomatitis	9.5%
Angioneurotic Oedema	5.7%
Muscle Dystonia	3.8%
Others	12%



SOME INTERESTING CASES

A case of medical negligence was observed on 27/5/06. Mr. M.S. a 60 yrs male was operated for hemorrhoids and was given Injection Diclofenac 1 amp. by nursing staff. At around 11.15 a.m. he developed itching on whole body followed by multiple circular reddish – purple lesions on both extremities associated with burning.



When we contacted the patient and elicited history, he gave a positive H/O allergy to NSAIDs, sulfa drugs, penicillin since last 10 years. No surgeon of team informed the nursing staff about this or were themselves unaware of this allergy.



Ms. S. a 33 yrs female was prescribed strontium granules (Glenmark) 2 gm. OD orally × 2 weeks for type III osteoporosis since last 9 years. She complained of feeling of fullness in head, insomnia which appeared 2 days after starting the drug. There was positive rechallenge and de-challenge in this case as these problems were observed after two courses of the same therapy.



Mr. T. 14 yrs male was operated for phimosis. On the 3rd postoperative day when dressing of the wound was done with Betadine, he developed swelling & redness at local site.



Ms. S.G. 36 yrs female complained of severe nausea after taking anti-oxidants (Essen Cap.). A positive rechallenge and dechallenge seen.

Ms. M.D. 60 yrs female was prescribed Bevon 1 Cap. OD for diabetic retinopathy. She complained of itching, macular rashes on lower extremities.




Two cases of acute adrenocortical insufficiency were seen after anti-tubercular therapy. This was due to microsomal enzyme induction caused by Rifampicin.



A case of corticosteroid induced Cushing's Syndrome





No ADR reporting for the months of October & November 2006 was made as no ADR forms were received.

Reasons:

- ❖ **Lack of motivation in Hospital Staff.**
- ❖ **Change of faculty members esp. in hospital so new members are not aware of this programme.**
- ❖ **Laxity from our side in terms of regular visits, follow – ups.**



Problems faced in conducting Pharmacovigilance Programme:-

- 1. Non – cooperation, disinterest & lack of motivation in the clinicians. Many of them simply say, “Our prescription is safe”. They refuse to report known & common side effects of drugs.**

How to MOTIVATE THEM?



2. Our busy schedule does not allow us to regularly follow up and contact the clinicians.

Can we hire a person who can help us in distribution of pamphlets, and collection or replacement of ADR forms? If yes, mode of payment/ salary of this person?



Suggestions:-

- 1. Extensive & frequent Advertisement in media to bring awareness in the general public.**
- 2. Regular information about this programme to be sent to major National Journals (one main journal of each specialty) from CDSCO.**



- 3. Information to IMA and other medical associations about this programme.**

- 4. Measures should be taken to ensure inclusion of compulsory ADR monitoring in Medical Sciences Curriculum i.e. MBBS, BDS, BPT, Nursing, Paramedical courses.**



THANK YOU