RAMAIAH
Medical College

Ramaiah Medical College

Pharmacovigilance

Adverse Drug reaction Monitoring Centre
Department of Pharmacology

MSR Nagar, MSRIT Post, Bangalore – 560 054
Tel: 080 23605190 / 1743/ 5408; Fax: 080 23606213
E mail: msrmedical@msrmc.ac.in
Web: www.msrmc.ac.in; www.ramaiah-india.org

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BACKGROUND

Pharmacovigilance is the science and activities related to collection, detection, assessment, monitoring and prevention of adverse effects or any other drug related problems. The ultimate goal is to promote safer use of drugs and help patients and clinicians make wise therapeutic decisions. Modern-day pharmacovigilance is also concerned with not only with the purely physical effects but the impact of medicines on patients' quality of life.

Medicines heal, but can also harm

Safer use of modern and traditional medicines / drugs is an ambitious goal in therapy.
It depends on patients and health professionals, health ministries, regulators and manufacturersworking actively together. The priority is to identify patients who suffer any kind of harm fromtheir therapy and to reduce the risk of this problem occurring in the future.

WHY IS PHARMACOVIGILANCE NEEDED?

Drugs have brought enormous benefits to mankind, but no drug is 100% safe for all people in every situation. While some drugs can seriously injure or even kill, most have predominantly beneficial effects for most people - even while they may cause occasional minor harm (such as headache, rash or tiredness).

Every time a treatment decision is made, the prescriber and patient must decide if the benefits are sufficient to accept the possibility of discomfort or harm, which may already be known and recorded on the patient leaflet. Sometimes there is unexpected minor or serious harm. This is why watching and reporting are so important: the more we know about what patients have experienced, the more all of us can be accurately informed, and harm can be prevented in the future. The risks of vaccines causing harm are much lower than those of medicines but monitoring is still necessary.

How do drugs cause harm?

Drugs are a powerful, usually chemical or biological invasion of the body; which is why they can cure diseases but also why they sometimes cause damage. The benefits and harms that any drug can cause is not completely known when it is tested in clinical trials. These involve only a few hundred or thousand carefully selected people, so they do not represent the whole population of patients (maybe millions) who will eventually use the drug. It is only after it has been used by large numbers of patients over a long periods of time, that more of its effects become clear, especially effects that are rare. Reporting of rare effects is particularly important in building up a full picture of a drug's character and safety profile.

Different people react differently to medicines, because everyone has different risk factors – related to genetics, other diseases and medication, allergies, social conditions, psychology and so on.

How do we reduce the risk of harm from medicines?

Wise therapeutic decisions, which give patients the greatest benefits with the least risk, must be made jointly by health professionals and patients. Asking a number of essential questions and having satisfactory answers for them is the starting point.

AIMS OF PHARMACOVIGILANCE





Early detection of unknown ADR	To detect increase in frequency of known ADR	To identify risk factors and mechanisms underlying ADR	To estimate the benifit/risk analysis	To disseminate information needed for improving prescription pattern & drug therapy.

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

The Central Drugs Standard Control Organization (CDSCO), New Delhi, under aegis of Ministryof Health and Family Welfare (MoHFW), Government of India,had initiated Nationwide Pharmacovigilance Programme in July 2010.

The Programme transferred to Indian Pharmacopoeia Commission as National Coordinating Centre in April, 2011 by a notification issued by the MoHFW, Govt. of India. IPC-PvPI became the NCC for Materiovigilance Programme of India (MvPI) from July, 2015.

IPC, NCC-PvPI became a WHO Collaborating Centre for Pharmacovigilance in Public Health Programme & Regulatory services from July 2017.

The PvPI is to safeguard the health of the Indian population by ensuring that the benefit of use of medicines outweighs the risk associated with its use.

Adverse drug reactions (ADRs) are reported from all over the country to the National Coordinating Centre (NCC), which works in collaboration with global ADR Monitoring Centre (WHO-UMC), Sweden to contribute to the global ADR Database.

NCC-PvPI monitors the ADRs among Indian Population and helps the regulatory authority of India (CDSCO) in taking decisions for safe use of medicines.

ADVERSE DRUG REACTION MONITORING CENTRE (AMC)

Milestones:

2008

Pharmacovigilance activity started in our hosital

2012

Faculty trained in Modular course in Advanced Pharma-covigilance (ICMR)

2013

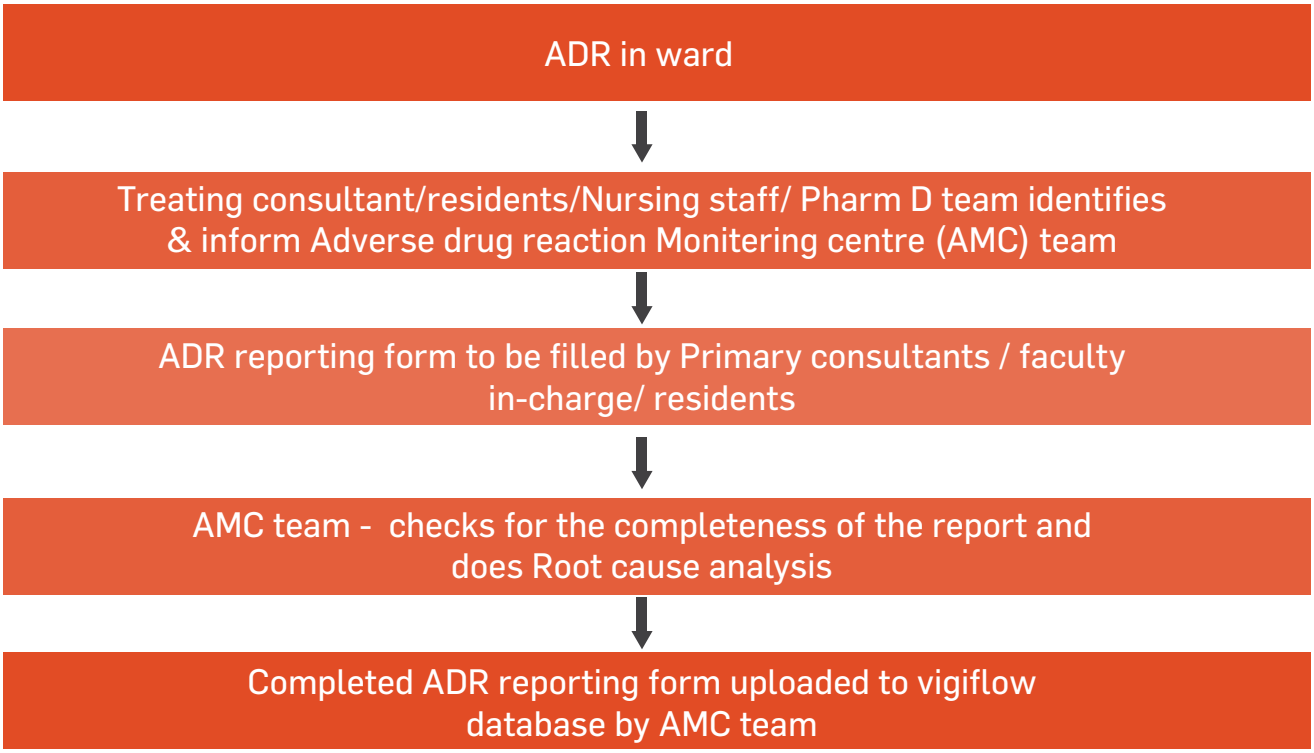
Letter of intent sent to NCC, PvPI Scanned ADR reports sent to NCC

2014

Our AMC center recognized as one by PvPI

Procedure for reporting ADR

- Any patient who is admitted with ADR or a known case of ADR or has developed an ADR while in care in our hospital will be notified to the pharmacologist.
- Time frame of notification is immediately/ within 24 hours.
- ADR reporting form to be filled by the Consultant/residents/staff nurse/ Pharm D staff and to be duly submitted to pharmacologist for causality assessment.
- ADR uploaded to the National Coordinating Centre through Vigiflow application.
- Educating (patient/care giver) about ADR by clinical pharmacologist.



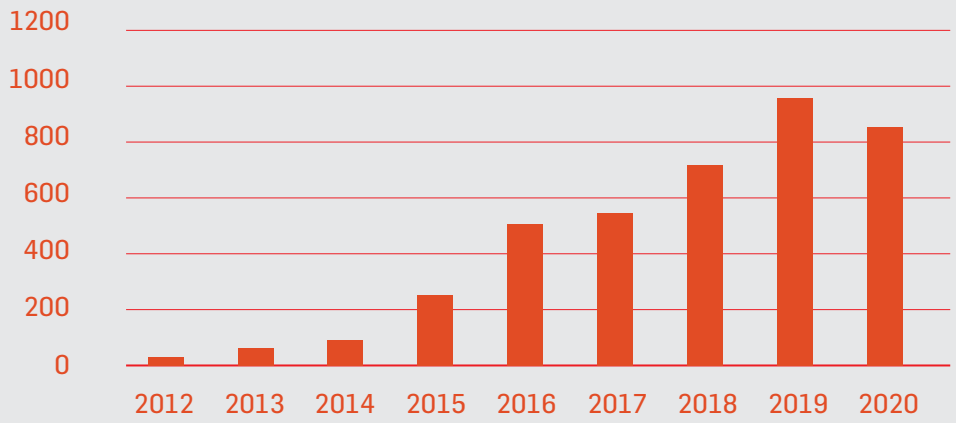
PHARMACOVIGILANCE COMMITTEE:

The Pharmacovigilance Committee comprises of 7-13 members; however,it is to be ensured that a mandatory quorum of at least 5 members to be present at each review meeting. Pharmacovigilance committee will comprise of pharmacologist, clinicians, administrators and a representative from the nursing department. Pharmacovigilance meetings will be held twice in a year.

Members of the Pharmacovigilance Committee are as follows:

1. Principal & Dean, M.S Ramaiah Medical College & Hospital, Chairperson
2. Professor and Head, Department of Pharmacology, Convener
3. Registrar academics, M.S Ramaiah Medical College & Hospital
4. Assistant / Associate Professor in Pharmacology, Member secretary
5. Administrator, M S Ramaiah Medical College Hospital, Member
6. Administrator, M S Ramaiah Memorial Hospital, Member
7. Professor and Head, Department of Oncology, Member
8. Assoc. Professor / Professor, Department of Medicine, Member
9. Assoc. Professor / Professor, Department of Endocrinology, Member
10. Assoc. Professor / Professor, Department of Dermatology, Member
11. Assoc. Professor / Professor, Department of Paediatrics, Member
12. Senior Nursing Staff.

ADR REPORTING STATUS OF OUR AMC (2012-2020)



DRUG SAFETY ALERTS FROM IPC (NCC - PvPI)

Suspected drug	Adverse Drug Reactions
Clobazam	DRESS Syndrome
Rosuvastation & Ticagrelor interaction	Rhabdomyolysis
Etoricoxib	Acute Generalized Exanthematous Pustulosis (AGEP)
Baclofen	Encephalopathy
Torsemide	DRESS Syndrome
Quetiapine & Valproic Acid Interaction	Neuropsychiatric Adverse Events (Depressed level of Conciousness / Coma & Disorientation)
Sofosbuvir	Stevens - Johnson Syndrome
Dimethyl Fmeate	Alopecia
Cefazolin	Acute Generalised Exanthematous Pustulosis (AGEP)

PROGRAMMES CONDUCTED:

CME ON PHARMACOVIGILANCE - 5th April 2016

Department of Pharmacology, M S Ramaiah Medical College Conducted "CME on Pharmacovigilance " on 5th April 2016, in collaboration with JSS Medical College and Hospital (RTC-PvPI) at MSRMC auditorium. The CME was inaugurated by the Honourable Chairman, GEF, Dr M R Jayaram in the presence of Dr Guruprasad D V, Chief Executive GEF, Dr G. Parthasarathi, Co-ordinator, RTC- PvPI, Mr Sten Olsson, WHO - UMC Programme Expert, Sweden, Dr. Shivamurthy, Prof and Head, Dept of Pharmacology. Dr.Medha Y Rao, Principal & Dean, MSRMC delivered the inaugural address. CME was attended by more than 200 delegates from Pharmacology, Pharmacy and Clinical backgrounds.

Webinar on "Role of Aggregate Reports in Pharmacovigilance" - 27th June 2020

This webinar was conducted online on 27th June 2020 and attended by post graduates and faculty across the country. The speaker of the webinar was Dr Ashwin Ravi, Manager, Aggregate Report Analyst, Safety Evaluation and Reporting, Pfizer Healthcare India Pvt Ltd.

Aggregate reports are the reports that emphasize on evaluation of safety profile of drugs. It reviews the cumulative safety information from a wide range of sources on a periodic basis and the findings are submitted to regulators worldwide. The speaker provided excellent coverage of the purpose, types and content of aggregate reporting in pharmacovigilance. The recent guidelines in the timeline of aggregate reporting and risk management cycle were also dealt with in detail.

Guest lecture on Signal detection from industry perspective-21st July 2021

This webinar was conducted online on 21st July 2021 and was attended by post graduates and faculty. The speaker was Dr Rachana Rajagopalan, Manager, Medical Director, Patient Safety Physician Oncology, AstraZeneca, Cambridge, United Kingdom

Sensitization Programmes on Pharmacovigilance conducted twice in a year for Nursing staff, Pharm D interns and MBBS interns

NATIONAL PHARMACOVIGILANCE WEEK 2021

The Department of Pharmacology MS Ramaiah Medical College in Collaboration with Indian Pharmacopoeia Commission, Ghaziabad celebrated National Pharmacovigilance week from 17th- 23rd September 2021. The theme was,
“Pharmacovigilance: A step towards patient safety”. The broad objective of the programme was to create awareness on the importance of reporting adverse drug reactions among healthcare professionals. Pharmacovigilance sensitization sessions were conducted for the nursing staff. An essay competition and an e-Poster competition were held for medical and allied health sciences students.

PAPER PRESENTATIONS RELATED TO PHARMACOVIGILANCE (Last 3 Years)

1. Dhruva Bhat, Anuradha H V, Mukunda N. Flagellate dermatitis due to bleomycin chemotherapy: a case report. CME on Pharmacovigilance: clinical implications. Bengaluru on July 19, 2019.

2. Swathi Bhat, Anuradha H V. Carbamazepine induced acute hepatorenal toxicity: an accidental poisoning in a child. CME on Pharmacovigilance: clinical implications. Bengaluru on July 19, 2019.

3. Abhishek T, Anuradha H V. Intravenous iron sucrose infusion induced thrombocytopenia in an adult female with iron deficiency anemia: A case report.ASCENT 2019. First Annual Sri Ramachandra Clinical Pharmacology Event & Training. Held at Chennai on 11th &12th Oct 2019.

4. Abhishek T, Anuradha H V. Assessment of Adverse Drug Reactions in Patients on Cardiovascular Drugs: A prospective observational study. ISRPT Con 2019. Held at Kolkata from 26 – 30 November 2019.

5. Sanjana Prabhu P, Anuradha H V. Acyclovir induced reversible acute kidney injury. World Congress on Infectious Diseases & Antibiotics. Held at Bangalore on 17th October 2020

6. Abhishek T, Mukunda N Anuradha H V. Olanzapine induced bruxism. APPSCON 2020. Held virtually on 4th and 5th December 2020

7. Abhishek T, Mukunda N Anuradha H V. L-thyroxine induced maculopapular rash. ASPIRE 2021. Held virtually on 23, 24, 30 and 31st January 2021

8. Sneha C. Assessment of Adverse Drug Reactions in patients admitted to intensive care unit of a tertiary care center. National conference on medication safety SRMC, Chennai on October 29 and 30, 2021

9. Madhurya Shetty, Anuradha H V, Acute generalised Exanthematous Pustulosis Following COVID 19 Vaccine: An unusual case report. National conference on medication safety SRMC, Chennai on October 29 and 30, 2021.

PUBLICATIONS ON PHARMACOVIGILANCE:

1. Rachana PR, Anuradha HV & Reddy M. Stevens Johnson Syndrome - Toxic Epidermal Necrolysis overlap secondary to interaction between methotrexate and etoricoxib: A case report. Journal of Clinical and Diagnostic Research 2015; Vol-9(7): 01-03.

2. Anuradha HV, Shivaswamy KN & Rachana PR. Evaluation of cutaneous adverse drug reactions due to antimicrobial agents: A prospective study. Journal of Dental and Medical Sciences 2015; 14(11):19-22.

3. Shravani B, Anuradha HV and Shivamurthy MC. Tramadol induced partial seizure: A rare adverse drug reaction- Case report. World Journal of Pharmacy and Pharmaceutical Sciences 2017; 6(5):1271-1275.

4. Vibhashree GN, Anuradha HV and Kalra P. Methimazole induced lichenoid eruptions: an unusual case. International Journal of Basic and Clinical Pharmacology 2017; 6:1535-1537.

5. Thyagaraj V, Anuradha HV, Sneha C, Kulkarni SG. Exploring the pattern of polypharmacy and proportion of drug to drug interactions and adverse drug reactions in the elderly J. Evid. Based Med. Healthc. 2017; 4(53):3250-3254.

6. Bhagwat B, Anuradha HV. Evaluation of immediate reactions to beta lactam antibiotics using a comprehensive diagnostic protocol. International Journal of Basic and Clinical Pharmacology 2017; 6:2366-2371.

7. Anupama C, Anuradha HV, Maka VV. Trastuzumab induced radiation recall dermatitis: an interesting case. International Journal of Basic and Clinical Pharmacology 2018; 7:2465-7.

8. Radha A, Anuradha HV, Radhika K. Occurrence of linezolid induced thrombocytopenia and its association with the risk factors: a review article. International Journal of Basic and Clinical Pharmacology 2018; 7:2483-7.

9. Bezawada S, Anuradha HV, Kalra P. Prevalence of insulin induced lipodystrophy in patients with diabetes mellitus in a tertiary care centre: A Cross-sectional study. Int J Basic Clin Pharmacol 2019; 8:710-6.

10. Sujive G, Mathew BT, Mamatha K, Anuradha HV. Predictors associated with adverse drug reactions among geriatric patients in an outpatient clinic.Asian J Pharm Clin Res 20019; 12(9):106-110.

11. Lalitha K, Suman G, Priyadarshini C,HV Anuradha, Shivaraj NS, Poonam RN, Arundhati D, Somashekar N, Sharath BN. Have we missed reporting adverse drug reactions under revised National TB control programme? - AMixed method study in Bengaluru, India. Indian Journal of Tuberculosis 2020; 67:20-28.

12. Namratha MV & Anuradha HV. Anticonvulsant Hypersensitivity Syndrome induced by Phenytoin- An atypical Presentation. World Journal of Pharmacy and Pharmaceutical Sciences 2020; 9(5):1951-1954.

13. Swathi Bhat & Anuradha HV. Bendamustine Induced Erythema Multiformae – A Case Report. World Journal of Pharmacy and Pharmaceutical Sciences 2020; 9(6):1063-1067.

14. Dhruva Bhat, Anuradha HV & Mukunda N. Flagellate Dermatitis Due To Bleomycin Chemotherapy: A Case Report. World Journal of Pharmacy and Pharmaceutical Sciences 2020; 9(6):1225-1228.

15. Sneha C, Anuradha HV, Karthik A. Assessment of adverse drug reactions in patients on cardiovascular drugs: A prospective study. J Pharmacol Pharmacother 2020; 11:59-63.

16. Sanjana P and Anuradha HV. Acyclovir Induced Reversible Acute Kidney Injury World Journal of Pharmacy and Pharmaceutical Sciences 2021; 10(8):1963-1066.

17. Abhishek T, Anuradha HV & Mukunda N. Iron Sucrose Infusion Induced Thrombocytopenia In A Pregnant Women With Iron Deficiency Anaemia: A Case Report World Journal of Pharmacy and Pharmaceutical Sciences 2021; 10(8):2091-2094.

APPRECIATION FROM INDIAN PHARMACOPOEIA COMMISSION, GOVT. OF INDIA

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

To,
Dr. Anuradha H V
Coordinator,ADR Monitoring Centre
M.S. Ramaiah Medical College, MSR Nagar, Gokula, Bengaluru-560054

Subject: - Appreciation for contributing towards ICSRs to National Coordination Centre- Pharmacovigilance Programme of India

Sir/Madam,

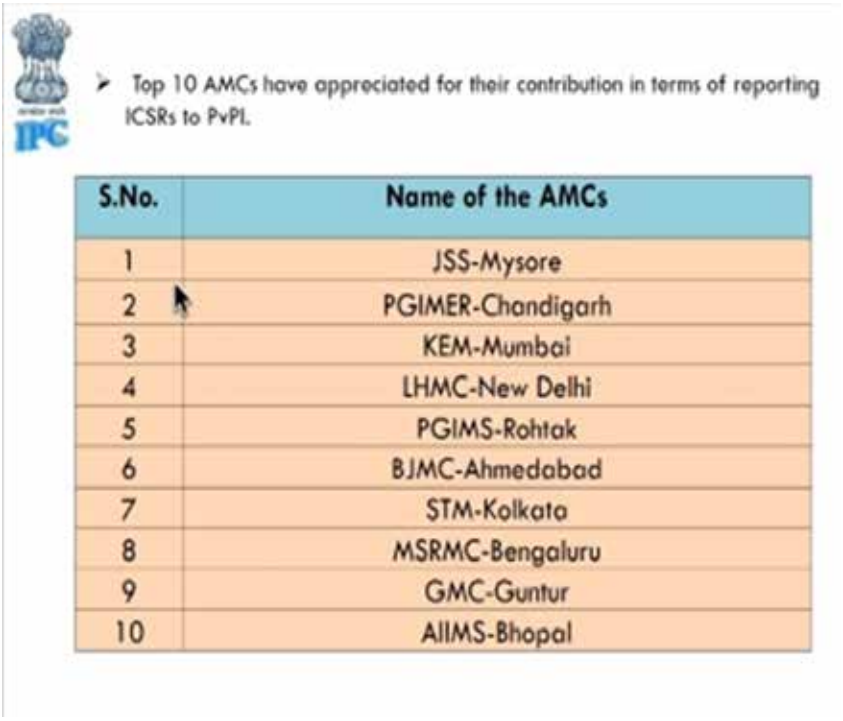
Greetings from Indian Pharmacopoeia Commission, NCC-PvPI

This is with reference to ICSRs submitted by your AMC to NCC-PvPI for the period of January 2017 to June 2019. We appreciate your efforts for submission of 1315 ICSRs to NCC-PvPI. It will strengthen our India specific drug safety database which will help in data mining/signal detection.

I hope you will keep on supporting for this nationwide programme to monitor drug safety.

(Dr. Jai Prakash)
Sr. Principal Scientific Officer and
Secretary-cum-Scientific Director (In charge)

Copy to: -
The Principal/Director/Dean of M.S. Ramaiah Medical College, Bengaluru for information.



- Top 10 AMCs have appreciated for their contribution in terms of reporting ICSRs to PvPI.

S.No.	Name of the AMCs
1	JSS-Mysore
2	PGIMER-Chandigarh
3	KEM-Mumbai
4	LHMC-New Delhi
5	PGIMS-Rohtak
6	BJMC-Ahmedabad
7	STM-Kolkata
8	MSRMC-Bengaluru
9	GMC-Guntur
10	AIIMS-Bhopal

National Coordination Centre-Pharmacovigilance Programme of India
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad - 201002

CERTIFICATE OF APPRECIATION

awarded to

M.S. Ramaiah Medical College (MSRMC), Karnataka

in recognition of appreciable contribution from your AMC for submission of ICSRs, organizing training programmes and creating awareness about Pharmacovigilance Programme of India

Dr. Jai Prakash
Officer-in-Charge,
Pharmacovigilance Programme of India
Indian Pharmacopoeia Commission
Ghaziabad

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ghaziabad

Compiled by:

Dr. Anuradha H V, Professor & Head, Department of Pharmacology and Coordinator, AMC

Dr. Mukunda N, Asst. Professor, Department of Pharmacology and Deputy Coordinator, AMC

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