All India Institute of Medical Science

Saket Nagar, Bhopal

Department of Pharmacology

# PHARMACOVIGILANCE UPDATES

Volume 1 October

## Pharmacovigilance in AIIMS Bhopal

The ADR Monitoring centre (AMC) under the Pharmacovigilance Program of India (PvPI) became functional at AIIMS Bhopal in March 2014. With excellent cooperation from our clinical colleagues, we have been receiving Adverse Drug Reaction reports, which are assessed for causality and then forwarded to the National Coordinating Center at Indian Pharmacopoeia Commission, Ghaziabad. PvPI aims to disseminate this information to increase awareness among physicians and health care workers as well as the public, to promote spontaneous reporting of ADRs and also safe and rational use of medicines. In our First Newsletter we share the results of the first 6 months i.e. March to August 2014.

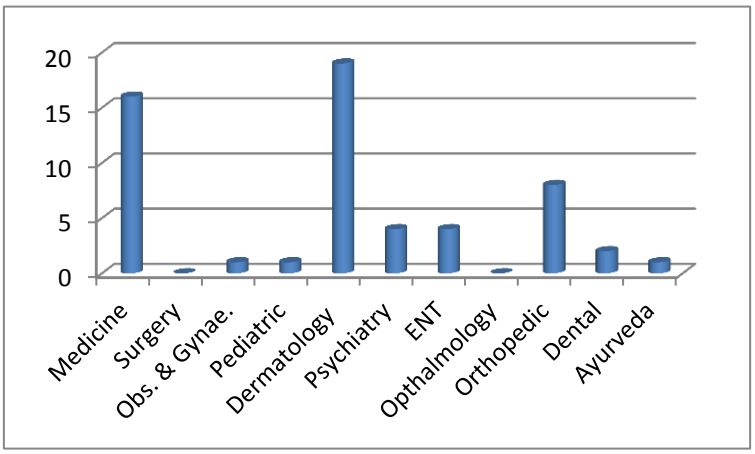
## Common ADRs and causative agents

From March to August 2014, we received 56 ADR reports. The most common ADRs were cutaneous reactions (23) e.g. papular rashes, urticaria and fixed drug eruptions. Other ADRs were oedema (13), diarrhea (8), ulcers (4), fever (3), vomiting (2), palpitation (1), syncope (1), and hepatotoxicity (1).

Antimicrobial agents (25) and NSAIDs (24) were most commonly implicated in causing ADRs. Other drugs suspected to cause significant ADRs were proton pump inhibitors (6), antihypertensives (5), antiepileptics (4), immunosuppressants (4) and antidepressants (4).

## The Contribution of Different Departments in ADR Reporting

Maximum ADR reports were reported from the department of Dermatology .




## Etoricoxib

From March to July 2014, we came across 4 ADRs with Etoricoxib, 3 of which were with the brand Etrobax. All patients were women between the age of 42 to 58 years. 2 patients developed facial and pedal edema, 1 patient presented with generalized edema and 1 developed a fixed drug eruption. In 2 cases etoricoxib was the only drug prescribed.

Being a COX-2 selective inhibitor, etoricoxib shares their adverse effects, including an increased risk of thrombotic events. Etoricoxib may also be associated with more frequent and severe hypertension than some other NSAIDS and selective COX-2 inhibitors, particularly at high doses. (Updated advice on the safety of selective cox-2 inhibitors. www.mhra.gov.uk/home)

## Safety Alert

**Co-trimoxazole and sudden death in patients receiving inhibitors of renin-angiotensin system: population based study.** *BMJ* 2014;349:g6196 (Published 30 October 2014)

A Population based nested case-control study in Ontario, Canada, from 1 April 1994 to 1 January 2012, recruiting Ontario residents aged 66 years or older treated with an angiotensin converting enzyme inhibitor or angiotensin receptor blocker has concluded that in **older patients** receiving **angiotensin converting enzyme inhibitors** or **angiotensin receptor blockers**, **co-trimoxazole** is associated with an increased risk of **sudden death.** Unrecognized severe hyperkalemia may underlie this finding. When appropriate, alternative antibiotics should be considered in such patients.