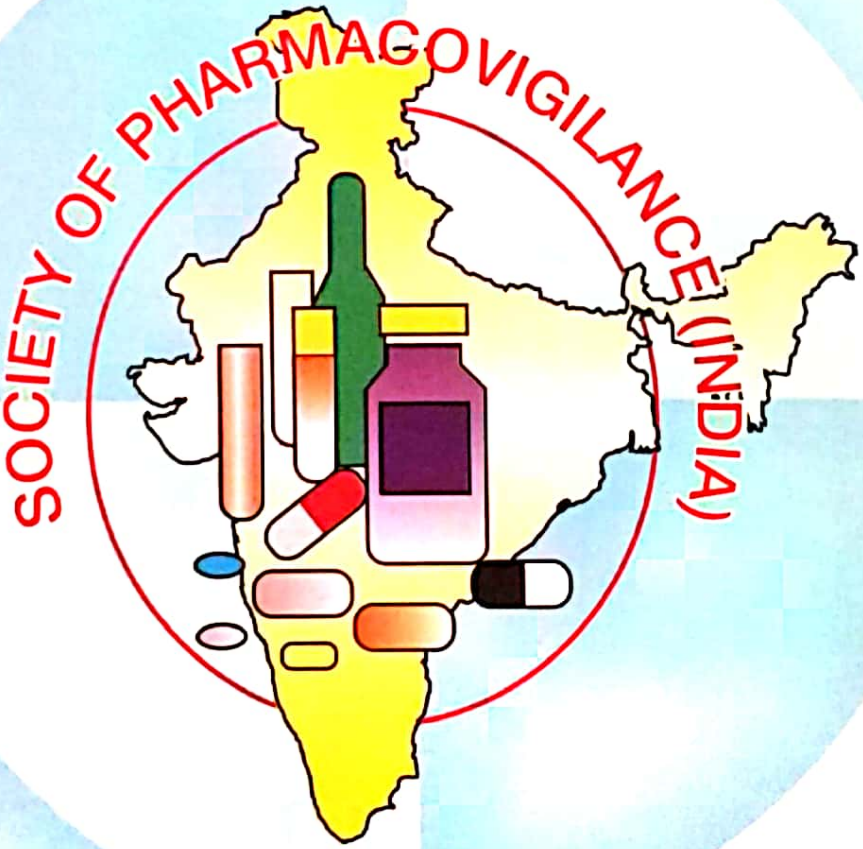
# Journal of Pharmacovigilance & Drug Safety

VOLUME 8 NUMBER 4 OCTOBER - DECEMBER 2011

## Conference Special - (SOPI) 2011, Patna




Editor-in-Chief
Dr. Anurag Tomar

Guest Editor
Prof. Harihar Dikshit

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Society of Pharmacovigilance, India

JOURNAL OF PHARMACOVIGILANCE & DRUG SAFETY VOLUME 8 NUMBER 4 OCTOBER - DECEMBER 2011

# Journal of Pharmacovigilance & Drug Safety

**(Official Publication of Society of Pharmacovigilance, India)**

**Volume 8, No 4, 2011**



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# Journal of
# Pharmacovigilance & Drug Safety

VOLUME 8
NUMBER 4
OCTOBER - DECEMBER 2011


## Conference Special (SOPI)

18-20 November, 2011
Nalanda Medical College, Patna

## SAFE DRUG : SAVE LIFE

Organizing Secretary : Prof. Harihar Dikshit (IGIMS) Patna
Co-Editor : Dr. B.K. Prasad (NMCH) Patna

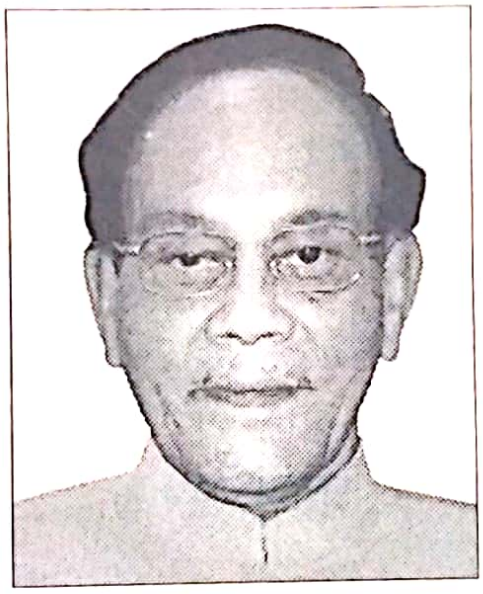

(Official Publication of Society of Pharmacovigilance, India)

देवानन्द कुँवर
राज्यपाल

सत्यमेव जयते
GOVERNOR OF BIHAR

RAJ BHAVAN, PATNA-800 022
Tel.: 0612-2217626, Fax: 2786184

20 September, 2011



*Devanand Konwar*
Governor

# Message

It gives me great pleasure to learn that Nalanda Medical College, Patna is organising 11th National Annual Conference of Society of Pharmacovigiliance on 18-20 November, 2011 on "Safe Drug : Save Life".

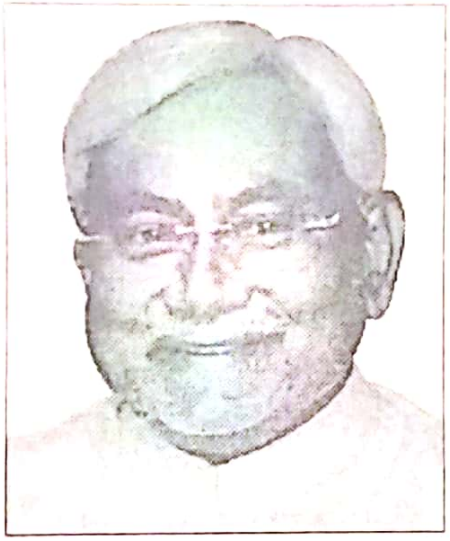
I hope, the deliberations of the conference will focus attention on adverse drug reaction and relevant medical topic and add new dimension for the cause of suffering humanity.

I extend my greetings to the organisers, participants and wish the event a great success.

(Devanand Konwar)

मुख्य मंत्री
बिहार

पटना
20.09.2011



नीतीश कुमार

# Message

It is matter of pleasure to know that Nalanda Medical College, Patna is going to organise a three day Medical conference on Pharmacovigilance on the occassion of 11th annual conference of society of Pharmacovigilance from 18th-20th November, 2011 and to mark the occasion a souvenir is also being published.

At a time when the new drugs are being developed and introduced, holding of this medical conference on Pharmacovigilance, a burning topic in the field of medicine, is highly praiseworthy. I appreciate the theme of the conference 'SAFE DRUGS SAVE LIFE.

I convey my heartiest felicitations to distinguished participants and wish the conference and souvenir every success.

( नीतीश कुमार )

अश्विनी कुमार चौबे
मंत्री
स्वास्थ्य विभाग
बिहार, पटना

कार्यालय : विकास भवन, प्रथम तल, बेली रोड, पटना ।
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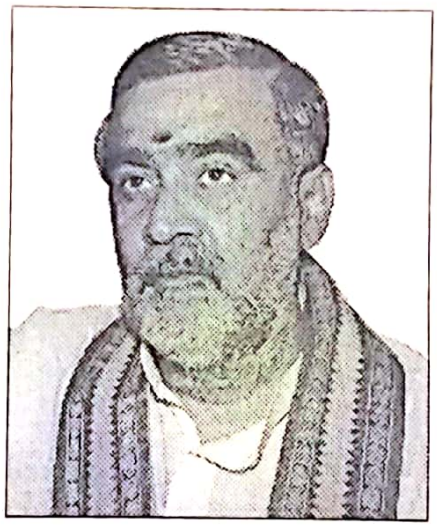

# Message

It gives me great pleasure that Nalanda Medical College, Patna is organizing a three day medical conference on Pharmacovigilance from 18.11.11 to 20.11.11. The theme of the conference is "Safe Drug : Safe Life". It is, indeed, a burning topic in the field of medicine. With the rapid growth of pharmaceutical sector it is very important to have adequately strong pharmacovigilance system to monitor adverse drug reaction. I have come to know that souvenir is being published to commemorate this function.

I hope this conference will succeed in sensitizing doctors as well as pharmaceutical sector. I wish the publication of souvenir and conference would be a great success.

(Ashwini Kuamr Choubey)


अमरजीत सिन्हा, भा०प्र०से०
प्रधान सचिव
Amarjeet Sinha, IAS
Principal Secretary



बिहार सरकार स्वास्थ्य विभाग
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Government of Bihar
Health Department
Vikas Bhawan, Panta - 800 015
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E-mail : amarjeet_sinha@hotmail.com
health-bih@nic.in


Patna, dated 19th September, 2011

# Message

I am happy to know that the 11th Annual Conference of Society of Pharmacovigilance, India is going to be held on 18-20 November, 2011 at Nalanda Medical College, Patna in which doctors of eminence and repute of the country will attend. I have also come to know that on this occasion a Souvenir is also going to be published.

I hope useful deliberation will take place on the theme of the conference 'SAFE DRUG:SAVE LIFE which is very relevant for the benefit of the suffering people and wish the conference all success.

(Amarjeet Sinha)

Sanjay Kumar, IAS
Secretary, Health
cum
Executive Director

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Parivar Kalyan Bhawan
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Tel. : 0612-2281232, 2290328 Fax : 0612-2290322
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Website: www.statehealthsocietybihar.org

# Message

It gives me great pleasure to know that Nalanda Medical College, Patna is organizing a three day conference on "Pharmacovigilance", an important topic in the field of medicine, from 18th to 20th November 2011 with the theme "SAFE DRUG: SAVE LIFE".

With the advancement of technology and development of pharmaceutical industry, new drugs are being developed and launched for treatment of various ailments. It is imperative to monitor the adverse effects of these newly launched pharmaceutical products amongst the users. For this a strong pharmacovigilence system is the need of the hour. With this objective, The Central Drugs Standard Control Organization (CDSCO) and Directorate General of Health Services, Ministry of Health, Government of India in collaboration with India Pharmacopeia Commission has initiated a nation-wide Pharmacovigilance Programme of India (PvPI).

I sincerely hope that the conference will not only generate awareness regarding the medical & pharmaceutical industry but also help alleviate the sufferings of humanity.

Best Wishes,

15/11/2011
(Sanjay Kumar)

डॉ विश्व मोहन कटोच
सचिव, भारत सरकार
महानिदेशक, आई सी एम आर
Dr. Vishwa Mohan Katoch
MD, FNASc, FAMS, FASc, FNA
Secretary to the Government of India
(Department of Health Research)
Ministry of Health & Family Welfare &
Director-General, ICMR

भारतीय आयुर्विज्ञान अनुसंधान परिषद
(स्वास्थ्य अनुसंधान विभाग)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029 (भारत)

Indian Council of Medical Research
(Department of Health Research)
Ministry of Health & Family Welfare
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029 (INDIA)

## Message

I am happy to note that Nalanda Medical College, Patna, Bihar is organizing *11th National Annual Conference of Society of Pharmacovigilance, India* on 18th -20th November 2011.

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality in health care. The pharmacovigilance programme mainly concerns with identifying, validating, quantifying, evaluating and minimizing the adverse effects of medicines thereby increases the safety of drugs in use. In order to foster the capacity building in medical colleges and hospitals such initiatives are of significant value for successful implementation of National Pharmacovigilance Programme in the country. Encouraging hospitals/ institutions within the country to intensify Adverse Drug Reaction (ADR) reporting and monitoring system and creation of awareness amongst healthcare professionals is need of the hour.

I am happy that an extensive and comprehensive programme has been planned to discuss the recent trends, prospects and future directions of research in the area. Through this forum the information can stimulate the researchers to have in-depth discussions and fruitful recommendations for implementation. The sharing of experiences of various experts and participants will surely help in improving this programme in India.

I wish, the conference a great success.

(V.M. Katoch)

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# NIMS UNIVERSITY

JAIPUR, RAJASTHAN

**PROF. K.C. SINGHAL**
M.D., Ph.D. (Med.), D.Sc.
FIAMS, FIAN, FIPS
VICE - CHANCELLOR

## Message

It is matter of great pleasure that 11th Annual Conference of Society of Pharmacovigilance of India is being held at the ancient city of Patliputra (now Patna). SOPI has made a Yoeman effort to create awareness and propagate the need to assess and measure the adverse reaction of drug and plan strategies to establish or to deny not so well understood laymen concepts and hypothesis proposed, generally based on fragmented and isolated informations or evidences.

Society of Pharmacovigilance India has ascended from a modest beginning to attain an international status. It is a matter of great pride that experts in Pharmacovigilance from all over world are participating and deliberating in the SOPI conferences each year. This year too Dr. R H B Mayboom and Prof. Saad Shakir who have been associated with the discipline of Pharmacovigilance, since its inspection on world map, after Thalidomide tragedy, are with us to interact, aquint and sensitize Physicians and Pharmacists especially the younger generation with their knowledge, experience and expertise.

I wish the organizer the best of luck in their efforts to set up an interesting and rewarding programme for all of us to attend.

**Prof. K.C. Singhal**
**Patron**
**Society of Pharmacovigilance India**

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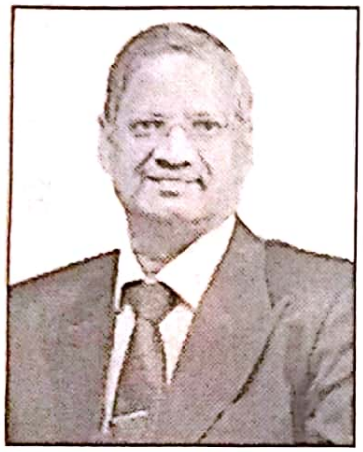


**Prof. Ramesh K. Goyal**
**President, SOPI**
(Former V.C. M. S. University of Baroda )
**Director,** I.S.F. College of Pharmacy, **MOGA 142 001 (Punjab)**

# Message

In India, the first multicentre study for monitoring ADR was initiated in 1989by ICMR through Prof. K. C. Singhal as the co-ordinator. It collected a data of 54194 cases monitored for ADR from 6 centres. Later data was collected from 12 centres. In 2005 the national Pharmacovigilance was started finally in 2008 Central Drugs Standard Control Organization (CDSCO) initiated Pharmacovigilance Program in India (PvPI) in 2010 and laid down targets for 5 years to monitor ADRs throughout the country. One of the impact of program in India has been the realization of concerns over pharmacovigilannce for Herbal drug and it has been taken up by WHO. In 2006 a new concept of pharmacovigilance in environmental pharmacology, entitled as 'Pharmacoenvironmentology'

As a strategy in pharmacovigilance, the process of collection of information about a drug begins in phase I of the clinical trial, before approval of the drug, and continues even after approval and should end with; post-market surveillance studies conducted around the world. Introduction of the Schedule'Y' and its amendments in 2005 and 2007 have certainly brought some control over clinical trials in India. Although, clinical trials tell enough of the ADRs but the "enough" is determined by legislation and by contemporary judgements about the acceptable balance of benefit and harm. Further, a clinical trial can never tell you the whole story of the adverse effects of a drug in all situations. Post-market surveillance studies uses tools such as dart mining of spontaneous reporting systems and, and investigation of case reports to identify the relationships between drugs and ADRs. One of the major weaknesses of the system is under-reporting and reports are almost always submitted voluntarily. Further, no regulation has been even thought about for iatrogenesis or pharmacovigilance.

In spite of almost three decades programs of pharmacovigilance world wide iatrogenic diseases continues to be the major cause of morbidity and mortality. In India, the problem is more complex. The doctors tend to overprescribe, over-utilize and overuse drugs. Their prescription and use is influenced by pharmaceutical companies who operate with purely profit motives. The drug industry is controlled by the Ministry of Chemicals rather then Ministry of Health. The patients also invite problems by self-administration of drugs. It has been reported that about 50 per cent of the drugs are sold over the counter.

Under all these circumstances it is essential to have a different strategic program for pharmacovigilance in India encompassing practicing doctors not only those who use drugs without having ever studied (Ayurvedic, Homoepathic or Unani doctors using modern medicines) but even the current allopathic doctors getting knowledge mainly from the medical or sales representatives. I am sure the Patna meeting of SOPI will come out with a resolution to this effect extending horizons of pharmacovigilance beyond the WHO or International societies for India (may be Patna Delaration for prevention of Iatrogenesis: Role of Pharmacovigilance.

**Prof. (Dr.) Mrs. Geeta Singh**
Principal
NMC, Patna

# Facundity : Principal, NMC, Patna

It is indeed a privilege to pen this facundity for the 11th National Annual conference of Society of Pharmacovigilance, India - that is being organized at the august Nalanda Medical College, Patna from 18 to 20 November 2011.

Pharmacovigilance - the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problem - is the talk of the medical parlance now a days.

A great deal of effort has gone into the very coining of the theme of the conference "SAFE DRUGS:SAVE LIFE". The idea is to highlight the rightful place of the topic in the core areas of pharmacovigilance - in terms of awareness, policy making and implementation.

The Organizing Committee has put in its best efforts to make this occasion a memorable one. I am sure the delegates would participate with equal vigour and in the process make it a wonderful learning experience to meet the challenges in Pharmacovigilance.

I, on behalf of, NMC Patna wish the conference a grand success.

Geeta Singh

[Prof. (Dr.) Geeta Singh]
Principal
NMC, Patna

**Prof. Shivkumari Prasad**
Superintendant,
Nalanda Medical College, Patna.

# Message

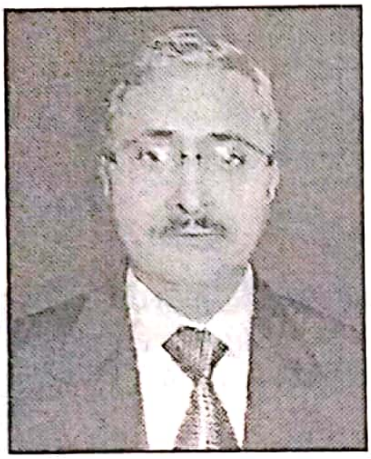
It is a matter of great pleasure and my privilege that my Institution Nalanda medical college, Patna is hosting the Conference of SOPI -2011.

The monitoring of safety of drug has prime importance in saving the life and so is the theme of the conference SAFE DRUG : SAVE LIFE.

I welcome all the Faculty, delegates and participants who have taken pain to come from different part of India and abroad.

I wish a great success of this conference SOPI-2011

Thank you all.



**Dr. (Prof.) U.C.Isser**
Professor & Head: Surgery
N.M.C.H. Patna
Chairman
Reception Committee
11th N.A.C.S.P., India

## FACUNDITY: CHAIRMAN, RECEPTION COMMITTEE

It is with warm friendship that I, in the capacity of the Chairman; Reception Committee, welcome all the delegates to the 11th National Annual Conference of Society of Pharmacovigilance, India that is being organizad from 18to 20 November 2011.

It is indeed very pleasing to acknowledge that the aforesaid conference is being actualized at Nalanda Madical College, Patna-a well recoqnized institute with 41 glorious years of medical educations and care.

Pharmacovigilance - a relatively newer discipline is all about detection, assessment, understanding and prevention of adverse effects or any other drug related problem. In the present times, with increasing numbers of drugs a rational use of medicines is of great significance for the ailing population. It is only prudent to have optimally strong Pharmacovigilance System to monitor ADRs (Adverse Drvg Reactions). In this light the theme of the Conference- "Safe Drug; Save Life" is most appropriate and timely.

**वैसे तो मशहूर-ओ-महबूब शायर जनाव निदा फ़ाज़ली साव ने कहा है कि,**

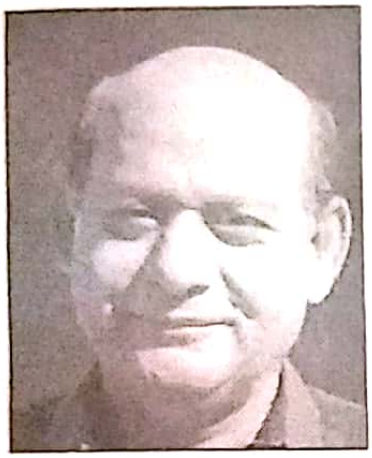
**"कोशिश के बावजूद ये उल्लास रह गया**
**हर काम में हमेशा कोई काम रह गया।"**

Nevertheless, every effort has been made to make the conference pleasant and educative.

The Organizing Committee has toiled day in and day out to make these maneuvers to the clock, apt and complete in all aspects.

we hope you cherish the experiences of this academic endeavor.

I wish you all the best and am certain that the delegates to this conference shall return satiated, as well as inspired to translate into practice the treasure of knowledge they would hove acquired in these days of the event.



**Prof. (Dr.) A.K.Vatsyayan**
HOD Anaesthesiology
NMC, Patna
Organizing Chairman

# Welcome to Patna

It is my proud privilege to express my deep sense of gratitude on behalf of the organizing committee to all who have come from various part of country and abroad, accepting our invitation to attend the 11th Annual National Conference of society of pharmacovigilance of India ( SOPI) Patna.

I feel delighted in welcoming the distinguished gathering of members, delegates, faculty as well as of allied faculties from various part of India and abroad in this very ancient town Patliputra. Bihar is known to have the first Lok tantrik government in Vashali, ancient educational university like Nalanda and Vikramshila, Rajgir the capital of great warrior Jarashandh as mentioned in Mahabharata. Patna was capital of Magadh Empire in 6th BC. As well as favorite abode of Lord Budha, Mahavir, Tirthankar, etc.

Dr. Harihar Dikshit, Organizing Secretary with his other dedicated members of the committee, from I.G.I.M.S Patna & other Medical Colleges of Bihar with other colleague have planned the events in such a way that you will enjoy your stay, scientific bonanza of the conference. I appreciate their tireless hard work.

It will unfair on my part if I do not express my thanks to pharmaceutical manufacturing houses and sponsorers for their active participation in the conference.

At the end I hope we will be successful in our efforts in making this conference as a big event in friendly atmosphere of elders, youngsters, and very entertaining time for accompanying persons.

Thanking you once again.

**Dr.B.K.Prasad**
Nalanda Medical College
Patna

# From the Desk of Co-editor

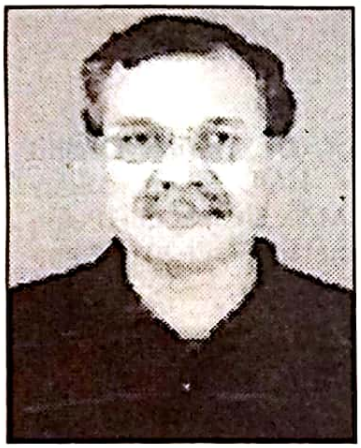
In modern practice of Medicare, where every day things are changing; newer developments, newer thoughts, newer recommendations and to keep pace with them, it is essential to assemble and exchange your ideas and experiences.

Monitoring of the safety of available drugs, and errors in using these drugs, is an important health protection service. SOPI -2011 conference is a similar event, in which I have been given the responsibility to compile these SOPI-2011 scientific lectures during the whole conference. The Organizing Committee has shown confidence in me. I feel privileged.

The scholars have written and will deliver their lectures in front of learned delegates. I feel all the deliberations are related to safety of drugs and to save life. This will certainly be a scientific bonanza for newer generation upcoming scientists of newer Medicare system.

Finally I sincerely apologize for any shortcomings, which you can come across in this book despite my sincere efforts.

I am very much thankful to all the contributors of this SOPI-2011, conference.



**Prof. (Dr.) Harihar Dikshit**
HOD, Pharmacology
I.G.I.M.S., Sheikhpura
Patna

# From the desk of Organizing Secretary

On behalf of the Organizing Committee, it is a great privilege and honour for me to welcome you all to the 11th Annual National Conference of Society of Pharmacovigilance India (SOPI) at Patna. The land where it all started in 1966 when the Indian Pharmacological Society was founded and the city hosted the first National Conference of Indian Pharmacological Society. So we've indeed come full circle!

We're grateful to the Society of Pharmacovigilance, India for reposing full faith in us to make this event a reality. The Organizing Committee has strived really hard to put up a wonderful scientific programme for all of you under the dynamic leadership of Prof. K.C.Singhal: Patron of SOPI, Prof. S.K.Tripathi, Prof. G.P.Singh, Prof. Govind Mohan, Dr. Anurag Tomar and many other office bearers of SOPI & local Organizing Committee members such as Prof. A.K.Vatsayayan, Prof. (Dr.) Arun Kumar, Dr. Ajay Kumar, Dr. Nirmal Kumar Sinha, Dr. Rajiv Ranjan, Dr. Kamlesh Tiwary, Dr. B.K.Prasad and Dr. Deepak Kumar, Dr. Arun Kumar Singh, Dr. Keshav Kumar Sinha & Dr. Manish Kumar to name a few.

I am certain that the scientific congregation will generate great awareness among clinicians and medicare providers regarding the importance of strong Pharmacovigilance. With **"Safe Drug : Save Life"** as the theme, we're hopeful that the conference will go a long way in saving many lives with the rational usage of safer drugs.

Once again, I extend a warm welcome to all of you at an event that promises to be exciting as well as enriching. Just like the spirit of the historical Patna city. Hope you have a pleasant stay here and have lots of sweet memories to carry back home!

**Prof. (Dr.) Harihar Dikshit**
Organizing Secretary

# The theme of the conference
# SAFE DRUG : SAVE LIFE

**Prof. (Dr.) Harihar Dikshit**
HOD, Pharmacology
I.G.I.M.S., Sheikhpura, Patna
Organizing Secretary SOPI 2011 Patna

All drugs, no matter how skillfully used, may cause adverse drug reactions (ADRs). There is nothing like an absolutely safe medicine. The risk of adverse drug reactions is but one probable consequence in drug therapy. Our aim on one hand is to develop medicines that are relatively safe as well as enough efficacious, and on the other hand to ensure their safer prescribing and usage. Medication-induced problems are known to cause serious patient safety concerns including mortality. The ADRs remain the fifth leading cause of death in the United States - a vast majority of these deaths are avoidable.

For a new drug to be approved for marketing it has to be enough safe and efficacious for its intended use. The beneficial effects have to outweigh any potential harm resulting in a favorable risk-benefit balance. The safety and efficacy are determined in randomized clinical trials (RCT) prior to regulatory approval. Although the RCT is the gold standard for evaluating efficacy, it cannot be relied on to detect rare, late, and unexpected ADRs. Premarketing RCTs are of limited size and duration and tend to focus on carefully selected, uncomplicated patients in a tightly controlled setting. Only low-risk patients are enrolled, excluding concomitant co-morbidities, concomitant medications, individuals at extremes of age, pregnant and lactating females. This precludes the chance of detecting many ADRs. Thus, our knowledge about the medicine's safety profile is grossly limited at the time of its marketing approval. The real test of safety starts when it is introduced to the market.

Postmarketing initiatives to identifying ADRs have been the mainstay of pharmacovigilance today. Pharmacovigilance refers to the study and sub-discipline of medicine safety. The World Health Organization (WHO) defines pharmacovigilance as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems'. Issues of relevance to pharmacovigilance include: medication errors, abuse and misuse of drugs, substandard drugs, lack of efficacy, use of drugs for indications that are not approved and for which there is inadequate scientific basis, acute and chronic poisoning, assessment of drug-related mortality, drug interactions, etc.

Postmarketing observational studies contribute much more to ADR detection than clinical trials. The main types are reports of individual patient cases or case reports, case-control studies, cohort studies, and registry studies. Although case reports usually have limited clinical value, they can sometimes give important warning signals for serious, unexpected, or rare adverse events. Thus, observant health care providers play an important role in identifying drug safety problems. There is marked underreporting of safety information in the published literature.

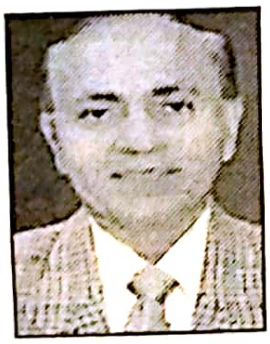
Avoiding drug-induced harm and iatrogenic injury to patients has been a major challenge. Drug safety information is too difficult to generate, often incomplete and almost always inadequately communicated. This makes determination of the benefit-to-harm balance difficult, if not impossible at times. Clinicians not only need to orient themselves to and engage in pharmacovigilance activities, but also should be well-informed about potential safety problems. Only then can they assess the benefit-to-harm balance and avoid causing harm to their patients.

# ORGANIZING COMMITTEE
# OF
# SOPI 2011 PATNA

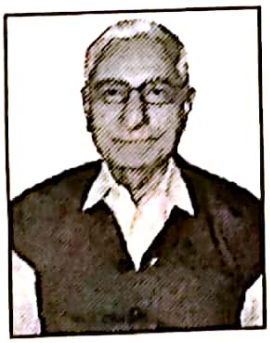
## CHIEF PATRON

Dr.(Prof.) S.N.P. Sinha
Former Vice Chancellor, Patna University

## PATRON



Dr.(Prof.) M.L. Verma
Principal
Narayan Medical College, Sasaram



Dr.(Prof.) C.B. Choudhary
Former Principal
N.M.C., Patna

Dr.(Prof.) R. N. Sharma
Prof. & HOD
R.D. Gardi Medical
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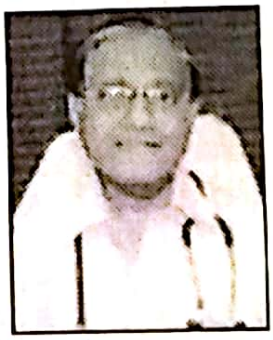

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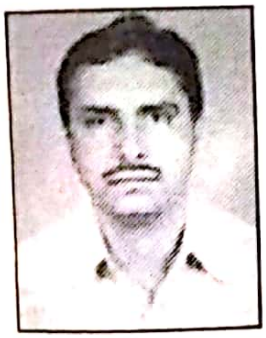

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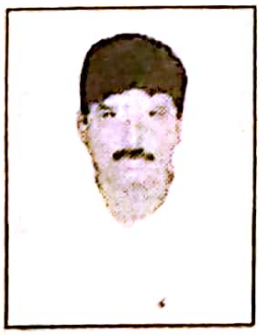

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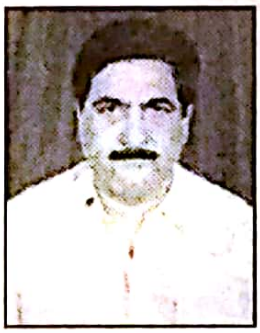

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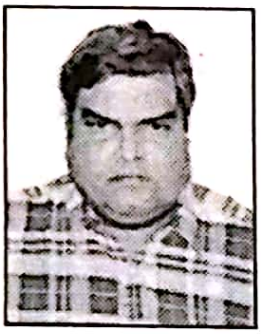

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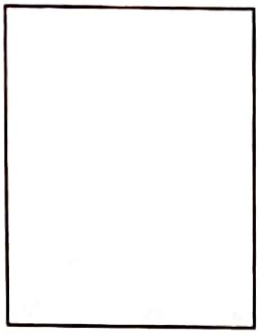

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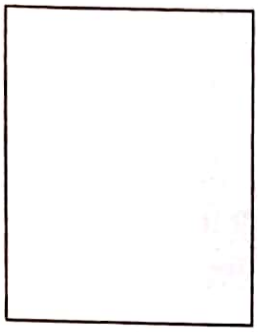

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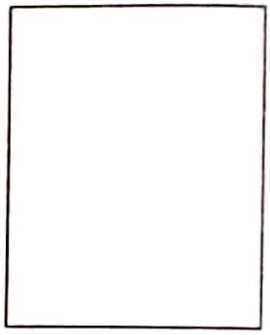

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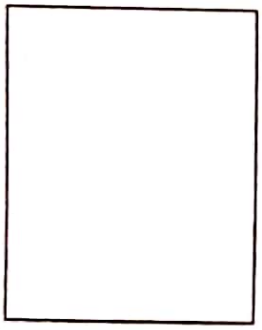

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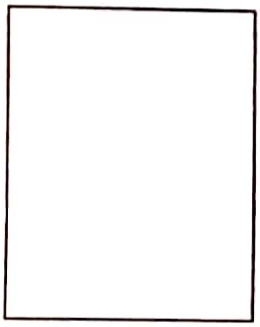

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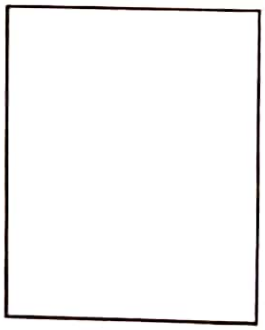

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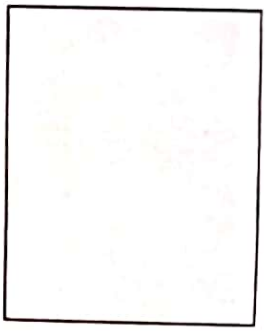

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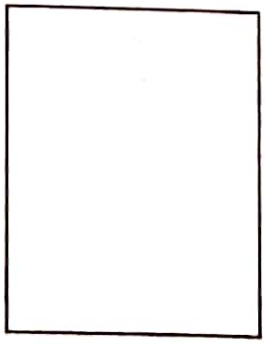

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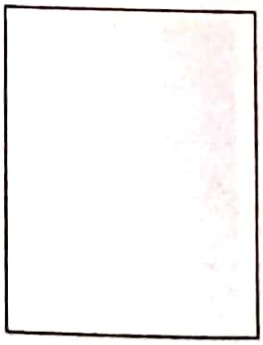

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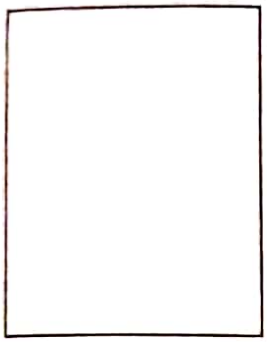

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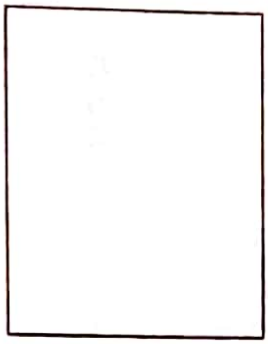

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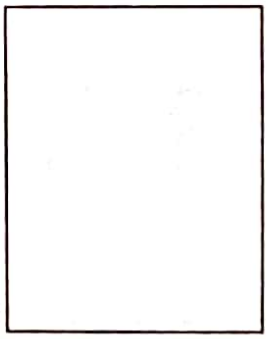

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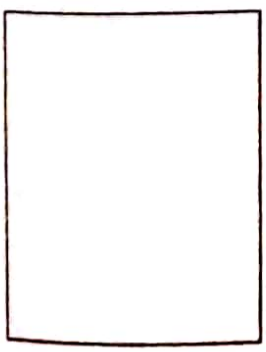

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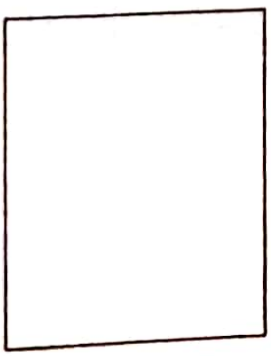

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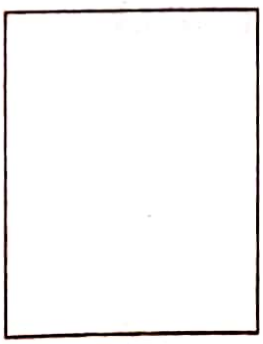

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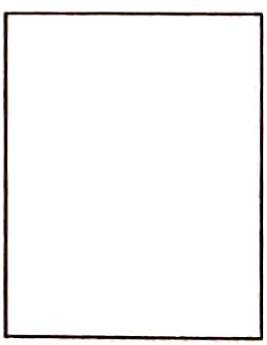

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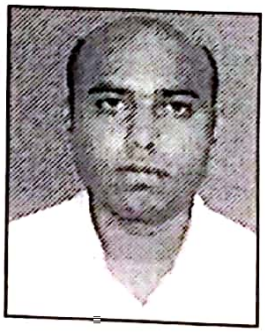

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# SCIENTIFIC PROGRAMME

# Scientific Programme

## November-18-2011

## Lecture Theatre -1 N.M.C.Patna

### 09:00 – Reception, Registration, Tea & Breakfast

| Time | | Topic | Speaker |
|---|---|---|---|
| 9:40 to 11:45 | **Symposium-1**<br>**Awareness in pharmacovigilance** | | |
| | Chair person<br><br>Prof. M.L.Verma<br><br>Prof. Raj Ranjan Prasad | Pharmacovigilance- History, Need, & Relevance (30 min) | Dr.Saad Shakir. Director Drug Safety Research Unit , Southampton.UK |
| | | Pharmacoepidemiology & pharmacovigilance- The Symbiotic link (30 min) | Dr Hari Dayal, Adjunct Professor of Health Policy and Management, UNTHSC School of Public Health, Fort Worth, Texas, USA |
| | | Pharmacovigilance – Methods & PvPI (20 min) | Prof S K Tripathi, Professor of Clinical & Experimental Pharmacology, School of Tropical Medicine, Kolkata |
| | | Spontaneous Monitoring – Time to Reform - (25 min) : | Dr Ronald H B Meyboom : Medical Advisor, Uppsala Monitoring Committee (UMC), Sweden |
| | | Causality Assessment and signal detection in Pharmacovigilance- (20 min) : | Dr Suparna Chatterjee, Associate Professor of Pharmacology, IPGMER, Kolkata |
| 11:45 to 12:00 | **TEA** | | |
| 12:00 to 13:15 | **Awareness in pharmacovigilance – contd.** | | |
| | Chair person<br><br>Prof. M.L.Verma<br><br>Prof. Raj Ranjan Prasad | Post Marketing Surveillance – Need, Relevance and Methods - (25 min) : | Dr. Sadhna Joglekar Vice President, Medical and Clinical Research, Glaxo Smith Kline, Mumbai |
| | | Safety Reporting in Clinical Trials- (25 min) : | Dr Jaydip Bhaduri Vice President - Medical Services, Cadila Pharmaceuticals, Ahmedabad |
| 13:15 to 13:35 | **Guest lecture -1**<br>Chair person<br>Prof.(Dr.) Arun Kumar<br>Dr.Renu Rohtagi | Adverse Drug Events and Patient Safety Issues in G & O Practice – (20 min) : | Dr. R. Sharma, Professor, Dept. of Gynae & Obs, J L N Medical College, Aligarh Muslim University, Aligarh |
| 13:35 to 14:30 | **LUNCH** | | |

| | | | |
|---|---|---|---|
| 14:30 to 15:30 | **Panel Discussion -1** | | |
| | Chair person<br>Prof S.K.Tripathi<br>Dr.Anurag Tomar | Ensuring Medicine Safety – Pre & Post-Approval Efforts | Panelists: Dr. Saad Shakir, Dr. Ronald H B Meyboom, Dr. Sadhna Joglekar, Dr. Hari Dayal, Dr. Jaydip Bhaduri |
| 15:30 to 16:00 | TEA | | |
| 18:00 to 22:00 | **Inauguration Programme –**<br>**Cultural Evening & Dinner** | | **I.M.A Hall I.M.A Building , South Gandhi Maidan, Patna.** |

# Scientific Programme

## November-19-2011

## Lecture Theatre -1 N.M.C.Patna

| Time | | Topic | Speaker |
|---|---|---|---|
| 09:30 to 09:50 | **Guest Lecture -2**<br>Chair Person –<br>Prof. C.B. Chaudhary<br>Dr. Amrendra kumar | Transnational Research in Safety Pharmacology : A Novel Approach. (20 min) | Dr. Kavita Gulati. Associate Professor, Patel Chest Inst. New Delhi. |
| 09:50 to 10:10 | GUEST LECTURE- 3: .<br>Chair Person –<br>Dr. Jitendra kumar singh<br>Prof.(Dr.) Kumari Indu Sinha | Today's challenges in Pharmacovigilance in Patna – (20 min) | Dr. Manisha Singh<br>Head, Medical Oncology. Mahavir Cancer Sansthan, Patna |
| 10:10 to 10-30 | TEA | | |
| 10:30 to 11:10 | K C Singhal Oration :<br>Chair Person –<br>Prof. S.N.P.Sinha<br>Prof. R.N. Sharma | Signal Detection in a clinical Pharmacological perspective- | Dr Ronald H B Meyboom : Medical Advisor, Uppsala Monitoring Committee (UMC), Sweden |
| 11:10 to 12:45 | SYMPOSIUM - 2 -<br>Pharmacovigilance in Indian Systems of Medicine<br>Chair Person-<br>Prof. K.C.singhal<br>Prof. Shafique Aslam | Impediments in the Monitoring of Drugs of Indian System of Medicine (25 min) | Prof K C Singhal<br>Vice Chancellor, NIMS University. Jaipur |
| | | Medicine Safety in Ayurveda - Commitment of AYUSH- (25 min) | Dr S K Sharma, Advisor to Govt of India |
| | | National Pharmacovigilance Programme for Ayurveda, Unani and Siddha (ASU) drugs -(25 min) | Dr R N Acharya, Jamnagar University |
| | | Ensuring Safety of Proprietary Ayurvedic Formulations. - (20) | Dr. Arun Gupta, Head of Medical Affairs, Dabur India Ltd. |

| | | | |
|---|---|---|---|
| 12:45 to 13:15 | **PANEL DISCUSSION 2** – Chair Person – Prof K.C.Singhal Prof. Shafique Aslam | Drug Safety in Indian Systems of Medicine | Panelists: Prof. K. C Singhal, Dr. A. Gupta, Dr. S. K. Sharma, Dr. R. N. Acharya |
| 13:15 to 13:45 | **GUEST LECTURE 4:** Chair Person – Prof Hari Dayal Dr.Sandeep Agarwal | Safety Pharmacology Studies in New Drug Development Research (30 min) | Dr. Shoibal Mukherjee, Vice President – Clinical Research, Quintiles India, Gurgaon |
| 13:45 | to 14:30 **Lunch** | | |
| 14:30 to 15:10 | **GUEST LECTURE 5:** Chair Person – Prof R.K.Goyal Prof. Govind Mohan | Risk Management in Pharmacovigilance (40 min) | Dr Saad Shakir, Director, Drug Safety Research Unit (DSRU), Southampton, UK |
| 15:10 | TEA | | |
| 15:20 to 17:20 | **SYMPOSIUM - 3**<br>**- Safer Use of Medicines in Clinical Practice**<br>Chair Person –<br>Prof. Arun KumarThakur<br>Dr. Nirmal Kumar Sinha | Iatrogenesis and Patient Safety – (20 min) – | Prof. R K Goyal |
| | | Medical Errors in Surgical Practice- (20 min) | Dr. Sandip Agarwal |
| | | Phamacovigilance in Respiratory Medicine- (20 min) | Prof. Arunabha Ray |
| | | Medication Errors and Patient Safety Issues, - (20 min) | Prof. S. K. Tripathi |
| | | Safety Issues in Medication Use by the Elderly -- (20 min) | Dr. Anurag Tomar |
| | | Drug-induced Skin Reactions – (20 min) | Prof. Govind Mohan |
| 17:20 to 18:00 | **GUEST LECTURE - 6** . Chair Person – Prof. Gita Sinha Prof. Rani Walia | Pharmacoeconomics: beyond safety, efficacy and Pharmacovigilance. – (40 min) | Prof. Hari Dayal |
| 18:00 | SOPI General Body Meeting | **Lecture theatre - 1** | |
| 19:45 | Entertainment & DINNER | **I.M.A Hall , I.M.A Building , South Gandhi Maidan Patna** | |

## Lecture Theatre -2 N.M.C.Patna

| **FREE PAPER – ORAL PRESENTATIONS :** | | | |
|---|---|---|---|
| **Time** | **Chair person--** | | |
| 09:30 to 12:00 | Prof. R.A. Shakur<br>Dr. Ashok Kumar Sinha | | **08 mts + 2mts** |
| | **Topic** | | **Speaker** |
| 1 | Study of side effects of Amphotericin – B , in relation to age and | | Dr. Zaki Anwar Zaman |

| | | |
|---|---|---|
| 2 | Chloroquine induced photosensitive dermatoses – A case report | Dr. Padmavati S. |
| 3 | Comparative analysis of online ADR Reporting forms of different countries | Dr. Tulsi Raman P |
| 4 | A survey on how many people read the patient information leaflets | Dr. Rajesh Kumar R |
| 5 | Knowledge attitude and skills of nurses towards ADR Reporting | Dr. Amrita Parle |
| 6 | Therapeutic potential of Increatin Axis – | Dr. Abha Kumari |
| 7 | Status of ADR Monitoring and Pharmacovigilance among health care professionals of Delhi – | Dr. Amrita Parle |
| | **Chair Person** | |
| 8 | Drug prescribing pattern for Major Depressive Psychosis patients in Geriatric clinic of a teaching hospital in Northern India | Dr. Farida Ahmad |
| 09 | Observation of ADR of injection Artesunate in 20 cases of Falciparum Malaria in a tertiary care hospital – | Dr. Parul Singh |
| 10 | Pharmacovigilance of an Ayurvedic drug combination against Rheumatoid Arthritis – | Dr. Rajiv Ranjan Sinha |
| 11 | Oral Cucumin in prevention of cervical cancer – | Dr. Rashi |
| 12 | Over the counter drugs : A challenge to Pharmacovigilance – | Dr. Manish Kumar Prasad |
| 13 | Somatostatin induced Anaphylactic reaction in a patient for Fundic Varix – A case Report – | Dr. Sawarkar Hindustani. |
| | | |
| 17:20 to 18:00 | Pharmacovigilance- Quiz- ( PG students) | Lecture Theater 2 |
| 10:30 to 16:00 | FREE PAPER – POSTER - PRESENTATIONS : | Gallery Near Lecture Theater-2 (19-11-2011) |
| | Chair Persons Prof Ali Ahmad, Dr. P.S.Singh | Presenter |
| 01 | A randomized open label active control study comparing safety and efficacy of Levetiracetam and Oxcarbazepine as monotherapy in newly diagnosed partial onset seizures – | Dr. Jacob Jesurun RS |
| 02 | Pattern of ADRs Reported in hospitalized Indian patients – | Dr. Jagjit Singh |
| 03 | Biosimilar Drugs : current status – | Dr. Rajiv Kumar |
| 04 | Allergic drug reaction of Levocetirizine : A case report – | Dr. Anuj Pathak |
| 05 | ADRs & IEC Interventions at community setup : A way forward in patient safety – | Dr. Rajendra P. Keskar |
| 06 | Attitudes and perception towards ADR Reporting among Doctors of Medical Colleges in Patna - - | Dr. Marya Ahsan |

| | | |
|---|---|---|
| 07 | Miltefosine & ADR – Risk Management – | Dr. Arshad Hasan. |
| 08 | VACCINE PHARMACOVIGILANCE-<br>AN ISSUE OF CONCERN - | Dr Priyanka Singh, |
| 09 | Drug prescribing pattern among pediatricians in an out-patient and PICU, NICU department of teaching hospital in Rajasthan- | Dr. Gnaneshwari D, Dr.Singh Savita, Dr.Gupta Nakul, Dr.Ahmad Ayaz, Dr..Mohan .G |
| 10 | PRESCRIBING PATTERN OF DRUGS IN THE DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY IN EXPECTED MOTHERS IN RAJASTHAN- | Dr.Chauhan Prerna, Dr.Sharma Ishan, Dr.Mohan Govind, Dr. Gupta Nakul, Dr.Ahmad Ayaz |
| | Chair Person – Prof.Anjani Dayal & Prof. R.C.Sinha | |
| 11 | Prescription Audit of anti-psychotics drugs in the department of Psychiatry- | Dr. Soni Gaurav, Jain Gaurav, Gupta Nakul, Ahamad Ayaz, Mohan Govind |
| 12 | Prescription Audit of medical college and associated hospital of Jaipur- | Dr.Srivastava DP*, Mandloi A*, Kulshreshtra S, Mohan G* |
| 13 | The prescribing pattern of non-steroidal anti-inflammatory drugs (NSAIDs) in 900 bedded multispecialty hospital.- | Dr.Singh Manglesh kumar, Faizul mohd, Ahmad Ayaz, Gupta Nakul, Mohan Govind |
| 14 | PHARMACOVIGILLANCE STUDY OF ANTI-INFLAMMATORY DRUGS IN ORTHOPEDICS DEPARTMENT AT A MULTISPECIALTY HOSPITAL | Dr.Selkari Rohit, Sharma Rohit, Ahamad Ayaz, Gupta Nakul, Deb Binayak, Mohan Govind |
| 15 | Prescription Audit in a medical College associated hospital of Rajasthan- | Dr.Sengupta S., Bishnoi H., Rai J., Gupta N., Ahmed A |
| 16 | Prescription Audit of Antacids and PPIs- | Moyal Urmila, Khan Hina, Mohan Govind, Gupta Nakul, Ahamad Ayaz. |
| 17 | A STUDY ON THE USE OF DRUGS IN I.C.U OF MULTI SPECIALITY HOSPITAL- | Sonkar A, Yadav J, Gupta N, Ahmad A, MohanG |
| 18 | Zauberkugeln-Paul Ehrlich's quest for specific medication, | Riemke de Boer, University Medical Center, Leiden University, |
| 19 | COMPARATIVE STUDY OF ADVERSE EFFECTS OF I.V. AMPHOTERICIN B AND ORAL MILTEFOSINE IN CASES OF VISCERAL LEISHMANIASIS | Manish Kumar1, J.R. Keshari2, Prof. (Dr.) Harihar Dikshit3, Dr.(Mrs.) Ranjana4 |
| 20 | ASSOCIATION OF HOMOCYSTEINE AND OXIDATIVE STRESS IN PATIENTS OF PREECLAMPSIA. | Juhi Aggarwal1, Mayur Kumar2 and JR Keshari3, Manish Kumar4 |

# Scientific Programme

## November 20, 2011

## Lecture Theatre -1 N.M.C.Patna

| Time | | Topic | Speaker |
|---|---|---|---|
| 09:30 to 10:00 | **GUEST LECTURE - 7:** Chair Person – Prof. Hemant Kumar Dr. Rajiv Ranjan | Study of Antidepressants: SSRIs, SNRIs and St John's Wort from the 45 and Up Database (30 min) | Dr.Syed Ziaur Rahman |
| 10:00 to 10:20 | **GUEST LECTURE -8 :** Chair Person – Prof. Janardan Sharma Dr. B.K. Prasad | Drug Allergy (20 min) | Dr. Vivek Sharma, Cachet Pharmaceuticals Ltd. Mumbai |
| 10:20 to 10:40 | **GUEST LECTURE- 9:** Chair Person – Prof. Mahendra Singh Prof. G.P.Singh | ADR(Adverse Drug Reaction) : The Indian Perspective - (20 min) | Dr. Ajay Kumar Past National President I.M.A, |
| 10.40 | TEA | | |
| 11:00 to 11:45 | **John Autian Oration :** Chair Person – Prof. K.C.Singhal Dr. Ram Raghubir | Medicine Safety – The Lifetime Experience of a Veteran Practitioner | Padma Shree, Prof. (Dr.) C P Thakur, Formerly Union Health Minister, Government of India |
| 11:45 to 12:15 | **GUEST LECTURE - 10 :** Chair Person – Prof. S.K. Tripathi Prof. A. N. Mishra | Spontaneous monitoring and Biopharmacovigilance – do Biopharmaceuticals cause infections and neoplasms? (30 min) | Dr Ronald H B Meyboom : Medical Advisor, Uppsala Monitoring Committee (UMC), Sweden |
| 12:15 to 12:35 | **GUEST LECTURE -11** Chair Person – Dr. Rani Indira Sinha Dr. Vijay Achari | Pharmacovigilance in Pharma industry & Regulatory perspectives – (20 min) | Dr. Shubhadeep Sinha, Head & Associate Vice-President - Clinical Development & Medical Affairs, Hetero Drugs Ltd. Hyderabad |
| 12:35 to 13:30 | **VALEDICTORY FUNCTION – Nalanda Medical College Campus, Patna.** | | |
| 13:30 | **LUNCH** | | |

Note : Oration 2, Symposium 3, Panel Discussion 2, Guest Lecture 11, Quiz 1, Free Paper Session 3 (ORAL – 13 papers, POSTER – 20)

Padmshree Professor C. P. Thakur, MD, FRCP (London & Edin)
Emeritus Professor of Medicine, Patna Medical College.
Member of Parliament, (Rajya Sabha) Former Union Health Minister, Govt. of India
Several No. of Publication & Vast experience of teaching, training & research.

Abstract

Medicine Safety- The life time experience of a veteran practitioner – John Autian Oration by C. P. Thakur MD, FRCP (London & Edin), Member of Parliament, Former Union Health Minister, Govt. of India.

World Health Organization (WHO) and UNESCO in 1949 formed an Independent International Organisation of Medical Sciences (CIOMS) to monitor drug safety, a system of pharmacovigilance.

Thalidomide disaster in 1961 stirred this organisation to be fully active to formulate rule and regulations to monitor drug safety both during manufacturing of the drug and during marketing also.

In 1986 CIOMS came out with adverse drug reporting form CIOMS form, and also the Medical Dictionary for Drug Regulatory Affairs (Med DRA)

An adverse drug reaction (ADR) has been described as harm associate with use of a given medication at a normal dosage and as any noxious or unintended reaction to a drug that is administered in standard doses by the proper route for the purpose of prophylaxis, diagnosis or treatment.

Serious adverse events have been described on death, life threatening hospitalization, disability, congenital anomaly, and intervention required to prevent damage or permanent impairment.

Sulphaguanadine, a sulpha drug used for treatment of dysentery killed a person due to severe reaction and he had experienced a moderate reaction 9 months earlier.

In earlier days ganglion blockers used in the treatment of hypertension produced severe postural hypotension which was corrected by discontinuing the drug and one patient developed hemiplegia due to that. Raulfia group of drug produced suicidal tendency in persons taking this drug. This feeling happened in a VIP and disappeared when the drug waswithdrawn. Some leaves of a plant taken for the treatment of eczema killed that person. He had myocardial infarction before.

The careless anaesthesia given in some patients produced irreversible brain damage and death.

A long acting anti diabetic drug produced irreversible hypoglycemia and death. A patient given insulin to a patient who was already comatosed due to overdose of insulin and developed vegetative life and was made to die.

A badly manufactured sodium antimony gluconate produced cardiac toxicity and death in large number of patients in Bihar. Even a good SAG also killed patient due to cardiac toxicity.

Many life threatening complication of amphotericin B like cardiac and renal complications could be prevented by taking proper precautions. Tetany produced by paromomycin was observed after all phases of trial were over. Similarly the SAG and miltefosine produced severe thrombocytopenia and hemorrhage during routine treatment, an act of pharmacovigilance.

**Dr. Ronald Meyboom, MD, PhD**
Department of Pharmacoepidemiology and Clinical Pharmacology,
University of Utrecht, The Netherlands
The WHO Uppsala Monitoring Centre, Uppsala, Sweden

Dr Ronald Meyboom graduated as a medical practitioner at the University of Leiden in the Netherlands. With a keen interest in pharmacology and in medicines as a paradoxical cause of disease, he has headed for almost 20 years the National Pharmacovigilance Centre in the Netherlands. In that time he also pioneered hospital pharmacovigilance at the Leiden University Hospital (Dr H. Mattie). In 1998 he defended a PhD thesis at the University of Nijmegen based on his experiences in practical pharmacovigilance, entitled "Detecting Adverse Drug Reactions. Pharmacovigilance in The Netherlands".

After having assisted in the creation a new organization for pharmacovigilance in his country (in the form of an independent non-profit foundation), he became more involved in international pharmacovigilance (WHO Uppsala Monitoring Centre) and initiated collaboration between the centre in Uppsala and the Department of Pharmacoepidemiology and Clinical Pharmacology of the University of Utrecht (The Netherlands), combining research and teaching.

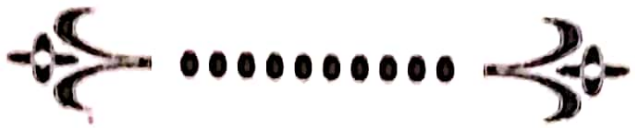
Dr Meyboom has published over 100 articles and chapters relating to pharmacovigilance in specialised journals and books. He is an honorary member of the Society of Pharmacovigilance of India (SOPI), a founding board member of the International Society of Pharmacovigilance (ISOP), a member of the editorial boards of the journals Drug Safety and Pharmacoepidemiology and Drug Safety, and co-author of the Meyler's Side Effects of Drugs series. Having recently reached 65, the further development and improvement of pharmacovigilance around the world is his major commitment.

Abstract

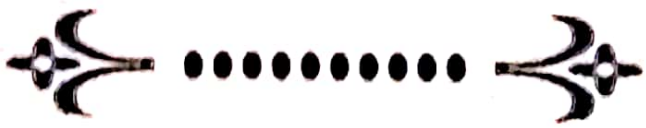
## Signal detection in a clinical pharmacological perspective

Signal detection in pharmacovigilance aims at the discovery in an early phase of hitherto unknown adverse reactions and any other possible drug-related problems. Signals of potential importance can be found in different places – in experiments, observations in patients or observations in populations – and may have different forms and content. Whatever the origin and content of a signal may be, its scientific assessment is essentially a clinical pharmacological process. In this paper a review is given of what pharmacovigilance is, which tools are used in it, and of what signals are and how they are assessed and followed-up.

हार्दिक शुभकामनाएँ



# देशरत्न डॉ. राजेन्द्र प्रसाद दुग्ध उत्पादक सहकारी संघ लिमिटेड बरौनी, जिला (बेगुसराय)



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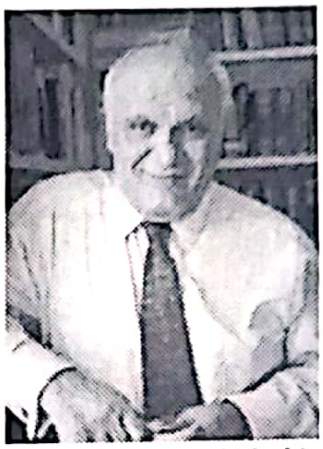

**Professor Saad Shakir**
MB ChB LRCP&S FRCP FFPM FISPE MRCGP
Director - Drug Safety Research Unit, Southampton, UK

Saad Shakir qualified in Medicine in and worked in hospital medicine and general practice. He has been working in pharmacovigilance & pharmacoepidemiology for nearly twenty years and has been the director of the Drug Safety Research Unit (DSRU) in Southampton, UK for more than ten years. The DSRU is an academic Unit associated with the University of Portsmouth.

At the DSRU Saad Shakir leads a research team with an active programme for monitoring and studying the safety of medicines. Saad Shakir is a Fellow of the Royal Colleges of Physicians in Glasgow, Edinburgh and London, Fellow of the Faculty of Pharmaceutical Medicine and Fellow of the International Society of Pharmacoepidemiology. He is a Member of the Royal College of General Practitioners in the UK and continues to practice clinical medicine part-time.

Saad Shakir has high national and international profiles in pharmacovigilance, pharmacoepidemiology and risk management. He is heavily involved with advising on and conducting studies on risk management of medicines, he has studied and advised on many drug safety issues including product withdrawals and major drug safety hazards. He is an author of more than one hundred publications in scientific journals on pharmacovigilance and pharmacoepidemiology and is a member of the editorial boards of the journals of Drug Safety and Pharmacoepidemiology & Drug Safety. He has acted as a chairman and member of Data Safety Management Boards (DSMBs). He is an examiner at the Faculty of Pharmaceutical Medicine in the UK. Saad Shakir has led, co-ordinated and participated in many postgraduate educational and training programmes. He supervises postgraduate students for higher degrees and has been involved with a number of international initiatives to promote and develop pharmacovigilance and pharmacoepidemiology.

## ABSTRACT

## Pharmacovigilance : History Needs and Relevance

The development of modern pharmacovigilance in the early 1960s following the thalidomide disaster was the society's response to protect public health from the hazards of medicines. A general consensus remained since then that no matter how confident medical science can be about the pre-marketing safety of medicines based on clinical trials, the safety information is incomplete and must be supplemented by methodical post-marketing monitoring and study. The limitations of pre-marketing clinical trials in understanding drug safety are well known: small numbers of selected patients who receive the drugs in artificial settings for shorter periods of time than the real world indicate that they

cannot provide the picture to be expected when the drugs are used by unselected populations for large periods of time in day to day clinical settings.

Spontaneous reporting systems (SRS), the first method used to monitor post-marketing adverse drug reactions (ADRs) continue to serve us well as a source for detecting and strengthening signals. However, SRS have well known limitations, it was recognised more than forty years ago that other methods need to be used to broaden the range of post-marketing safety methods. The other approaches generally apply epidemiological methods to strengthen, verify and evaluate safety signals. The application of information technology in health services research and management increased (and continues to increase) the sources available to conduct pharmacoepidemiological studies.

Safety studies to better understand the safety of medicines need to focus on answering specific questions and to be integrated to provide a coherent picture of the effects of any particular drugs. Hence the concept of risk management and pharmacovigilance planning which aim to provide such focus and integration have emerged and now they are a requirement for all new medicines, new indications, new populations and new formulations.

The story of pharmacovigilance so far has been to shift from a fire fighting reactive approach to a more planned and evidence based methodology. This can only be good for patients and for optimal use of medicines.

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Professor Dayal worked in public health and international health and held academic positions at the State University of New York at Buffalo, Johns Hopkins School of Public Health, Medical College of Virginia, and Fox Chase Cancer Center. He has recently retired as Professor of Preventive Medicine and Community Health from the University of Texas Medical Branch.

Professor Dayal conceived, developed, and delivered for more than ten years a curriculum in clinical research methods for clinicians, advanced medical students, residents, fellows, and faculty. This module is easily adaptable and transportable to any setting in the world.

As Statistical Advisor to the Afghan Demographic Studies, a USAID sponsored project, he directed the data collection and analysis of the first census-survey in Afghanistan. He has done several original epidemiological research works of great scientific impact.

## Abstract

## Pharmacoepidemiology and Pharmacovigilance: the symbiotic link

Modern medicine is blessed with pharmaceutical innovations, which has given health care system the ability to provide better care for the patients. However, these innovations have also led to concerns and product liability lawsuits associated with adverse drug reactions (ADRs). Pharmacoepidemiogy is essentially the study of effects of drug, including ADRs, in a population by employing epidemiological methodology such as controlled studies. Thus, pharmacoepidemiology uses the methods of epidemiology to study the content area of clinical pharmacology. Pharmacovigilance, a conjunction of 'pharmaco' and 'vigilance', stands for 'watchfulness' in guarding against danger from drugs. The relationship between the two disciplines can sometimes be blurred because it is symbiotic. To some, pharmacoepidemiolgy encompasses pharmacovigilance; to some it is the other way around. In any case, the essential element in both disciplines is the linkage of pre-market safety data with post-market safety evaluation. We discuss epidemiological and statistical methods that are employed, or should be employed, in each discipline to link the strategies for pre-market safety assessment with strategies for post-market safety evaluation.

**Prof. Santanu K Tripathi, MD, DM**
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Calcutta School of Tropical Medicine, Kolkata
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Coordinator & Investigator, ADR Monitoring Centre at School of Tropical Medicine, Kolkata under Pharmacovigilance Programme of India, Government of India.

AREAS OF INTEREST

# Innovations in health and medical education, training and capacity building activities
# Clinical research management & Pharmacovigilance

EDUCATION : MBBS, Calcutta, 1979 / MD, BHU, 1984 / DM, PGIMER, Chandigarh, 1991

WORK EXPERIENCE

- Engaged in clinical pharmacological research in different areas [with special reference to rational drug use, pharmacovigilance, pain research and indigenous herbal drug research] since 1985
- Acts as Research Guide to postgraduate students in fields or faculties of Medicine, Phamacy
- Provides professional inputs to various pharmaceutical companies in the area of clinical research and regulatory compliance as an extramural expert as and when solicited
- Authored and published research papers and scientific reviews in national and international journals
- Associated with a Kolkata-based clinical research site management organization (SMO) @-Pharma Intel Drug Research & Consultancy Group @- in key Advisory capacity ever since its inception in 1998 @ also remained responsible for the overall project management activities for a number of multi-centric phase 2 or 3 clinical trials at local sites @ interacting with investigators, extending assistance for IRB/IEC submission, coordinating with site coordinators, communicating with CRAs and liaising with the Sponsors
- Experience as Principal Investigator / Coordinator in some regulatory clinical trials
  1. A phase III, prospective, comparative, randomized, double blind, multicentric clinical study to assess safety, tolerability and efficacy of a fixed dose combination of Nitazoxanide & Ofloxacin in adult (>18 yrs) patients
  2. An open, non-comparative, multicentre, 12 weeks study to assess efficacy and safety of 5 % Imiquimod cream in the treatment of adults and adolescent Indian patients with genital warts
  3. Evaluation of the Safety, Efficacy, Tolerance and Antiviral Efficacy of 3% Sorivudine (ARYS-01) Cream in Herpes Zoster Patients between the ages of 18 and 55
  4. Post Marketing Surveillance Study for Magnex (Injection Sulbactum + Cefoperazone, 1:1)
  5. A randomized, double-blind, comparative, multicentric clinical study to evaluate the safety and efficacy of Nicorandil extended release formulation in patients of chronic stable angina

6. A Phase II, Double-Blind, Randomized, Placebo-Controlled Study of the Efficacy and Safety of EpiCeptTM NP-1 Topical Cream (amitriptyline 4% / ketamine 2%) Applied Twice Daily in Patients with Pain from Diabetic Peripheral Neuropathy (DPN)
7. A Phase II, double-blind, Randomized, placebo-controlled, Non-inferiority Trial of EpiCeptTM NP-1 Topical Cream
(4% amitriptyline / 2% ketamine) vs. Oral Gabapentin in Postherpetic Neuralgia (PHN)

- Coordinator & Investigator, National Pharmacovigilance Programme, Government of India, 2004-08.

PROFESSIONAL RESPONSIBILITIES / AFFILIATIONS

- Secretary - Clinical Pharmacology, Indian Pharmacological Society/ Member of ISCR and many associations.

ACHIEVEMENTS

- Recipient of the 'Doctor of the Year Award' from Students Health Home, Kolkata in 2005
- Councilor Elect from India, International Union of Pharmacology (IUPHAR) - Clinical Division
- Acted as the Key Expert Contributor in developing the State Drug Policy for West Bengal
- Contributed in the development of the international document on pharmacovigilance, 'ISDB EU: Berlin Declaration on Pharmacovigilance', Berlin, January 2005

Publications:-27
Chapters Contributed in a Book:-2
Books Authored / Edited:-6


ABSTRACT

## Pharmacovigilance Methods

Use of any medicine is always associated with some risks. The aim of pharmacovigilance is to minimize such risks to an extent that is acceptable and outweighed by the overall benefits. The World Health Organisation defines pharmacovigilance as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem'. The pharmacovigilance methods and approaches are varied and continue to evolve. The ever-dynamic processes of pharmacovigilance strive to integrate safety data throughout a product life cycle, and thus to ensure that patients receive safe drugs.

While pre-registration safety evaluation studies, both non-clinical and clinical, may be considered, a part of the broader specter of pharmacovigilance, traditionally, the latter is considered for licensed products. Thus for a product that has been marketed, there are several methods used to collect safety information in pharmacovigilance. These mainly include (1) passive surveillance like spontaneous (individual case) reporting, stimulated / solicited reporting with a focus on a pre-designed case definition, (2) active surveillance like drug event monitoring (DEM), cohort event monitoring (CEM), use of patient registries longitudinal patient records, and (3) traditional observational research designs namely, cross-sectional, case control and cohort studies.

Besides, in order to ensure safer prescribing of certain products wherein significant risks are identified from pre-approval clinical trials, targeted investigations like genetic testing, therapeutic drug monitoring etc may be advised by the marketing authorization holder as a part of product risk management plan. Specific safety information can be derived systematically from such targeted investigations. Population pharmacokinetic studies constitute another pharmacovigilance strategy for some specific drugs if it is so warranted. Descriptive studies are also sometimes used in pharmacovigilance, primarily to obtain the background rate of outcome events and/or establish the prevalence of the use of drugs in specified populations.

In fact, there is no single method that can be relied on exclusively for global adverse drug reaction monitoring and surveillance. A judicious mix of multiple methods and approaches can yield optimum information based on which a regulatory or non-regulatory action towards safer prescribing and use, can be taken.

Abstract

## Medication Errors and Patient Safety Issues

Safer prescribing of medications, improving their judicious use and minimizing adverse drug reactions have always been key areas of concern in health care delivery. The drug regulatory authorities, the pharmaceutical industry, health care professionals, and patients – all are concerned. A related issue, a serious patient safety concern that is in the centre of attention today is medication errors. Medication errors leading to iatrogenic injuries are a well known worldwide phenomenon and are common, costly, and clinically important. More than one fourths of all adverse drug events are due to medication errors and they are preventable. Reducing medication errors and improving patient safety have become common topics of discussion today around the world. Although the problem has been known since long, the landmark publication from the Institute of Medicine (IOM) "To Err is Human: Building a Safer Health system" released in 2000, created an appreciable impact and people around the world were reawakened.

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding, dispensing, distribution, administration; education; monitoring; and use."

Some common types of medication errors include the following:

- Incomplete patient information (not knowing about patients' allergies, other medicines they are taking, previous diagnoses, and lab results, for example);
- unavailable drug information (such as lack of up-to-date warnings);
- miscommunication of drug orders, which can involve poor handwriting, confusion between drugs with similar names, misuse of zeroes and decimal points, confusion of metric and other dosing units, and inappropriate abbreviations;
- lack of appropriate labeling as a drug is prepared and repackaged into smaller units; and
- environmental factors, such as lighting, heat, noise, and interruptions, that can distract health professionals from their medical tasks.

Focusing on the word error has drawn attention to "prevention" and what can be done to minimize mistakes and improve patient safety. What should be done is generally known as "the five rights": the right drug, right dose, right route, right time, and right patient. One can make an error of omission (failure to act correctly) or an error of commission (acted incorrectly). The practice of medicine, pharmacy, and nursing in the hospital setting is very complicated, and so many steps occur from "pen to patient". There is a lot to analyze. Implementing safer practices requires developing safer systems. Reducing medication errors is an ongoing process of quality improvement.

This presentation will summarize what is currently known about medication errors and how they could have been minimized, if not eliminated totally.

**Dr. Ronald Meyboom,**
Medical Advisor, Uppsala Monitoring Committee (UMC), Sweden

Dr Ronald Meyboom graduated as a medical practitioner at the University of Leiden in the Netherlands. With a keen interest in pharmacology and in medicines as a paradoxical cause of disease, he has headed for almost 20 years the National Pharmacovigilance Centre in the Netherlands. In that time he also pioneered hospital pharmacovigilance at the Leiden University Hospital (Dr H. Mattie). In 1998 he defended a PhD thesis at the University of Nijmegen based on his experiences in practical pharmacovigilance, entitled "Detecting Adverse Drug Reactions. Pharmacovigilance in The Netherlands".

After having assisted in the creation a new organization for pharmacovigilance in his country (in the form of an independent non-profit foundation), he became more involved in international pharmacovigilance (WHO Uppsala Monitoring Centre) and initiated collaboration between the centre in Uppsala and the Department of Pharmacoepidemiology and Clinical Pharmacology of the University of Utrecht (The Netherlands), combining research and teaching.

Dr Meyboom has published over 100 articles and chapters relating to pharmacovigilance in specialised journals and books. He is an honorary member of the Society of Pharmacovigilance of India (SoPI), a founding board member of the International Society of Pharmacovigilance (ISOP), a member of the editorial boards of the journals Drug Safety and Pharmacoepidemiology and Drug Safety, and co-author of the Meyler's Side Effects of Drugs series. Having recently reached 65, the further development and improvement of pharmacovigilance around the world is his major commitment.

ABSTRACT

## Spontaneous Monitoring - Time to Reform

Division of Pharmacoepidemiology and Pharmacotherapy, University of Utrecht, Utrecht, The Netherlands The Uppsala Monitoring Centre, Uppsala, Sweden

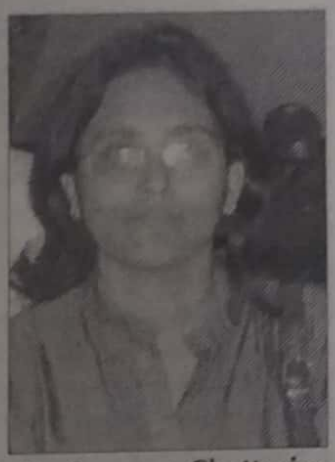
During the 'pharmacotherapeutic revolution', midway through the last century, a series of unexpected and serious adverse drug reactions have lead to the understanding that there is a need for continuous monitoring of the safety of medicines after their introduction. Around 1970 in countries in different parts of the world national pharmacovigilance centres were introduced, using the technology and focussing on the concerns of that time.

Since then advances in medical diagnosis and treatment and in computing and medical-pharmaceutical

administration, together with changes in organisation and financing, have altered the landscape of healthcare in many respects. Unprecedented possibilities have become available for comprehensively studying the benefit and harm of medicines.

While also pharmacovigilance has developed and changed enormously, it is today to a large extent still based on the 'spontaneous reporting' principle of 50 years ago. A succession of safety issues has emphasised the continuing need for alertness and improvement, the more so since the recent 'biopharmaceuticals' are again revolutionising pharmacotherapy. In recent years many proposals for improvement have been made and attempts been initiated, but evidence as to the timeliness and effectiveness of the new requirements and novel methods is still limited. A critical follow-up of their performance, ethics and costs is necessary.

In addition to these developments, there is an urgent need for a careful reconsideration of the current and future roles of 'spontaneous reporting', and of its organisation and governance, in order to ensure that data of the best possible quality be collected and used to their best advantage, also paying due attention to the differences between various parts of the world.



**Dr Suparna Chatterjee**
Associate Professor of Pharmacology, IPGMER, Kolkata
Email: drsupchat@gmail.com

- Core Competence: In Clinical Pharmacology domains - Clinical trial designing and conduct, Pharmacovigilance, Pharmacoepidemiology and Pharmacogenetics
- Publications in peer reviewed International and National journals: 30 papers
- Author of several chapters in books: 6
- Other Academic achievements

Chief Coordinator, Training and Technical Support of Eastern Regional Resource Centre of the Pharmacovigilance Program of India (PvPI)

Member expert by the Drugs Controller General of India, Government of India for regulatory review of Clinical Trials.

Abstract

## Causality assessment and Signal Detection in Pharmacovigilance

Drug safety issues have become a zero tolerance issue due to increasing concerns amongst consumer groups, media and drug regulatory authorities. Regulatory authorities should be able to detect safety threats early using scientifically correct techniques and take appropriate measures accordingly to minimize risks associated with drug usage. However, early detection of such threats is by no means an easy task and has several roadblocks.

Causality assessment in Pharmacovigilance implies finding out the relatedness of an adverse event to the drug. Various methods may be used for causality assessment. Basically they can be -

Global Introspection- where inference is drawn on clinical judgment of an individual or an expert panel. Though this a simple and easy method it has several limitations like subjectivity, imprecision and lack of reproducibility. Algorithms for causality assessment therefore emerged as an alternative- as they are standardized instruments - for reliable and reproducible measurement of causality in a structured way. These algorithms contain sets of specific questions with associated scores for calculating the likelihood of a cause-effect relationship. The commonly used CA algorithms are WHO ADR Probability Scales; Naranjo's Scale; European ABO system, French Imputation system, Karsch and Lasanga.

Algorithms share several common features- questions are used to capture details of the ADR and

different procedures are thereafter adopted to convert answers from these questions to estimates of probability. However, they too have several disadvantages - no universally acceptable algorithm is available, scoring may be arbitrary since response to questions can be subjective.

Causality assessment is based on: temporal relationship of the drug and the adverse event, dose relationship, effect of de-challenge/re-challenge, pharmacological plausibility, exclusion of other underlying illness/concurrent conditions or medications. Regardless of number of factors present, the completeness and quality of the information is critical for the assessment.

The WHO ADR probability scores which is one of the most commonly used algorithm has the following causality analysis categories-Certain; probable/Likely; Possible; Unlikely; Conditional/unclassified and Unassessable/ Unclassifiable. The Naranjo's scale is also similar and has the following categories-Definite; Probable; Possible and Unlikely.

In recent times however, computational tools are used for CA since postmarketting drug surveillance and spontaneous reporting system databases have become enormous and cannot be analyzed manually. Several statistical methods can be adopted- either the classical frequentist (non-Bayesian) or the Bayesian approach for detecting unknown or less commonly known drug safety alerts which in Pharmacovigilance terminology is referred to as signal.

A Signal is defined as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.

A signal is something which is considered important and needs further attention and investigation.

However a signal does not imply causation, is not a confirmed finding and can help only in generating a hypothesis but cannot test it. Computational signal detection algorithms assist drug safety experts to discover potentially relevant drug-adverse event relations.

Signal detection process in a spontaneous ADR database is based on different statistical methodology - either the Bayesian or Frequentist statistical approach. Whichever method is employed basically it involves computation of measures of disproportionality i.e determination to what extent the number of observed cases differ from the number of expected cases. All disproportionality algorithms despite having operational technique variability actually calculate surrogate observed to expected ratios in which the reporting experience of each reported drug-adverse event combination is compared to the background reporting experience across all drugs and events in the database using an independence model.

The WHO UMC (Uppsala Monitoring Centre) uses the BCPNN - (Bayesian Confidence Propagation Neural Network) while US FDA uses the MGPS- (Multi item Gamma Poissson Shrinker) methodologies. Other disproportionality analyses methods using the frequentist approach are ROR (Reporting Odds Ratio), PRR (Proportional Reporting Ratio) which are employed by some national reporting centres (MHRA, UK) and drug safety research units.

In the BCPNN methodology computation of the Information Component (IC) is based on prior and posterior probabilities. The IC is a measure of the disproportionality between the observed and the expected reporting of a drug-ADR pair. IC=0, combination reported as often as expected relative to background of database, if drug and ADR are independent. If IC>0, combination reported unexpectedly frequently; IC<0, combination reported unexpectedly infrequently and IC025 is the lower bound of the 95% Credibility interval for the IC and if this is greater than zero and it should be highlighted for clinical review.

The US FDA which uses the MGPS approach generally the Empirical Bayesian Geometric Mean (EBGM) is computed which is an observed/expected score output of the MGPS method. EB05 and EB95 are the upper and lower bounds of the two- sided CI around the EBGM. If EB05 ≥2 it is considered for clinical review.

The frequentist approach based tools like the ROR or PRR are also used to detect signals and some experts suggest a PRR ratio ≥2, chi squared statistic ≥ 4 and 3 or more cases for defining a signal.

However, whichever method is used each has its advantages and disadvantages and there is no single method which can be considered as the gold standard for signal detection. Data mining tools should enhance, rather than replace, signal detection procedures in large ADR databases. Quantitative signal detection methods are used for hypothesis generation not for hypothesis testing and it should be tested using other types of research studies. Clinical case review knowledge are mandatory to imply causation.

**Dr. Sadhna Joglekar**
Area Medical Director - South Asia;
Executive Vice President, Medical & Clinical research, GSK Pharmaceuticals Limited.

Dr Sadhna Joglekar is a MD (Pharmacology) from KEM Hospital. She is a gold medalist in pharmacology from Mumbai University.

Dr Sadhna Joglekar is currently Area Medical Director for South Asia and Executive Vice President, Medical and Clinical Research at GlaxoSmithKline Pharmaceuticals Ltd. She leads a team of approx 45 people engaged in Regulatory Affairs, Medical Affairs and Clinical Operations and medical governance. Prior to joining GSK, she worked in Pfizer, initially in Medical Affairs and later in Strategy and Business Development, followed by Regulatory Affairs.

During her career in the pharmaceutical industry, she has had extensive experience in clinical research, medical affairs and pharmacovigilance. She is the Vice Chair of the OPPI Medical Committee since 2008 and has been a member of several ad hoc task forces convened by regulatory authorities to look at India Clinical Trial Regulations, India GCP Guidelines, etc. She has over 25 publications to her credit and is an invited speaker at several congresses and workshops. She has a chapter to her credit in the API textbook of Medicine (2008) and another in Innovative India, a Medialand London Publication. She has been a visiting faculty at Narsee Monjee Institute of Management Studies for the Post graduate Diploma in Pharmaceutical Medicine.

Abstract

## Post Marketing Surveillance - Need, Relevance and Methods

Postmarketing surveillance (PMS) is a safety monitoring and risk assessment program to identify mainly newer adverse effects of a drug after its approval. It is an important part of the science of pharmacovigilance.

When a new drug is approved and enters the marketplace, the available clinical safety and tolerability information is based on the data generated from only a few thousand very carefully selected patients, in a tightly controlled intervention setting. The design of the trials is to focus on the drugs' benefits, and usually does not include a large enough sample size to elicit less frequent adverse effects. Once the drug is available for widespread use, the real safety profile of the drug may be evaluated. PMS can add to and/or refine the safety information of a drug after it is used in the general population by large numbers of people who have a wide variety of other medical conditions.

PMS uses a number of approaches to monitor the safety of licensed drugs, including spontaneous reporting databases, prescription event monitoring, electronic health records, patient registries and record linkage between health databases. These data are reviewed to highlight potential safety concerns in a process known as data mining.

This presentation makes a brief overview of the state-of-the-art issues related to PMS

**Dr Jaydip Bhaduri**
Vice President - Medical Services,
Cadila Pharmaceuticals, Ahmedabad

Dr Jaideep Bhaduri is graduate from Calcutta Medical College and post graduate in Pharmacology from IMS, BHU. Dr Bhaduri has served the pharmaceutical industry since last 22 years. He has been instrumental in setting up and restructuring Medical Affairs functions of some of the leading organizations of the country. Dr Bhaduri takes keen interest in clinical research and teaching. He has quite a few publications to his credit.
Currently he heads Medical Affairs function of Cadila Pharma and is based at Ahmedabad.

Abstract

## Safety Reporting in Clinical Trials

Adequate attention is to be paid to assessment of risk versus benefit ratio for any intervention be it drug, device or any diagnostic tool. Generally scientific standards for assessment of safety are rarely employed as they are for efficacy variables and unsurprisingly safety assessment plays second fiddle to efficacy assessment. The recent experiences with Rofecoxib, Atenolol, Rosiglitazone and Pioglitazone are a few examples where safety issues encountered after millions of patients world over have been exposed have either led to withdrawal of the drug from the market or a severe restriction of their being prescribed. While controlled trials before approval of a new therapy has an intrinsic deficiency in detecting many potentially serious adverse events, relaxation of statistical criteria born out of conservatism sometimes leads to according significance to some adverse events which in actual clinical usage may not be relevant (e.g. nausea with an anti-cancer). The FDA has in recent past incorporated inclusion of safety data in the NDA (new drug application) in certain therapy categories like anti-diabetic treatment; anti-inflammatory agents and anti-histamines to name a few. The protocols must necessarily define every adverse event and how they will be collected. A detailed analysis of the adverse events using various statistical tools (like is done for efficacy variables) in lead publications of results must necessarily be incorporated in the report. While reporting all adverse events is impractical at least those known or caused by the intervention, any serious event and those where a significant difference is detected between groups must necessarily be reported.

**Prof K C Singhal**
Vice Chancellor
NIMS University, Jaipur India

Professor Krishan Chandra Singhal earned both his Bachelor of Medicine and Bachelor of Surgery in 1964 and his Doctor of Medicine in 1968 from King George's Medical College Lucknow. His Philospher's degree in 1976 from Rajasthan university and Doctor of science in 2001 from Aligarh Muslim University, Aligarh, India. Dr. Singhal's major areas of research are Pharmacovigilance, Clinical Pharmacology and Chemotherapy. He has established a new method for screening potential antifilarial agents using Setaria cervi as test organism. He was Professor and Chairman Department of Pharmacology, Jawahar Lal Nehru Medical College, AMU Aligarh before he joined as Vice Chancellor, NIMS University Jaipur, India.

Dr. Singhal has been President (1994); Treasurer (1982-1984) of Indian Pharmacological Society; President (1999), General Secretary (1994-1998), Treasurer (1982-1993) of Indian Academy of Neurosciences, President, Chief Editor, Indian Journal of pharmacology (1989-1991), Editor (Pharmacology) Indian Journal of Physiology and Pharmacology, Vice President, Indian Society of Hypertension; President, Society of Pharmacovigilance, India (2000-2005), Consultant, Clinical Pharmacology on committee for Categorization of Essential Drug in the Country. At present he is patron Society of Pharmacovigilance, India, member advisory committee National Pharmacovigilance Programme, Indian Medical Association, member apex committee on Pharmacovigilance of drugs of Ayurveda, Unani & Siddha.

Dr. Singhal has been Organizing Secretary National Conferences of Indian Academy of Neurosciences, Association of Physiologist and Pharmacologist of India, Association of Gerentology of India, International Workshop on Adverse Drugs Reaction Monitoring in India, International workshop on Problem Based learning, Workshop on Pharmacovigilance of Drugs of Indian Systems of Medicine. He was Co-ordinator and Principal Investigator of multicentric Indian Council of Medical Research sponsored task force on @Monitoring of Epidemiological profile and factors responsible for Adverse Drug Reaction in India@. He was co-ordinator of WHO special center for ADR Monitoring in India. He has participated in workshop on teaching methodology at Rapino, Russia; Indo-US workshop on Problem Based Learning and Computer oriented teaching. He has more than 200 research publication in National and International Journals and presented more than 205 paper/lectures at National and International conferences. Prof. Singhal is a founder fellow of IMA Academy of Medical Specialities, Founder fellow of Indian Pharmacological Society, Founder fellow of Indian Academy of Neurosciences and Founder of Society of Pharmacovigilance India. He has been consultant WHO centre for International Drug Monitoring Uppsala, Sweden for eight years.

He was visiting Professor to Health Science Centre, University of Tennessee at Memphis, USA during 1995, The John Autian Distinguished International visiting Professor at University of Tennessee at Memphis during 2000. He has been invited speaker to many national and International meetings, seminars and universities.

Abstract

## Impediments in the Monitoring of Drugs of Indian System of Medicine

The growing popularity of Indian Systems of Medicine around the globe has created new challenges for the ISM fraternity. Systems of Indian Medicine including Ayurveda, Unani and Siddha are holistic systems of medicine having legacy of thousands of years and well documented texts accounting to more than few hundreds, but the clinical validation of the efficacy and safety claims of these texts on modern statistical parameters are lacking. What Indian systems of medicine need today is documentation of clinical data related to safety profile in accordance with the pharmacovigilance parameters applicable to modern medicine.

According to WHO, 3 billion people in developing countries (80% of population) and 1 billion in western countries (30-50% of population) use traditional medicine. India has 3004 hospitals, with 60666 beds, 23028 dispensaries and 611416 registered practitioners of ISM. Thus India has approximately seven ISM & H physicians per 10,000 populations. In India out of 15000 plant species available, about 2000 of these are used as medicinal plants.

Monitoring drugs of ISM pose a bigger problem than those of Allopathic system. There are too many products to monitor. Single and multiple ingredient formulations are numerous. Many a times, herbal and allopathic drugs are included in the same formulation or are taken together by the same patient. Formulations can be changed at will keeping the same brand name. Methods of preparation of harbs can differ and complicate ADR monitoring of the 'same' herb. Quality checking is ambiguous affecting the causality of an ADR. Moreover, herbal drugs are usually taken over the counter by patients and prescribed by all specialties.

Fixation of standards of traditional medicine is a great challenge for the scientific field, particularly for those drugs that are derived from plants. It is due to the variation of active principles present therein. This variation is quite natural due to ecological factors, where the groups are grown. Similarly standardization of compound formulation is even a tougher jobs. Many times a compound formulation contains a large number of herbs and it is very difficult to analyze each and every herb quantitatively as well as qualitatively.

Difficulty for ADR monitoring of drugs of ISM is further complicated with the substitution of drugs (Al-Abdal for drugs of Unani medicine and pratinidhi Dravya for Ayurvedic Drugs). In Unani system of medicine provision has been made for the substitution of 122 drugs in a book abdal al Adviya by Rhazes. Later 50 more herbs have been added to the list. The substitutions in unani medicine can be made even for the active ingredient responsible for main pharmacological action. Whereas, in Ayurveda substitution is not permitted for herb with active principal and can only be done for exipient or additives.

Department of AYUSH took initiative by holding a consultative meeting of experts on 29-30 August 2008, and formal launching of Pharmacovigilance programme was don on 29th September, 2008.

Gujrat Ayurved University was selected as national Phamacovigilance Resource Centre (NPRC) with eight regional centre and thirty peripheral centres.

Greater need it felt to develop ADR reporting culture among physicians of ISM. The effort taken so far has yielded little. However, the steps undertaken so far are welcome and will help in establishing credibility of ASU drugs and will also improve their manufacturing and prescribing.

**Dr R N Acharya**
Associate Professor & Member Secretary,
National Pharmacovigilance Resource Centre for ASU drugs, IPGT&RA,
Gujarat Ayurved University, Jamnagar

Publications / Research : Co authored 4 books related with terminology, contributed two course writing for IGNOU, one chapters in WHO funded monograph and two chapters in AYUSH funded e-learning programme., Published/ accepted/ communicated 63 research articles in peer reviewed - International / National seminar proceedings/other reputed research journals, Presented more than 45 research papers (self/co-author) in International / National and semi Supervisor : Awarded / Submitted / Working as supervisor/ co supervisor for 10 PhD(Ayu), 8 MD(Ayu.), 5 M Pharma (Ayu.) and 1 M Sc ( medicinal planta) scholars
Guest lecture : Delivered more than 50 guest lecture during RoTP, CME and National and International seminars
Other activities :

- Member secretary, National pharmacovigilance Resource centre for ASU drugs.
- Working as a member of different developmental committees of the institute/ University.
- Worked as organizing secretary of different Seminars and educational programmes.
- Life member of different societies related with Ayurvda / Medicinal plants/ pharmacovigilance
- Member board of studies RAU, Jodhpur
- Worked as member of syllabus reforms committee of CCIM for UG and PG syllabus of Dravyaguna
- Working as an examiner for PhD and MD Ayu exam. of more than 10 universities
- Preparing MCQ for various competitive, Institutes, universities and organizations.
- Working as reviewer of four international peer reviewed journal.
- Working as principal investigator (one) and co investigator (two), AYUSH funded projects.
- Attended more than 60 National and International seminars

Abstract

National Pharmacovigilance Programme for Ayurveda, Unani and Siddha ( ASU) drugs

From prehistoric times, medicinal plants are being used, by various communities and civilizations throughout the world, to combat different disease conditions. In India, Ayurveda, Siddha and Unani (ASU) systems medicine, considered to be oldest system of medicines, also prescribes drugs of herbo-mineral and animal origin for the treatment of many diseases. Being time tested systems of medicine and majority of drugs are of herbal origin, it is considered that these drugs are safe. The use of ASU medicines continues to expand rapidly across the world. People are now consuming these medicines, as an OTC drug, in the name of herbal medicines or herbal products for their health care in different national health-care settings which results a high demand of these medicines in the national as well as

international market. Due to inadequate regulatory measures, weak quality control systems and largely uncontrolled distribution channels (including mail order and Internet sales) and improper administration some adverse events has also been reported.

It is observed that, the majority of adverse events related to the use of ASU medicines that are reported are attributable either to poor product quality or to improper use. It is the high time to have knowledge about genuine adverse reactions to herbal medicines, and to avoid wasting scare resources for identifying and analysing adverse events, events resulting from such situations will need to be reduced or eliminated. However, mass media reports of adverse events tend to be sensational and give a negative impression regarding the use of herbal medicines in general rather than identifying the causes of these events, which may relate to a variety of issues. The safety of herbal medicines has become a major concern to both national health authorities and the general public.

Department of AYUSH, Ministry of Health and F &W, Govt. of India, New Delhi, recognised Institute for Post Graduate Teaching & Research in Ayurveda (IPGT&RA), Gujarat Ayurved University, Jamnagar as National Pharmacovigilance Resource Centre for Ayurveda, Siddha and Unani Drugs(NPRC-ASU) in India under the Central sector scheme for up gradation to Centre of Excellence since 2008-09. As per the protocol, NPRC-ASU Drugs, is coordinating this National Pharmacovigilance programme (NPP-ASU) under the aegis of Department of AYUSH, Ministry of Health & Family Welfare, Government of India. Under NPRC-ASU drugs, there are eight Regional Pharmacovigilance Centre (RPC) for ASU drugs. There are 30 Peripheral Pharmacovigilance Centre (PPC) for ASU drugs which are working under these eight RPCs, across the country. Adverse drug reaction related to any ASU drugs is being reported to these PPC, in a specially designed ADR reporting form, which are transmitted up wards after proper evaluation at each level. Till today, NPCC-ASU drugs met thrice and NPTAC-ASU drugs met once to review the Programme as well as reported ADRs.

To full fill the primary aim of this programme i.e To develop the culture of notification and to involve healthcare professionals and professional associations in the drug monitoring and information dissemination processes, Teachers, physicians and pharmacists of ASU systems, were being sensitized on the concept of pharmacovigilance and how to report ADR through CME programme, across the country and till today more than 2000 teachers/ physicians and paramedical staff were trained in this regard. Further, Phamracovigilance for ASU drugs, is being included as a topic, in the module of each CME and RoTP of Dravyaguna/ Rashashastra, coordinated by RAV, New Delhi. A web portal, 'ayushsuraksha.com' has been launched for on line registration of ADR related to ASU drugs through an @e format@.

To achieve operational efficiencies that would make National Pharmacovigilance Programme for ASU drugs a benchmark for global drug monitoring endeavors Pharmacovigilance has been included in the curriculum of graduate and post graduate level studies of Ayurveda. Now steps have been taken to open one Pharmacovigilance centre at each affiliated ASU colleges. Clinical research units of different pharmacies including institutes conducting Post graduate and doctoral level research were requested to include Pharmacovigilance aspect as one of the criteria in their research projects. Department of AYUSH, Govt. of India, has been requested to instruct the drug licensing authorizes to include pharamcovigilance aspect as one of the criteria while giving permission for a new drug.

As a part of promotional activities brochures on Pharmacovigilance for ASU drugs were prepared and being distributed at stall at Arogya / CME etc, guest lectures were delivered during scientific sessions of different National and International seminars and research scholars and public were informed by putting advertisement related to NPP ASU drugs in different journals and souvenirs.

**Dr Arun Gupta**
Head of Medical Affairs, Dabur India Ltd

Dr Arun Gupta is currently working as Head @ Medical Services & Clinical Research in Dabur Research & Development Centre. He has completed his MBBS and MD Pharmacology from Post Graduate Institute of Medical Sciences, M D University, Rohtak. Before joining Dabur, he has worked in Global Clinical Research Organization as Sr. Manager Medical & Regulatory Affairs; and as Medical Advisor in an Indian Pharmaceutical Company. Overall he has more than 10 years of Pharma industry experience. He has also worked as a Resident in Medicine Department in Medical College before joining the Pharmaceutical industry.

He has a rich experience in Pharmacovigilance, Clinical Research, and Regulatory Affairs of Pharma as well as Indian Systems of Medicine. He has worked on various phase II and phase III global clinical trials. The main therapeutic areas, he has been involved in global clinical research, are Psychiatry and Neurology.

He has participated as a speaker in various workshops on Pharmacovigilance, Good Clinical Practices, and Regulations in Clinical Research. He has also participated in DIA webinar as speaker on Pharmacovigilance. He has won the prestigious Servier Young Investigator's Award by Institutet de Recherches Internationales Servier, France for his research work presentation on Azadirachta indica leaf extract in International conference on Pharmacology.

Abstract

Ensuring Safety of Proprietary Ayurvedic Formulations

Proprietary Ayurvedic formulations are formulations made using the ingredients mentioned in authorative text books mentioned in First Schedule of Drugs and Cosmetics Act and Rules of India, which are being used by a route other than parenteral for their medicinal (diagnosis, treatment, mitigation or prevention of disease), positive health promoter, and beautifying properties; in which Ayurvedic ingredient is used as such or in the form of dry/wet extract from the plant.

It was a general view earlier that Ayurvedic medicines have no or minimal side effects. However WHO (World Health organization) in 2008 emphasized the need of establishing safety and efficacy of traditional medicines. Moreover, recently, safety of Ayurvedic and other traditional medicines has gained utmost importance due to growing global interest, competition and scientific discovery along with changing regulatory requirements globally.

As per the recent Gazette of India notification vide G.S.R 663(E) dated 10th August 2010, safety studies are required for the following categories of Patent or Proprietary medicine:

1. Patent or proprietary Ayurvedic drugs / positive health promoter / beauty products: If the formulation contains ony of the ingredients of Schedule E(1) of The Drugs and Cosmetics Act and Rules.
2. Ayurvedic formulation containing hydroalcoholic extract of medicinal plant and is indicated in a new indication

3. Ayurvedic formulation containing extract of medicinal plant other than Hydro / Hydro-alcoholic needs to undergo extensive safety studies including acute, chronic, mutagenicity and teratogenicity.

Safety of proprietary Ayurvedic formulations may be ensured through various modalities e.g.

1. Ensuring qualitative and consistent quality raw material usage without any adulteration
2. Ensuring standardized and quality compliance formulation
3. Ensuring safe amount of heavy metals and contaminants
4. Ensuring rational use of the formulation
5. Long term traditional and current usage
6. Preclinical toxicity studies
7. Clinical studies
8. Pharmcovigilance

Ensuring safety of Ayurvedic formulation is as important as of Pharma formulations; however, it is a bit complex issue and a holistic view needs to be taken and accordingly the appropriate measure should be taken starting from raw material sourcing till Pharmacovigilance.

**Prof. R K Goyal**
Director
I.S.F. College of Pharmacy, MOGA 142 001

Dr. Ramesh K Goyal, Director, I.S.F. College of Pharmacy, Moga (Punjab) has been the Vice-Chancellor of The Maharaja Sayajirao University of Baroda (2008-2011) and Professor of Pharmacology in L. M. College of Pharmacy, Ahmedabad with over 33 years of experience in Teaching and Research particularly in Cardiovascular Pharmacology & Diabetes. In between he was a post doctoral scholar (1984) and visiting scientist (1995) at University of British Columbia, Vancouver, Canada and visiting Professor, Institute of Cardiovascular Sciences, University of Manitoba, Canada (1999, 2001, 2003and 2006). He has three patents, 15 books, over 260 full papers ('h' index 14), 400 abstracts published and guided 41 Ph D and 153 M. Pharm students. He is the recipient of 59 awards including Best Pharmacy Teacher and Best Pharmaceutical Research Scientist (APTI) and Life Time Achievement & Distinguished Service Awards from International Academy of Cardiovascular Sciences, Canada. He is the Fellow of seven professional bodies (FIPS, FIACS, FAMS, FIC, FICN, FNASc , FSCH) and Member of different committees (ICMR, AICTE, UGC). He has been the President of Indian Pharmacological Society (2009) and Currently President of Society of Pharmacovigilance(2010-11). He has attended number of Seminars, Workshops and Conferences as Resource Person and also chaired various sessions. Dr. Goyal has been invited to deliver about 115 lectures in India and 20 lectures abroad.

He is currently the Chairman of Central Regional Committee of AICTE, Bhopal and Member, Executive Committee of AICTE, New Delhi.

During three years as the Vice Chancellor at MSU, besides getting the University re-accreditation organized several International and National Conferences. Major ones being the International Conference on Buddhism with HH The Dalai Lama present and various top level dignitaries and the Satellite Conference of International Congress of Mathematicians which was held in India for the first time in 113 years. He has been successful in getting sizeable financial support to MSU(about 100 Crores) and to L M College of Pharmacy (Rs 1.5 Crore in individual capacity).

Abstract

Iatrogenesis and Patient Safety

As a strategy in pharmacovigilance, the process of collection of information about a drug begins in phase I of the clinical trial, before approval of the drug, and continues even after approval and should end with; post-market surveillance studies conducted around the world. Although, clinical trials tell enough of the ADRs but the "enough" is determined by legislation and by contemporary judgements about the acceptable balance of benefit and harm. A clinical trial can never tell you the whole story of the adverse effects of a drug in all situations. Post-market surveillance studies uses tools such as data mining of spontaneous reporting systems and, investigation of case reports to identify the relationships between drugs and ADRs. One of the major weaknesses of the system is under-reporting and reports are almost always submitted voluntarily.

In spite of almost three decades programs of pharmacovigilance world wide iatrogenic diseases continues to be the major cause of morbidity and mortality. In the United States, an estimated 44,000 to 98,000 deaths per year may be attributed in some part to iatrogenesis. Further, between 4% and 18% of consecutive patients experience negative effects of drugs in outpatient settings, with 116 million extra physician visits, 77 million extra prescriptions, 17 million emergency department visits, 8 million hospitalizations, 3 million long-term admissions, 199,000 additional deaths and $77 billion in extra costs. Similar is the case in many other developed countries wherein data are available.

In India, the problem is more complex. The doctors tend to overprescribe, over-utilize and overuse drugs. Their prescription and use is influenced by pharmaceutical companies who operate with purely profit motives. The drug industry is controlled by the Ministry of Chemicals rather then Ministry of Health. The patients also invite problems by self-administration of drugs. It has been reported that about 50 per cent of the drugs are sold over the counter (OTC).

Various evidence based case studies indicate that iatrogenesis in India is the cause and contagious. Under all these circumstances it is essential to have a pharmacovigilance on practicing doctors not only those who use drugs without having ever studied (Ayurvedic, Homoepathic or Unani doctors using modern medicines) but even the current allopathic doctors getting knowledge from mainly the medical or sales representatives.

## Iatrogenesis and Patient Safety
## SYNOPSIS

Pharmacovigilance is the pharmacological science related to detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines including biological, herbal and traditional medicines or medical devices. The process of collection of such information about a drug begins in phase I of the clinical trial, before approval of the drug, and continues even after approval and should end with; post-market surveillance studies conducted around the world.

Although, clinical trials tell enough of the ADRs but the "enough" is determined by legislation and by contemporary judgements about the acceptable balance of benefit and harm. Further, clinical trial are specified and controlled and the results relate only to the population of which the trial group is a representative sample (several thousand patients at most). A clinical trial can never tell you the whole story of the adverse effects of a drug in all situations. Many a times less common side effects and ADRs are unknown at the time a drug enters the market. Even very severe ADRs such as liver damage are often undetected because study populations are small.

Post-market surveillance studies uses tools such as dart mining of spontaneous reporting systems and, investigation of case reports to identify the relationships between drugs and ADRs. Spontaneous reporting is the core data-generating system of international pharmacovigilance of WHO, relying on healthcare professionals (and in some places consumers) to identify and report any suspected adverse drug reaction to their national pharmacovigilance center or to the manufacturer. The database, includes around 4.6 million reports (January 2009), growing annually by about 250,000. Some countries legally oblige spontaneous reporting by physicians and in some countries manufacturers are required to submit through a qualified person for pharmacovigilance. Others have intensive, focused programmes concentrating on new drugs, or on controversial drugs, or on the prescribing habits of groups of doctors, or involving pharmacists in reporting. One of the major weakness of the system is under-reporting and reports are almost always submitted voluntarily.

Iatrogenic diseases are those caused by medical intervention. This includes anything ranging from damage caused by an ill-fitting plaster cast to drug side-effects or long-term results of drug overuse. Side-effects of drugs, misuse of drugs, harmful drug combinations, medical negligence, medical error or misjudgement, contravention of contra-indications and nosocomial disease (one acquired in hospital) can all constitute iatrogenic disease. In the United States, an estimated 44,000 to 98,000 deaths per year may be attributed in some part to iatrogenesis and it is the third leading cause of death in the United States, after deaths from heart disease and cancer. Further, between 4% and 18% of consecutive patients experience negative effects of drugs in outpatient settings, with 116 million extra physician visits, 77 million extra prescriptions, 17 million emergency department visits, 8 million hospitalizations, 3 million long-term admissions, 199,000 additional deaths and $77 billion in extra costs. Similar is the case in many other developed countries wherein the data is available.

In India, the first multicentric study for monitoring ADR was initated in 1989by ICMR through Prof. K. C. Singhal as the co-ordinator. It collected a data of 54194 cases monitored for ADR from 6 centres. Later data was collected from 12 centres. In

2005, the National Pharmacovigilance was started finally by Central Drugs Standard Control Organization (CDSCO) and in 2008 it initiated Pharmacovigilance Program in India (PvPI) in 2010 and laid down targets for 5 years to monitor ADRs throughout the country.

One of the impact of program in India has been the realization of concerns over pharmacovigilance for Herbal drugs and it has been taken up by WHO. In 2006 a new concept of pharmacovigilance in environmental pharmacology, entitled as 'Pharmacoenvironmentology' was suggested by Syed Ziaur Rahman. It is a form of pharmacovigilance which deals specifically with those pharmacological agents that have impact on the environment via elimination through living organisms subsequent to pharmacotherapy

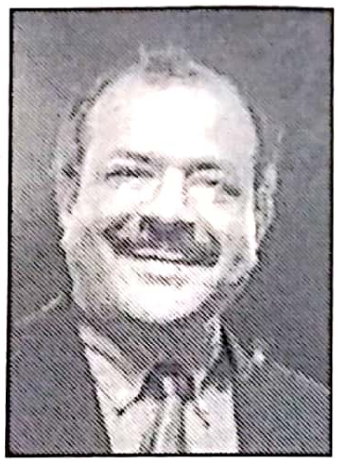
In India, the professionals are to be blamed for irrational use or prescription of drugs. The doctors tend to overprescribe, overutilize and overuse drugs. Their prescription and use is influenced by pharma companies. As students they are taught about drugs but not the economics behind the drugs. After passing out, their drug information sources are medical representatives who give restricted information meant to promote their companies' drugs.

These are the manufacturers, producers who operate with purely profit motives. Although drugs are different from other consumer goods, all their energies are concentrated at 'market making' or pushing the drugs, called peddling. They are the ones who manufacture irrational drug combinations, banned or bannable drugs and then market the products through advertising and sales promotions.

The drug industry is controlled by the Ministry of Chemicals rather then Ministry of Health. The existing ambiguities in the legislations are being exploited by the manufacturers to continue producing drugs of doubtful efficacy. The existing laws are not being enforced. There is need for fresh enactments and amendments. The drug policies have brought liberalisation without nationalisation.

The patients also invite problems by self-administration of drugs. It has been reported that about 50 per cent of the drugs are sold over the counter (OTC). The free availability and access is also responsible for irrational use of drugs. Such use may be over / under, inappropriate, ignorant, biased. Thus the patients who take the drugs for betterment of health may actually be injuring themselves further. The overzealous, overconcerned patients are responsible for taking medicines for smaller problems which can be corrected by rest, diet, exercise.Then there are some who demand particular drugs in prescriptions. There are others who visit more than one doctor and mix the treatments on their own. Then we also have the type who stock the drugs and not only self-administer themselves but also become home doctors and dispense to servants, neighbours and friends. All this constitutes to irrational use of drugs.

Various evidence based case studies indicate that iatrogenesis in India is the cause and contagious. Under all these circumstances it is essential to have a pharmacovigilance on practicing doctors not only those who use drugs without having ever studied (Ayurvedic, homoepathic or Unani doctors using modern medicines) but even the current allopathic doctors getting knowledge from mainly the medical or sales representatives.



**Dr Sandip Agarwal**
ASSOCIATE PROFFESSOR, (NIMS) JAIPUR
E -mail- sandeepcancer@rediffmail.com

Bio Data : He has several (8) awards, Six publications, thirty nine presentation. He has served the different societies like IMA, Cancer society, surgical society & pharmacovigilance. Presently he is secretary SOPI, president elect 2011 IMA Agra.

Abstract

## Medical Errors in Surgical Practice

Medical error may be defined as a preventable adverse effect of care, whether or not it is evident or harmful to the patient. This might include an inaccurate or incomplete diagnosis or treatment of a disease, injury, syndrome, behavior, infection, or other ailment

About half of the adverse events occurring among inpatients resulted from surgery.Complications from drug treatment,therapeuticmishaps,diagnostic errors were the most common non-operative events. In the Australian study cognitive errors, such as making an

Which patients are most at risk?

Those undergoing cardiothoracic surgery, vascular surgery, or neurosurgery,Those with complex conditions,Those in the emergency room,Those looked after by inexperienced doctors,Older patients

Medical errors are associated with inexperienced physicians and nurses,newprocedures,extremes of age and complex care and urgent care.

Poor communication (whether in one's own language or, as may be the case for medical tourists, another language),Improperdocumentation,Illegiblehandwriting,Inadequate nurse-to-patient ratios.Similarly named medications are also known to contribute to the problem.

Medical errors while surgery

Surgery performed on the wrong body part

Surgery performed on the wrong patient

Wrong surgical procedure on a patient

Retention of a foreign object in a patient after surgery or other procedure

Intraoperative or immediately post-operative death in a normal healthy patient

Surgical Errors

A review of surgical errors has identified that patients with unusual physical characteristics, those undergoing multiple procedures, those with multiple surgeons, or those with time pressures to initiate the surgical procedure are at greater risk for surgical error. Other factors that contribute to surgical errors include:

Unusual equipment or set-up in the surgical suite;
Staffing problems;
Distractions;
Lack of access to pertinent information;
Failure to require adherence to verification processes;
Failure to verify and mark the operative site;
Failure to require a patient assessment; and
Human factors, such as communication breakdowns, novice providers, and lack of teamwork

Approaches to Surgical Error Reduction

In addition to implementing the Universal Protocol, other risk management approaches to reduce the incidence of surgical errors include:

Involving the surgeon in obtaining informed consent
Reducing reliance on memory
Improving information access
Standardizing surgical processes
Improving employee training
Improving staffing and work environments
Improving communication
Improving teamwork
Incorporating error proofing in processes
Involving the patient and family members in the verification processes
Maintaining or improving diligence in preparing for high-risk patients and procedures

The reduction of surgical errors is a national patient safety goal. To eliminate the incidence of surgical errors, surgeons and surgical providers must examine their surgical processes and systems, identify flaws in those systems and processes, address the potential for wrong surgeries, and become actively involved in improving patient safety

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Prof. Arunabha Ray, MD, Ph.D, FAMS, is Head, Dept. of Pharmacology at Vallabhbhai Patel Chest Institute, Faculty of Medicine, University of Delhi, Delhi, India.

Prof. Ray is a medical graduate from the University of Calcutta, with postgraduate (MD) and doctoral (Ph.D) degrees in Pharmacology from the Faculty of Medicine, University of Delhi. Subsequently, he had postdoctoral training/experience in the USA and Canada.

He has more than 32 years of teaching and research experience in basic and clinical pharmacology at undergraduate and postgraduate levels, and is actively involved in the teaching and supervising biomedical research activities of postgraduate as well as doctoral students in pharmacology and toxicology of the University of Delhi. He is prolific researcher and is actively pursuing extramurally funded projects involving clinical and pre-clinical research in different areas of pharmacology and toxicology.

He has more than 150 research publications to his credit. In addition, he is author of one Textbook and editor of three books in his areas of expertise. He has been invited faculty to several international and national universities/conferences as visiting faculty and is member of several technical/scientific advisory committees/boards in India and abroad. He has been the recipient of several awards and honors from apex scientific and professional bodies for his contributions in the area of medical teaching and research and has contributed significantly to the development of the specialty. Most notably, he is Fellow of Indian Pharmacological Society (FIPS) and National Academy of Medical Sciences (FAMS). Prof. Ray is actively involved in Pharmacovigilance activities and is an life member of SOPI since its inception. He was Organizing Secretary of 2nd Annual SOPI Conference in 2003 and is a former President of SOPI of 2007.

Abstract

Pharmacovigilance in Respiratory Medicine

*Respiratory diseases like bronchial asthma and COPD are a major cause of morbidity and mortality worlwide. Several etiological factors like allergy and smoking contribute to the genesis of such obstructive airway diseases, and optimization and rationalization of drug therapy is the key to effective management. Pharmacotherapy of bronchial asthma and COPD invariably involves polypharmacy whereby multiple drugs and routes of administration are seen. Thus, complex drug @ drug/disease interactions are always a possibility, a problem that is compounded by factors like*

long term therapy, sometimes with drugs with low therapeutic indices. Adverse drug reactions (ADR) are thus common and the detection, assessment and strategies of prevention/treatment is of utmost significance in the interest of safe and effective drug therapy. Pharmacovigilance is defined as @the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems@ (WHO 2002). Focussed pharmacovigilance studies are important for identifying potential areas for ADRs and also help in rationalizing drug therapy. In one such prospective study, 120 patients of bronchial asthma and COPD were selected from the Vallabhbhai Patel Chest Institute, University of Delhi. ADR profiles were recorded as per National Pharmacovigilance Programme proforma. Dechallenge and rechallenge were done wherever appropriate and causality assessment was done by using the Naranjo' s scale. Overall analyses of the data showed that 93% of enrolled patients were males whereas, 7% were females, and COPD patients were predominantly males. All patients received multi-drug treatment schedules (inhalation and oral) and whereas most patients received inhaled steroids and bronchodilators, few received mucolytics, antibiotics, analgesics, etc. General ADR incidence profile of patients revealed the following : inhaled steroids (56%), Inhaled anticholinergis (22.7%), oral methylxanthines (46.5%), oral steroids and antibiotics (21%) and short acting beta-2 agonists (5%). Detailed analysis of ADR characteristics showed that (a) inhaled steroids induced one or other ADR (sore throat, dysguesia, glossitis, hoarseness, etc.) in 90% of asthma and 50% of COPD patients; (b) Inhaled anticholinergics (dry mouth, thirst and urinary difficulty) in 62% asthma patients and 23% COPD patients; (c) inhaled beta agonists (hand tremors) seen in 43% asthma and 5% COPD patients; (d) oral steroids (weight gain, acne, cramps, mood changes) in 87% asthma and 21% COPD patients; and (e) oral theophylline (anxiety, dyspepsia, muscle spasms, paresthesia) in 70% asthma and 46% COPD patients. In recent years, there has been resurgence in therapeutic interest in theophylline, in view of the newly demonstrated anti-inflammatory and immunomodulatory effects. Thus, judicious use could be of benefit in obstructive airway disease in developing countries like India. Prescription monitoring showed that 565 of the total OAD patients (120) received oral theophylline (33% in asthma and 71% in COPD). ADR incidence with theophylline was 70% in asthma and 46% in COPD. Most patients complained of dyspepsia and anxiety (60%), whereas few other complained of muscle spasms and paresthesia. Causality analysis showed that muscle spasms fell in the highly probable category, whereas the other ADRs were in the probable category. Most ADRs were mild to moderate in nature and tolerable. Few, particularly those related to oral steroids and theophylline, were intolerable and required dose reduction. Such focused studies are helpful in reducing ADRs in OAD and rationalizing drug therapy. Further, studies adopting translational research concepts have been initiated to evaluate the reasons for such ADRs in order to able to suggest strategies to prevent or counteract them.

**Dr Anurag Tomar**
MD (Pediatrics)
chief editor of Journal of Pharmacovigilance and Drug Safety

Dr. Anurag Tomar is a medical graduate of 1999 from S.M.S. Medical College, Jaipur and MD (Pediatrics) from M.S. Ramaiah Medical College, Bangalore. He is a leading pediatrician of Jaipur and is also Director, NIMS University, Jaipur. He is a pride recipient of International Kohinoor Award 2010 for education awarded in Bangkok. Dr. Anurag is life member of 11 Societies including Indian Academy of Pediatrics, SOPI and Indian Academy of Neuroscience, Dr. Anurag is the chief editor of Journal of Pharmacovigilance and Drug Safety and is state coordinator and Principal Investigator of Indian Clinical Epidemiology Network of Model Injection Centers Program - India (2005-2007) - Safe Injection Practices, Integrated Management of Neonatal and Childhood Illnesses (IMNCI) (2006-2007) and State Coordinator & Principal Investigator (India Clinical Epidemiology Network ) of Determinants of Under nutrition in Children and Assessment of Management at Different Level of Health Care. He has presented several papers in International and National conferences and has a Chapter on Ascites in the Indian Academy of Pediatrics (IAP) Text Book of Pediatrics to his credit. He has also given public awareness talks as radio programs on AIDS and Child nutrition. Dr. Anurag was the organizing secretary of two well organized Conferences namely SOPI 2007 and IAN 2009. He has published about 25 papers in National and International journals.

Abstract

## Safety Issues in Medication Use by the Elderly

Pharmacotherapy is an essential component of medical care of geriatric patients and in western world around two third of people over the age of 60 year use more 4 or more drugs (Average 5.7). The geriatric group has less muscle mass, lower activity of liver enzymes, lower body water, declined GFR and suffers from one or more chronic diseases like Arthritis, Diabetes etc. Therefore, they are more likely to cause drug-disease interactions. Although Polypharmacy is a well known risk factor for adverse drug events, as a geriatric patient in nursing home takes on an average 7.0 prescription drugs/day, use of multiple drugs may be unavoidable in the elderly with multiple co-morbidities. Polypharmacy and non-adherence are now well recognized drug related problem including poor monitoring of drugs, poor management of drugs in patients at home and poor communication between health professionals.

Therefore, the prescribing for geriatric patients needs special attention for the safer use of drugs for them.

**Prof Govind Mohan**
Principal
NIMS Institute of Pharmacy, NIMS University, Jaipur.

Fellow Specialist of Clinical Hypertension (FSCH). This honor was conferred to Prof. Mohan for his excellent contribution in the field of hypertension and Coronary Heart diseases. He has postulated that a hypertensive patient can get heart attack, if his serum copper starts increasing in absence of other diseases. Before joining GLA group, prof. Govind Mohan was associated with S. N. Medical college as Lecturer, Asst. Professor & Asso. Prof. since 1973 after passing B. Pharm. and M. Pharm., from B.H.U.. He was later awarded Ph. D. He had been elected as a member of executive committee, Secretary and Vice President of Indian Society of Hypertension. Prof. Mohan has a pharmacy background and by conferring this fellowship, which is generally meant for post-graduates with medical background, the Indian Society of Hypertension has setup a new precedent. Prof. Mohan is also a founder treasurer of Society of Pharmacovigilance (India), only society in world associated with International Society of Pharmacovigilance. He has to his credit many presentations/ publications in national and international conferences/journals and had won prizes like best paper (Poster) award in Asian Congress of Pharmacology & International conference of Society of Pharmacovigilance and best paper published in Indian Journal of Pharmacology. Prof. Mohan has chaired many scientific sessions at the annual conferences of Indian Pharmacological Society, Indian Society of Hypertension & Society of Pharmacovigilance (India). He is also on review panel of Indian Jr. of Pharmacology and Journal of Pharmacovigilance and drug safety and in the editorial board of Jr. of Pharmacovigilance and drug safety and Indian jr. of Hypertension. He has also been invited to deliver lectures in various national and international conferences.He is a member of many (8) and fellow of two academic societies.

Abstract

Drug-induced Skin Reactions

Drug eruptions can mimic a wide range of dermatosis. The morphologies are morbiliform, urticarial, papulosquamous, pustular and bullous. The medications also cause pruritis & dysthesia without apparent eruptions.

A drug induced reaction should be considered in a patients taking medication and who suddenly develops a symmetric cutaneous eruption. Prompt identification and withdrawal of offending agent may help limit the intensity of reaction .Immunocompromised persons have a 10 fold higher risk of developing drug induced cutaneous reaction than general population, especially hypersensitivity ,reactions including toxic epidermal necrosis. The methods to reduce dermatological reactions includes the observations like interval between drug administration and eruption ,route, dose ,duration and frequency of drug administration as parenteral administration have more chances of anaphylaxis ,use of topically applied drugs. The patient's education, lymphocyte toxicity assay are other strategies to reduce drug induced skin reactions.

# GUEST LECTURE

**Dr. R. Sharma**
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Field of Interest:
SAFE MOTHERHOOD, PREVENTIVE ONCOLOGY
& EmOC (emergency obstetrical Care)

Abstract

## Adverse Drug Events and Patient Safety Issues in Obstetrics & Gynaecology Practice

Adverse drug event (ADE): Any untoward medical occurrence including, undesirable signs & symptoms, disease or accidents, abnormal laboratory finding (leading to dose reduction / discontinuation / intervention) during treatment with a pharmaceutical product in a patient or a human volunteer that does not necessarily have a Relationship with the treatment given ADE does not imply causality but in ADR a causal role is suspected.

Potential adverse events are defined as errors that have the potential to cause harm. Potential adverse outcome are development of new symptoms, physical signs or laboratory test abnormality A preventable adverse event represents an adverse event which can be avoided by means available in routine practice.

Adverse events or poor patient outcome resulting from medical care are common. Studies from several countries, including Canada, indicate that 2.7–12.5% of hospitalized patients experience an adverse event. Little is known about adverse events in obstetric patients. The possibility of data describing adverse events in obstetrics reflects exclusion of Obstetric patients in some studies and low numbers of events in others. These low event rates would be reassuring were it not for the exceedingly high costs of litigation in obstetrics.

There are several challenges to conducting adverse event research in Obstetrics. The first relates to rarity of events because these are rare there are few opportunities to investigate them. A second challenge is the discordance between what is documented in the chart and what actually occurs. The third challenge is the anxiety created by the high risk of litigation. Obstetricians are more likely to be sued.

CONCLUSION : serious adverse events occur infrequently on an obstetric service. However, important quality problems are common and should be targeted for improvement. The efforts to improve safety through team building and improved communication strategies are appropriate targets for quality improvement. Infertility drug therapy has to be cautiously used as it may have adverse effect on pregnancy and fetus.

**Dr. Kavita Gulati**
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Dr. Kavita Gulati is Associate Professor in Pharmacology at Vallabhbhai Patel Chest Institute, University of Delhi. She obtained her masters degree in Pharmacology from the All India Institute of Medical Sciences and subsequently did her Ph.D from the University of Delhi. Dr Gulati has more than 22 years of teaching and research experience in Clinical and Experimental Pharmacology and Toxicology in different capacities in India and abroad. She is the recipient of several national awards including the Achari Prize and Uvnas Prize and the prestigious Prof. B.N. Ghosh Oration of the IPS She is member of several professional bodies/societies relating to pharmacology and allied sciences (viz. National academy of Medical Sciences, International Neuroendocrine Federation, New York Academy of Sciences, Society of Toxicology, Society of Pharmacovigilance, Indian Pharmacological Society, etc. Her biography has also been include in the Marqui' s "Who is Who" in the world in science. Her research interests are in Respiratory Pharmacology and Toxicology, Neuropharmacology and Stress Research, and she is the Principal Investigator of several extramurally funded research projects (viz. DST, AYUSH, CSIR, ICMR, etc.). She has the distinction of being invited to present talks at prestigious international meetings like IUPHAR (China), CMB Congress (France), World Stress Congress (Hungary), and CPT Congress (Australia). She has been visiting scientist to reputed international institutions like Semmelwies Medical University (Budapest, Hungary), University of Pittsburgh Medical Center (USA), Army Medical Institute (Xian, China), University of Minnesota at Minneapoilis (USA), University of Illinois at Chicago (USA), etc and expert member at different Institutions and Government organizations in her field. She has published extensively in leading national and international journals, is co-author of several chapters in reference and textbooks of Pharmacology, and co-editor of three books in Pharmacology. Dr. Gulati is an active member of SOPI since its inception.

Abstract

## Translational research in safety pharmacology : a novel approach

Translational research in health sciences is a novel and interactive specialty to explore bi-directional interactions between basic medical and clinical sciences for the betterment of human health. Since drugs form an integral part of the health care system and novel strategies are constantly being explored for safe and effective use of drugs and translational research on pharmacology and allied bio-medical sciences could contribute immensely. Pharmacology and its principles probably provides the most meaningful interface between preclinical and clinical sciences in which the academia, pharmaceutical industry and regulatory authorities provide their inputs.

Pharmacovigilance deals with detection, assessment and prevention of adverse drug reactions (ADR). ADRs can be a complex phenomenon and several factors like the drug, the individual, and the disease state could contribute to its genesis. Respiratory disorders are one of the major global causes of morbidity and mortality. Long-term drug use particularly those with low therapeutic index, polypharmacy, drug-drug/disease interactions and multiple routes of administration contributes to ADRs during therapy in respiratory diseases. Focused ADR reporting / monitoring could be of great help and provide specific information for prevention/alleviation of such ADR related problems, thereby cutting health costs. Environmental and occupational factors may further compound this problem. A prospective study was conducted in 140 patients of obstructive airway disease (bronchial asthma and COPD) at the Vallabhbhai Patel Chest Institute, University of Delhi. Ethical clearance was obtained and GCP guidelines followed. The pattern of ADR generation and profile were recorded as per the guidelines of the National Pharmacovigilance Programme and causality assessment was done using the Naranjo' s scale. All patients received multi drug therapy schedules by inhalation, oral or parenteral routes. Most patients received bronchodilators and/or corticosteroids, besides other forms of therapy. The results showed that 75% patients complained of one or other adverse effect. Oral steroids were associated with 25% incidence of ADRs in COPD as compared to 40% in bronchial asthma. 60% of the patients received inhaled anticholinergics out of which 25% complained of one or other ADR. Theophylline is rapidly re-emerging as a pharmacoeconomically viable adjunct for the treatment of obstructive airway disease. Our study focused on various strategies to promote the safe use of theophylline in such patients. Out of the 63 patients put on oral theophylline, a drug with a narrow therapeutic index, 45% complained/exhibited ADRs like anxiety, dyspepsia, muscle spasm, paresthesia, etc. Most ADRs were moderate to tolerable and were in probable category as per causality assessment. The anxiety and dyspepsia related symptoms were most prominent as ADR. In order to devise strategies for its safer use experimental studies were conducted in rats to evaluate the possible mechanisms of these ADRs. The data showed that theophylline induced (a) anxiety and (b) gastric ulceration in experimental models. These changes were associated enhanced oxidative stress and attenuated by antioxidant pretreatment. These results indicate that oxidative stress plays an important role in anxiety and gastrointestinal manifestations of theophylline and propose that use of antioxidants may prevent/reverse these unwanted effects of the drug during therapy in obstructive airway disease. Such translational studies provide a novel approach for enhancing safety of pharmacotherapy.

**Dr. Manisha Singh**
Head of Dept. Medical Oncology
Mahavir Cancer Sansthan, Patna

Experience - More than 10 years experience as faculty in medical oncology at Mahavir Cancer Institute & Research Centre (400 indoor bedded, hospital exclusively for cancer patient), Incharge of National Cancer Registry Programme at MCI & RC, Member of Task Force in Gall Bladder Research in Gangetic Belt, At present HOD, Medical Oncology & Day Care Unit (120 Bedded) at Mahavir Cancer Institute & Research Centre.

Training from - Advance Medical Research Institute (AMRI) Kolkata. Tata Memorial Hospital, Mumbai. Mahavir Cancer Institute & Research Centre, Patna

Official Post held (in different association) : Editor Journal of Breast Cancer Foundation - India, Editor Journal of Hyperthermic Oncology & Medicine, Editor Journal of Indian Society of Oncology, Executive Body Member of Association of Radiation Oncologist of India (AROI), Bihar Chapter.

Publications : Twenty one Publications in different National & International Journal in her credit., More than Forty Nine presentations of Scientific Papers in different National & International Scientific Meetings, Major contribution in three Oncological Books., Actively Participating in - Various programme of Community Oncology & Palliative Care work of Mahavir Cancer Institute & Research Centre.

## Abstract

### Today's Challenges in Pharmacovigilance

Highly publicized safety issues of medicinal products in recent years and the accompanying political pressure have forced both the US FDA and the European Medicines Agency (EMA) to implement stronger regulations concerning pharmacovigilance. These legislative changes demand more proactive risk management strategies of both pharmaceutical companies and regulators to characterize and minimize known and potential safety concerns. Concurrently, comprehensive surveillance systems are implemented, intended to identify and confirm adverse drug reactions, including the creation of large pharmacovigilance databases and the cooperation with epidemiological centres. Although the ambitions are high, not much is known about how effective all these measures are, or will be. In this review we analyse how the pharmacovigilance community has acted upon two adverse events associated with the use of erythropoiesis-stimulating agents: the sudden increase in pure red cell aplasia and the possible risk of tumour progression associated with these products. These incidents provide important insight for improving pharmacovigilance, but also pose new challenges for regulatory decision making.

A lot more about common chemotherapeutic drugs will be discussed with personal experience at Mahavir Cancer Sansthan.

**Dr Shoibal Mukherjee**
MD, DM,
Vice President
Clinical Research, Quintiles Research Pvt. Ltd. India

Dr Shoibal Mukherjee joined Quintiles in May 2011. He has postgraduate qualifications in Medicine and Clinical Pharmacology, and a Masters in Pharmaceutical Medicine from Hibernia College, Ireland. He started his career at Alembic Chemical Works in Vadodara, India. He was Medical Director for Pfizer India from 1997 to 2006, Vice President, Medical Affairs and Clinical Research at Ranbaxy Laboratories from 2007 to 2008 and Senior Vice President, Clinical Development at GVK Biosciences before he moved to Quintiles. Dr Mukherjee has been associated with the development of clinical research as a specialty within the pharmaceutical industry in India, having been among the founders and the first President of the Indian Society for Clinical Research. He has been closely involved with the evolution of pharmaceutical regulations in the country, representing the pharmaceutical industry through the Medical Committee of the Organization of Pharmaceutical Producers of India (OPPI), as a member of the Schedule Y Review Committee whose recommendation led to the revision of clinical trial and new product submission requirements in early 2005, as an executive committee member of the Indian Society for Clinical Research (ISCR), and as a member of the Clinical Trials Task Force of the Federation of Indian Chambers of Commerce and Industry. At Quintiles he serves as Chief Medical Officer, providing oversight to safety, ethics and public policy initiatives.

Abstract

## Safety Pharmacology Studies in New Drug Development Research

Safety pharmacology became a formal and recognized part of the regulatory development of new drugs when, in 2001, the ICH published guideline S7A. Prior to this, safety pharmacology was evaluated as part of non-standard discovery research without consistency in approach across the industry or across geographic regions. The Japanese MHW was the first to require reporting of systematic organ-system testing prior to marketing authorization and these had become standard practice within the industry by 1995. The concept of safety pharmacology is based upon the realization that standard toxicological testing, while appropriate for the study of stable structural effects of drugs on tissues and organs, is not designed to study functional effects and responses of organ systems to drug exposure at therapeutic dose levels. Yet it is precisely these effects and responses that have the potential to result in critical care emergencies during early human testing of new drugs. Safety pharmacology testing may include in vivo, ex vivo and in vitro studies. ICH guideline S7A requires mandatory testing of investigational drugs through a core battery of safety pharmacology studies that should minimally include evaluation of effects on the central nervous, cardiovascular and respiratory systems for all drugs with systemic exposure, including diagnostic agents and drug formulation excipients. The non-clinical evaluation of the potential for delayed ventricular repolarization, as described in guideline S7B, should also be considered as part of the core battery. The results from the core battery are expected to be available for evaluation prior to human testing. Any follow-up or supplemental studies resulting from concerns emerging from results of the core battery should also be completed prior to the first dose in humans. Additional studies can be carried out for further clarification and to test the effects on other less critical organ systems during clinical testing or prior to approval unless not doing so can be justified. These may include clinical studies such as the clinical evaluation of QT/QTc prolongation described in ICH guideline E14. Whenever possible, safety pharmacology studies should be conducted under GLP/GCP conditions.

**Professor Saad Shakir**
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Abstract

## Risk Management in Pharmacovigilance

Risk management (RM) in pharmacovigilance is defined by the EMA as the "set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products, including the assessment of the effectiveness of these medicines". In many ways RM can be considered as a synonym of pharmacovigilance. The aim of RM according to the EMA is to "ensure that the benefits of a particular medicine exceed the risks by the greatest achievable margin for the individual patient and for the target population as a whole."

Operationally RM aims to better understand the potential risk (events not reported in humans with possible causality or above), identified risks (events reported in humans with possible causality or above but not fully understood) and also fills any gaps identified as missing information during pre-marketing development, such as sub- populations which were not studied or studied incompletely e.g. children and the elderly.

The process of RM progresses during the life cycle of a product, ideally starting as early as possible in pre-marketing development, all the way through not only to the early post-marketing phase but well after that. Every step needs to be based on what is known about the safety of the product (and sometimes similar products), what needs to be done to improve that understanding and what methods are used to minimise identified risks. The process is not considered complete until studies are conducted to examine whether the methods implemented for risk minimisations were effective.

Risk management is a dynamic process which is continuously informed by evolving information.

The application of RM in pharmacovigilance expands the network of stake holders in the process beyond the traditional parties, manufacturers and regulators, to include others such as, researchers, health care professionals, patients and patient groups and others. It also transforms pharmacovigilance from an anecdote-based reactive discipline to an evidence-based science. This will hopefully show that the application of RM will have a protective effect on patients from drug related morbidity and mortality. Time will tell.

**Prof Hari Dayal**
Ph.D., F.A.C.E.
Adjunct Professor of Health Policy and Management
UNTHSC School of Public Health
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Professor Dayal worked in public health and international health and held academic positions at the State University of New York at Buffalo, Johns Hopkins School of Public Health, Medical College of Virginia, and Fox Chase Cancer Center. He has recently retired as Professor of Preventive Medicine and Community Health from the University of Texas Medical Branch.

Professor Dayal conceived, developed, and delivered for more than ten years a curriculum in clinical research methods for clinicians, advanced medical students, residents, fellows, and faculty. This module is easily adaptable and transportable to any setting in the world.

As Statistical Advisor to the Afghan Demographic Studies, a USAID sponsored project, he directed the data collection and analysis of the first census-survey in Afghanistan. He has done several original epidemiological research works of great scientific impact.

Abstract

## Pharmacoeconomics: beyond safety, efficacy, and phramacovigilance

The evaluation of pharmoceutical products has traditionally focused on considerations of safety and efficacy. Because of the growing concern over the cost of health care, however, it is also important to include patient outcomes and cost-effectiveness considerations in the equation. Health economics applies economic concepts to health and healthcare systems. Pharmacoeconomics addresses economic evaluations of the pharmaceutical products and programs. We discuss the methods and techniques of phrmacoeconmics, focusing particularly on statistical considerations in planning such studies and analyzing and interpreting the data. The methods are discussed in the theoretical framework of input-output analysis, invoking the concept of economic efficiency in the sense of optimizing health outcomes for fixed level of resources.

**Dr. Syed Ziaur Rahman**
School of Medicine, University of Western Sydney, Australia

Syed Ziaur Rahman did MBBS in 1995 and MD (Pharmacology) in 2000. Currently, he is pursuing PhD from School of Medicine, University of Western Sydney, Australia. As a scholar, he has to his credit 4 published books, three important chapters in medical science books and more than 50 research papers in both national and international journals. He also edited 9 publications. He is closely associated with 'Society of Pharmacovigilance, India (SOPI)'. He started as editor-in-chief, the official journal of SoPI viz 'Journal of Pharmacovigilance & Drug Safety' and edited its first 2 numbers. At present, he is representing SoPI as Secretary International Affairs. He coined the term "Pharmacoenvironmentology" for the study of drugs at therapeutic doses and its impact on environment and differentiated it with "Ecopharmacology".

Abstract

**Study of Antidepressants: SSRIs, SNRIs and St John's Wort from the 45 and Up Database**

Introduction: Depression is a common mental health condition affecting all age groups. First line treatment for moderate to major depression is antidepressants specifically SSRIs (selective serotonin reuptake inhibitors) and SNRIs (Serotonin@norepinephrine reuptake inhibitors) in addition to St John's Wort as a complementary medicine. Whilst side effect profiles of these have been studied extensively but its pattern of usage and association with general wellbeing in a society has not yet been perturbed.

Aims: To determine prevalence, patterns and drug interaction of SSRIs, SNRIs and St John Wort in a population over the age of 45, and to explore correlation of these antidepressants with self-rated memory, quality of life and overall health.

Methods: Cross-sectional data from baseline questionnaire of the '45 and Up Study' (Sax Institute) were used. Various statistical tests were applied using SPSS. Mean and median of drugs versus age and sex were compared along with its expected and observed count. Odds ratios with 95% confidence interval were calculated for correlation studies.

Observations: Most commonly taken SSRI and SNRI were sertraline and venlafaxine respectively. 4.8% of participants with a mean age of 61.4 were taking at least one SSRI while 1.3% with a mean age of 59.9 were on one SNRI. A significant correlation between younger participants taking these drugs was found ($p<0.001$) compared to mean age of 62.8 of the remaining participants. A larger proportion of participants taking SSRIs and SNRIs were females than males ($p< 0.001$). Participants taking SSRIs and SNRIs disproportionally rated their memory, QoL and overall health lower than the general population. Twelve cases were identified who concurrently using SSRIs and St John's Wort together.

Conclusion: SSRIs and SNRIs use are widespread among older population despite serious adverse effects. The use is more common in females. A quite number of participants were taking more than one SSRIs and SNRIs at a time with or without St John's Wort. The fatal combination of SSRIs and St John Wort shows there is still some miscommunication between health care practitioners and patients.

**Dr. Vivek Sharma**
Medical Advisor
Cachet Pharmaceuticals, Ltd., Mumbai

Abstract

## Drug Allergy

Drug allergy is an uncommon and unwanted side effect of medication. Reactions to drugs range from a mild localized rash to serious effects on vital systems. The body's response can affect many organ systems, but the skin is the most frequently involved.

Adverse drug reactions (ADRs) are classified as predictable or unpredictable. A predictable drug reaction is related to the pharmacological actions of the drug. Allergic drug reactions are mostly unpredictable in nature, are related to immunological response. They occur in a minority of persons receiving the drug - fewer than 10 percent of adverse drug reactions are allergic.

Drug allergy is defined as an adverse reaction to a drug by a specific immune response either directly to the drug or one or more of its metabolites alone, or to a drug bound to a body protein such as albumin, (Hapten). Such binding alters the structure of the drug/protein complex, rendering it antigenic. Allergic reactions have no correlation with known pharmacological properties of the drug and they often include a rash, angioedema, the serum sickness syndrome, anaphylaxis and asthma which are reactions similar to those of classical protein allergy.

The allergic reactions usually require an induction period on primary exposure but not on readministration. They disappear or abate on cessation of therapy and reappear after readministration of a small dose, and desensitization may be possible.

The criteria of the classification of drug allergy are based on the time required for the symptoms or skin test reactions to appear after exposure--- immediate and delayed hypersensitivity. They are also based on the nature of organ involvement.

This presentation shall briefly outline an overview of drug allergy.

**Dr. Ajay Kumar**
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Abstract

ADR (Adverse Drug Reaction) : The Indian Perspective

ADR is a global problem. One of the important factors is lack of transparency and "telescopic view" of clinical trials due to pecuniary interest of sponsoring pharmaceuticals industry. Also, special group of patients like children and pregnant women are not included in Clinical trials due to ethical and legal reasons . Elderly patient are another group where all the factors related to them is often not taken into consideration in designing the clinical trials. In India , matters becomes complicated due to concomitant use of "AYUSH" medicine and practice of CAM . Indiscriminate use of drugs by large no of "Quacks" and self medication without prescription is a matter of concern. India needs strong "Pharmocovigilance" network taking into consideration, all the factors relevant in the country. Awareness at ground level and involvement of Indian medical association and other NGO's working in the field of medical and health awareness is essential to have a widespread and effective network.

**Dr Ronald H B Meyboom**
Medical Advisor
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Dr Ronald Meyboom graduated as a medical practitioner at the University of Leiden in the Netherlands. With a keen interest in pharmacology and in medicines as a paradoxical cause of disease, he has headed for almost 20 years the National Pharmacovigilance Centre in the Netherlands. In that time he also pioneered hospital pharmacovigilance at the Leiden University Hospital (Dr H. Mattie). In 1998 he defended a PhD thesis at the University of Nijmegen based on his experiences in practical pharmacovigilance, entitled "Detecting Adverse Drug Reactions. Pharmacovigilance in The Netherlands".

After having assisted in the creation a new organization for pharmacovigilance in his country (in the form of an independent non-profit foundation), he became more involved in international pharmacovigilance (WHO Uppsala Monitoring Centre) and initiated collaboration between the centre in Uppsala and the Department of Pharmacoepidemiology and Clinical Pharmacology of the University of Utrecht (The Netherlands), combining research and teaching.

Dr Meyboom has published over 100 articles and chapters relating to pharmacovigilance in specialised journals and books. He is an honorary member of the Society of Pharmacovigilance of India (SoPI), a founding board member of the International Society of Pharmacovigilance (ISOP), a member of the editorial boards of the journals Drug Safety and Pharmacoepidemiology and Drug Safety, and co-author of the Meyler's Side Effects of Drugs series. Having recently reached 65, the further development and improvement of pharmacovigilance around the world is his major commitment.

Abstract

## Spontaneous monitoring and biopharmacovigilance - do biopharmaceuticals cause infections and neoplasms?

Biopharmaceuticals are revolutionising pharmacotherapy. These compounds differ in several respects from the "small molecule drugs'. It is as yet uncertain how effective the current adverse event reporting systems are in 'biopharmacovigilance'. The reported connections between biopharmaceuticals and infections and neoplasms will be discussed.

**Dr. Shubhadeep Sinha**
Head & Associate Vice-President
Clinical Development & Medical Affairs, Hetero Drugs Limited, Hyderabad

Dr. Shubhadeep Sinha, an M.B.B.S & M.D (Pharmacology) from Seth GSMC&KEMH and TNMC & BYLNair hospital mumbai respectively has more than a decade experience in clinical research, pharmacovigilance & medical affairs in pharmaceutical industry in pharmaceutical organizations such as Glenmark Pharma, Organon limited, Khandelwal labs, Dr. Reddy's Laboratories, Accenture, Indigene, Vimta Labs & Hetero group of Pharma companies. Currently, he is Associate Vice-President & Head- Clinical Development & Medical Affairs at Hetero & handling operations of clinical research, Medicoregulatory, pharmacovigilance & Medicomarketing activities. He has been part of setting up & operations of pharmacovigilance in at least two companies. He has six publications in medical journals & is a guest faculty for clinical research & pharmacovigilance in some reputed training institutes.

Abstract

## Pharmacovigilance in Pharma industry & Regulatory perspectives

Pharmacovigilance, defined by the World Health Organisation as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem' plays a key role in ensuring that patients receive safer drugs.

The withdrawal of rofecoxib worldwide directed renewed attention to drug safety. In the aftermath of the withdrawal of rofecoxib, the major regulatory authorities including but not limited to FDA & EMEA ensured an independent review of the current system of post-marketing surveillance. The main outcome message was that the regulatory authorities need to follow the safety of a drug during its whole life cycle. This life-cycle approach includes identifying safety signals, designing studies to confirm them, evaluating benefits as well as risks, using risk–benefit assessments to integrate study results and communicating key findings to patients, pharmaceutical industry and physicians.

Review mechanisms of safety used by pharmaceutical industry in pre-registration settings during clinical development of drugs are performed throughout the clinical research program by R&D and pharmacovigilance departments within the sponsor companies.

Serious, unexpected adverse reactions that occur during clinical trials and are suspected of being related to the study drug (SUSARs) must be submitted to the appropriate regulatory authorities within specified short time frames (expedited reports). They must also be notified to all investigators and to ethics committees. During the course of the clinical trial program, annual reports (Annual Safety Reports in the EU, IND Annual reports in the US) including a summary and analysis of all the serious adverse events that have arisen during that period and all new safety findings from animal studies, as well as evaluations of benefit and risk, must be submitted to the regulatory authorities and ethics committees. All of these submissions are required by law and compliance by the companies is checked by a combination of internal

company audit and regulatory authority inspections.

Pharmacovigilance in post-marketing settings include spontaneous reporting, intensive monitoring and database studies, besides documentation activities such as aggregate safety reports, risk management plans (RMP) & detailed description of pharmacovigilance systems (DDPS).

A spontaneous reporting system enables physicians, pharmacists and patients to report suspected ADRs to a designated pharmacovigilance centre and various regulatory authorities worldwide. The pharmacovigilance centres collect and analyze the reports and inform stakeholders of the potential risk when signals of new ADRs arise. Spontaneous reporting is also used by the pharmacovigilance centres of the pharmaceutical organisations to collect safety information about their drugs. By spontaneous reporting, it is possible to monitor all drugs on the market throughout their entire life cycle at a relatively low cost. The main drawback of this approach is the potential for selective reporting and under-reporting.

Intensive monitoring systems use prescription data to identify users of a certain drug. The prescriber of the drug is asked about any adverse event occurring during the usage of the drug being monitored. These data are collected and analyzed for new signals. The basis of intensive monitoring is a non-interventional observational studies such as post-marketing surveillance studies during marketing of the drugs. Through its non-interventional character, intensive monitoring provides real world clinical data involving neither inclusion nor exclusion criteria throughout the collection period.

Database studies are conducted in order to test a hypothesis and can be conducted using a variety of methods, including case–control studies and cohort studies. The limitations of these methods include power considerations and study design.

Another step in a more pro-active post-marketing surveillance is the introduction of risk management plans (RMPs). Such RMPs are set up in order to identify, characterize, prevent or minimize risk relating to medicinal products, including the assessment of the effectiveness of those interventions.

The Detailed Description of the Pharmacovigilance System (DDPS) is one of a number of essential documents for every company's pharmacovigilance system in Europe. The legal framework for the DPPS is contained within Volume 9A of "The Rules Governing Medicinal Products in the European Union. The Applicant for a marketing authorisation must provide a DDPS to accompany their application. The DDPS needs to contain an "overview of the pharmacovigilance system providing information on the key elements of that system". It must also include details of the specific European Qualified Person (QPPV) who is going to hold overall responsibility for the ensuing pharmacovigilance services.

In India, pharmacovigilance guidelines, though not so well defined as the international ones, is comprised of reporting of SUSARs & SAEs from investigators & pharmaceutical sponsors during clinical development and by patients or pharmaceutical organisations and submission of periodic safety update reports (PSURs) within well-defined defined time-periods to the regulatory bodies such as ethics committees (during clinical trials) and the Drugs controller General of India (DCGI).

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## Pharmacovigilance Programme of India
## [Source : CDSCO Website]

The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in collaboration with Indian Pharmacopeia commission, Ghaziabad has initiated a nationwide pharmacovigilance programme - Pharmacovigilance Programme of India (PvPI) for protecting the health of the patients by assuring drug safety. The programme is coordinated by the Indian Pharmacopeia commission, Ghaziabad as a National Coordinating Centre (NCC) that operates under the supervision of a Steering Committee.

The programme goal is to ensure that the benefits of use of medicine outweighs the risks and thus safeguard the health of the Indian population.

The objectives are to :

- monitor adverse drug reactions (ADRs) in Indian population
- create awareness amongst health care professionals about the importance of ADR reporting in India
- monitor benefit-risk profile of medicines
- generate independent, evidence based recommendations on the safety of medicines
- support the CDSCO for formulating safety related regulatory decisions for medicines
- communicate findings with all key stakeholders
- create a national centre of excellence at par with global drug safety monitoring standards

WHO and UMC work with and/or provide technical support to more than 94 countries worldwide. The long term objective of the PvPI is to establish a 'Centre of Excellence' for Pharmacovigilance in India. To achieve this objective, the PvPI-NCC has established collaboration with Uppsala Monitoring Centre (UMC) - the WHO Collaborating Centre based in Sweden. Under the agreement the WHO-UMC agreed to extend support as follows.

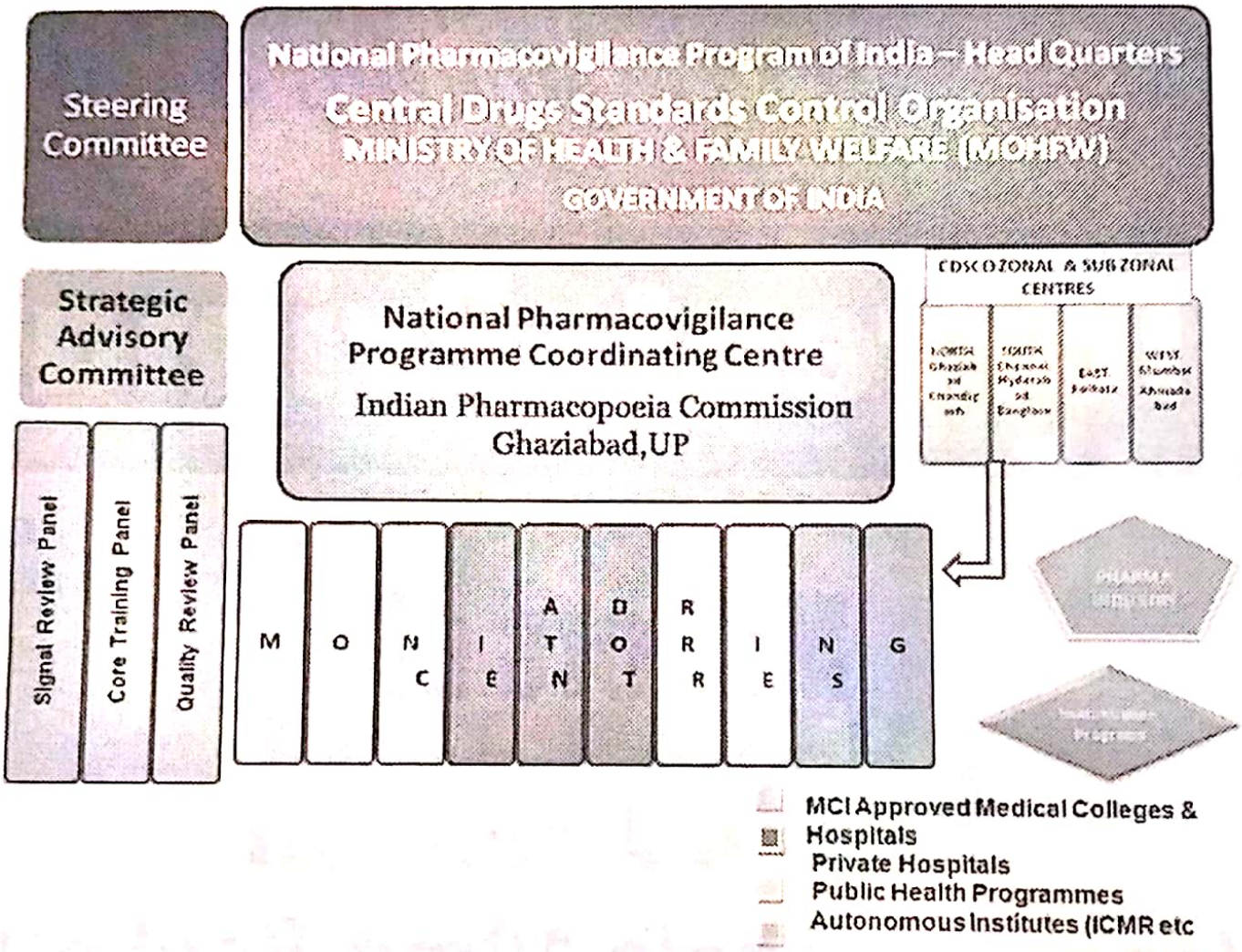
- Training of the staff of the ADR Monitoring centers across the country and also those at the PvPI-NCC at IPC Ghaziabad
- Usage of UMC's Vigiflow software (for medicines) and Paniflow (for vaccines) at no cost to PvPI.
- Access to Vigibase, which contains worldwide medicines safety data
- Access to early information about potential safety hazards of medicines (worldwide data)
- Technical support
- Technical assistance for a regular publication that will be issued by the PvPI NCC for distribution to the ADR Monitoring centers and other stakeholders.

CDSCO Headquarters held several meetings with UMC over the past few years to discuss the potential role and approach for technical collaboration.

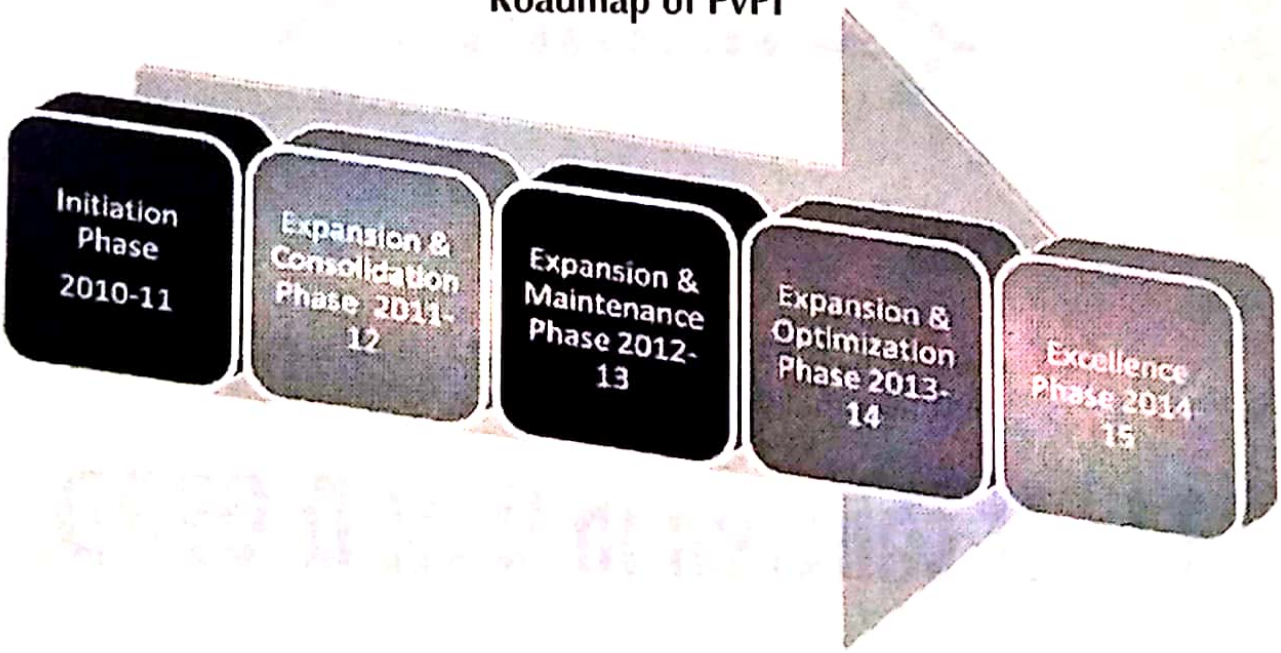
### Functions of ADR Monitoring Centres (PvPI-AMCs)

- Collect of ADR reports
- Perform follow up with the complainant to check completeness as per SOPs
- Data entry into Vigiflow
- Reporting to PvPI-NCC through Vigiflow with the source data (original) attached with each case
- Training/ sensitization/ feedback to physicians through newsletters circulated by the PvPI-NCC

## GOVERNANCE STRUCTURE




## Roadmap of PvPI



# FREE PAPER

## KNOWLEDGE, ATTITUDE AND SKILLS OF NURSES TOWARDS ADVERSE DRUG REACTION REPORTING

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AIM: To determine the awareness of nurses of Delhi about ADR reporting and pharmacovigilance.

METHOD: A questionnaire containing 23 questions was distributed and completed questionaire was collected on the same day.

RESULTS: The response rate of the survey was 65%. The meaning of term pharmacovigilance was known to 68.27% of nurses. Surprisingly only 51.92% of nurses understood the correct meaning of the term ADR. None of the nurses knew the pharmacovigilance centers of India. Only 7.69% nurses knew the reporting centers of Delhi while just 2.88% nurses had the phone number, address of these reporting centers. Most of the nurses (93.27%) inform patients about the expected therapeutic effects of the prescribed drugs. Their interaction with the patients regarding side effects was significant. Nurses (90.38 %) said that they report observed ADRs. Majority of the nurses said to report the ADRs to the physicians or hospital pharmacy. Nurses felt that, they need not report ADR either because ADR is well known (40.38%) or due to uncertainty about the causal drug (49.04%). About half of the nurses (47.12%) informed to have existence of set procedure of reporting ADR in their organization. Most (75%) of the nurses did not have ADR reporting forms. Remaining 25% nurses had only localized ADR reporting forms.

CONCLUSIONS: Nurses are not reporting ADRs to ADR monitoring centers of CDSCO. Education and training is essential for ADR reporting by nurses to the ADR monitoring centers.

Key Words: ADR, ADR reporting, pharmacovigilance, nurses.

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## CHLOROQUINE INDUCED PHOTOSENSITIVE DERMATOSES - A Case report

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INTRODUCTION: Chloroquine, a commonly used antimalarial drug and also a DMARD is known to cause adverse effects like severe gastritis, cycloplegia, blurring of vision, corneal opacity, toxic psychosis, photosensitive dermatoses and even retinal damage on prolonged use. Here we report a case of photosensitive dermatoses due to chloroquine seen in a tertiary care teaching hospital at Pondicherry.

CASE REPORT: A fifty years old female patient was prescribed chloroquine 150 mg orally for a period of one month for rheumatoid arthritis. At the end of one month she developed multiple, irregular, well-defined, pigmented, scaly plaques over the sun-exposed areas of the face, upper arms and forearms. A diagnosis of probable chloroquine-induced photosensitive dermatitis was made. Chloroquine was withdrawn and she was adviced to continue Tab ibuprofen and Tab methotrexate and she recovered from the cutaneous reaction.

DISCUSSION: The exact mechanism by which chloroquine is used as a Disease Modifying Anti Rheumatoid Drug is not known. In this case of dermatoses caused by chloroquine, the causality assessment was done using Naranjo s algorithm and the association was probable with moderate severity according to Hartwig et al scale. Preventability assessment was done based on modified Schomock and Thornton scale and found to be not preventable.

CONCLUSION: Chloroquine induced photo dermatoses is an uncommon adverse drug reaction seen in 1-2 % of population. Though routine ophthalmological examination is done for patients on chloroquine therapy, this adverse cutaneous drug reaction should also be outlooked with caution by the prescribing physicians.

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## Drug prescribing pattern for Major Depressive Psychosis patients in Geriatric Clinic of a teaching hospital in Northern India.

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Departments of Pharmacology & *Psychiatry, J. N. M.C. AMU, Aligarh-202002 (U.P.)

Objectives:

The aim of the study was to evaluate the current prescribing pattern of Psychotropic drugs in geriatic patients of MDP in a teaching hospital in Northern India.

Methods:

Records of geriatic patients who attended the Psychiatric out patient department of JNMC, AMU, Aligarh from January 2008 to 2011 were reviewed. Data were tabulated and analyzed for epidemiological characteristics and to discern prescribing frequencies and patterns.

Results:

During the period 360 patients were enrolled in the clinic of which 57% were male and 43% were females. 78% of the patients belonged to urban area and 22% were from rural background. About half of these (47%) were of 60-64 years age while the rest belonged to 65-75 years of age. About half of the patients suffered from MDP (43.5%). Of these 55.48% patients were prescribed SSRIs with Benzodiazepines being the other most commonly prescribed drug (36%), Others received TCAs (5.8%), Atypical antipsychotics (3.2%), Atypical antidepressants (2.5%) and Sodium valproate (2.5%). Among SSRIs Fluoxetine was the most commonly prescribed followed by Sertraline. In Benzodiazepines Clonazepam was prescribed most.

Conclusion:

This study shows that SSRIs were the most commonly prescribed drugs followed by benzodiazepines for patients of MDP in this age group.

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## Pharmacovigilance of An Ayurvedic Drug Combination Against Arthritis

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1. PG (R1) 2. PhD 3. MD (Asst Prof) 4 MD (Assoc Prof) 5. Prof & HOD, Dept. of Pharmacology; * Dept of Pharmacy; NIMS University, Jaipur, Rajasthan

ABSTRACT : Objectives : 1. Assessing ADE/ ADR of a common Ayurvedic drug combination (used in arthritis) 2. Searching non-therapeutic effects which are potentially useful (physiological modulations) in other clinical conditions Methods: 50 patients of arthritis were enrolled complying proper inclusion/ exclusion criteria, ethical committee and consent for interventional, open label, prospective study. A combination (capsulated) of Guggul (1 gm), Alarka (500 mg), Ashwagandha (2 gms) and Anantmool (1 gm) were given in standard dose and as most side effects were minor, rechallenge was used to apply Naranjo's algorithm of causation analysis. Result : Maximally reported ADE were burning micturation (23.8%) (definite), sedation (13.4%) (possible) and headache (12.4%) (probable). Sedation was commoner in females but non-therapeutic physiological changes (potentially useful elsewhere) were not seen. Conclusion : Against the myth of total safety of Ayurvedic drugs, they were not found totally free from adverse drug reactions. A larger/ more specific pharmacovigilance study is required.

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## STUDY OF SIDE-EFFECTS OF AMPHOTERCIN-B IN RELATION TO AGE AND SEX IN THE TREATMENT OF KALA-AZAR

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OBJECTIVE- To analyse Side-effects of Amphotericine-B and its incidence in different age groups and sex in the treatment of Kala-azar.

METHODS- Hospital records of 102 patients of Kala-azar receiving Amphotericine-B between 16th august 2010 to 15th july 2011 in S.K.Medical College Hospital were reviewed. Patients were divided on the basis of age and sex. Rise in body temperature ,clinical symptoms during infusion,fluctuation in serum potassium and Creatinine value (laboratory side-effect) were especially noted.

RESULTS-Out of 102 patients ,22% patients had clinical side-effects such as chills, fever,or nausea. Fall in serum potassium was found in 10% patient,6%patients had elevated creatinine value that did not exceed 3mg/dl.Age was significantly associated with clinical side-effects. Younger patients had comparatively more clinical side-effects.There were no significant differences in the incidence of either hypokalemia or renal insufficiency between different age groups. In both male and female patients incidence of clinical side-effects and laboratory side-effects were same.

CONCLUSION-Clinical side-effects of Amphotericine-B such as chills, fever or nausea are more common in younger age groups,whereas laboratory side-effects such as hypokalemia and elevated serum creatinine have no significant difference between different age groups in the treatment of Kala-azar .Both male and female patients have equal incidence of clinical as well as laboratory side-effects with Amphotericine-B.

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## THERAPEUTIC POTENTIAL OF INCREATIN AXIS

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Content : The term Diabetes Mellitus describes a metabolic cum vascular syndrome of multiple etiology characterize by chronic hyperglycemia with disturbance of metabolism. Type 2 DM comprises 85-95% of all cases of Diabetes mellitus. Insulin resistance, beta cell dysfunction and elevated hepatic glucose production are the 3 core patho-physiology of T2DM. Treating patients may require targeting either one , any two or all the 3 core defects. Patients with T2DM are generally treated with many pharmacological compound and are exposed to a high risk of drug Interactions. Increatin Axis is newer concept in T2DM management with promising result. Glucagon like peptide -1(GLP-1) and Glucose dependent insulinotropic peptide(GIP) are resulted from the GIT in response to food intake. These increatin hormones enhance insulin secretion in a glucose dependent manner. So, these compounds associated with least side- effects and drug-drug interaction. Various approaches have been tried to increase the concentration & duration of action of GLP-1 in plasma viz.-GLP-1 Analogues & DPP 4 Inhibitors. This presentation summarizes the available data on therapeutic potential and drug-drug interaction reports for DPP 4 inhibitors and GLP-1 Analogues

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## Oral Curcumin in Prevention of Cervical cancer

Name : Dr. Rashi

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OBJECTIVE To study the efficacy, safety, and side effects of curcumin on women with CIN lesions and compare it with conventional treatments.

METHODS All women with CIN lesions were subjected to VIA, cytology, & colposcopy , then curcumin was started in the form of oral tablets, 2gm BD for a period of 6 weeks. We follow the patients by repeat Pap smear and VIA after 6 weeks and 3 months of curcumin therapy. RESULTS A total no of 226 cases were screened by VIA, Cytology, HPE, and colposcopy. Out of these 135(59.73%) were VIA positive, & 91(40.26%) were VIA negative. Sixty cases received curcumin, and were followed at 6 week, 3 months, and 6 months, in terms of symptoms, clinical examination,cytology and HPE. Thirty seven (61.66%) cases felt better symptomatically, 13 (21.66%) didn't notice any improvement, 4 (6.66%) were lost to follow up , and 6(10%) are yet to report to our clinics. Out of those cases whom we were able to follow cytologically,25 (41.66%) lesions persisted,19(31.66%) lesions regressed, none of the lesions were found to progress. Some cases were lost to follow up.Seventy five cases were given conventional treatment such as antibiotics, cryotherapy, & LEEP and followed in the same manner.

CONCLUSION In recent years many phytochemicals have come up with having preventive and therapeutic role in carcinoma cervix, such as carotenoids, green tea extracts, catechins, flavonoids, vit C, vit E, selenium and folic acid. Curcumin is one such compound.Before we come to a conclusion more extensive studies are required detailing the pharmacokinetics of the drug.

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## Status of Adverse drug reaction monitoring and Pharmacovigilance among health care professionals of Delhi

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Objective: To evaluate the awareness of Health Care Professionals regarding Pharmacovigilance, ADR and its reporting.

Method: A self-structured questionnaire was delivered by hand to a sample of 590 health care professionals (HCPs) in Delhi. The filled questionnaire was collected on the same day.

Result: The Response rate of this survey was 63.73%. The health care professionals were Physicians (32.98%), pharmacists (39.36%) and nurses (27.66%). Only 58.24% HCPs were aware of the broad meaning of the Pharmacovigilance and ADR. All Physicians knew the meaning of ADR which was followed by 51.92% nurses and 27.70% pharmacists. Majority of HCPs (90.43%) felt that ADR monitoring is essential. Though 45.48% HCPs reported the ADRs encountered by them just 3.19% HCPs had faint information that reporting can be done at National Monitoring Centre (NMC) and/or Regional monitoring centres (RMC). AIIMS and LHMC as ADR monitoring centres of Delhi, were known to only 7.71% HCPs. Out of these, only 1.86% HCPs had the phone number and/or address of these centres. It indicates that the ADR reporting is done by HCPs at places other than NMC and RMC. HCPs reported ADRs to manufacturing industry, product management team, chief pharmacist, Physician, Department in-charge, purchasing department of hospital etc, which is worthless.

Conclusion: Reporting of ADRs by HCPs is poor. Among the HCPs, the knowledge, skill & attitude towards pharmacovigilance and ADR reporting was highest of physicians followed by nurses and then pharmacists. Education and training is essential to increase ADR reporting rate by health care professionals.

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## Obwervation of adverse drug reaction of injection artesunate in 20 cases of falciparum malaria in a tertiary care hospital

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Abstract

Objective : To observe adverse durg reactions of injection artesunate.

Method : This study was conducted on 20 patients of diagnosed severe falciparum malaria. The patients were treated with standard regimen of injection artesunate (2.4 mg/kg loading dose over 5 minutes, 2.4 mg/kg dose 12 hours later. 2.4 mg/kg once daily after that for 5 days). On pesentation a detailed history was taken and biochemical tests and complete blood counts done and recorded.

After 5 days of treatment biochemical parameters were repeated in an attempt to observe any adverse effects of artesunate therapy

Results : 5 patients died during the course of treatment. Rest of the patients made full recovery and all parameters had normalized in the repeat biochemical tests done on day 5. No adverse reactions were seen to artesunate injections. there was mild nausea in some patients earlier but was probably an effect of malaria rather than artesunate injection.

Conclusion : Artesunate was found to be a safe drug with minimal side effects.

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## somatostatin induced anaphylactic reaction in a case of fundic varix with cirrhosis & Portal HTN : A case report

Dr. Sawarkar Hindustani
Nalanda medical college Patna

Introduction: somatostatin and somatostatin analogue known side effect include g.i.t upset (nausea, Vomiting, abd.cramp), cholelithiasis ,effect on glucose metabolism, mild reaction & pain at injection site. Sinus bradycardia(25%) & conduction disturbance (10%)& vit B12 deficiency with long acting octreotide. Here we report a case of anaphylaxis due to somatostatin infusion in a case of anaphylaxis due to Somatostatin infusion in a patient of cirrhosis of liver with portal HTN for fundic varix after injection of Glue.

Case report: A 42 yr old HM, a diagnosed case of cirrhosis of liver with portal HTN with G.I bleed was Admitted superspeciality hospital after injecting glue, somatostatin infusion started as prophylactic Measure .As soon as bolus dose given patient developed local approx. 4 cm erythema at injection site of right fore arm and also to left fore arm when changed the injection site followed by severe bradycardia and shock.A Diagnosis of immediate type of hypersensitivity reaction Was made and infusion was stopped. Antihistaminic Atropine,& corticosteroid injections given and patient recoverd completely within 1 hr

Discussion:In this case anaphylactic reaction caused by somatostatin casuality assessment was done using Naranjo's Algorithm and the association was definite with moderate severity as per hartwing and sigel Scale.preventibility assessment done using schumock and thornton scale.

CONCLUSION: Somatostatin induced local erythema and bradycardia is known adverse effect.But this type Of anaphylactic reaction shows possibility of exceptional susceptibility of the patient to this drug.However Majority of patients which were prescribed this drug in that hospital complained only mild adverse effect Like nausea and occasionally vomiting,and one patient developed conduction abnormality. So this drug can be safely administerd but with great caution.

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## Over the counter drugs : A challenge to pharmacovigilance

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Abstract

OTC drugs are legally allowed to be sold without the prescription of a Registered Medical Practitioner. In India, all the drugs those are not included in the list of 'prescription drugs' are considered as Non-prescription drugs (or OTC drugs). OTC drugs are used commonly for headache, muscular aches, toothaches, cold & cough, acidity, loose motion, period pain etc. Self medication with over the counter products is remarkably consistent both in urban and rural adult age group. The vast majority of adults who reported minor illnesses had experienced these ailments before, and at some stage a quarter of them had consulted their general practitioner or dentist about them initially and later on continued it without consultation again. Children are also exposed to the OTC in same fashion. Cost and convenience seem to be major factors in determining whether, given the choice, patients purchase a medicine over the counter or obtain it on prescription. Taking OTC drugs on prescription provides good opportunity OTC Drugs are legally allowed to be sold without the prescription of a Registered Medical Practitioner. In India, all the drugs to register unknown side effects by treating doctor. India is showing great rise in usage of OTC drugs in urban groups thanks to literacy & availability of information in various form, the rural people are giving their inputs due to illiteracy, poor health services & poverty. Even if these drugs are available over the counter they are not free of side-effects. The pools of OTC drugs users are extensive so the need of vigilance is more important. We must develop a system for referral and recording details of OTC drugs and establish a direct way for community pharmacist to report adverse drug reaction related to OTC drugs.

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## Comparative Analysis of Online ADR Reporting Forms of Different Countries.

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Objectives: To study and analyze the online (ADR) reporting form of various countries for the adequacy of the data collected.

Methods: Online ADR reporting forms of 5 different countries (India, US, UK, Canada Malaysia) were analyzed and compared for data fields like patient information, adverse reaction, suspected drug, reporter information etc. Presence of different data field is expressed as yes (@ ) or no (ß ); presence of each data field is given the score one and absence as zero. Finally the scores are totaled.

Results: After analyzing online ADR forms we found that all the five countries including India did not include Pregnancy status in the online ADR reporting forms. Indian online ADR forms also did not include other parameters like actions taken or treatment given following ADR, ADR due to Medical Devices or other Health Products, option of whether this ADR to be reported to manufacturer / user facility, option of Identity disclosure etc.

Conclusions: Each country has its own online ADR reporting form as per the individual countries requirements. However, our study reveals that the online ADR reporting form from different countries fails to capture all the required information. Therefore, there should be international guidelines for drafting and designing of online ADR reporting form by countries.

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# A survey on how many people read the Patient information Leaflets

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Objectives: A general survey to estimate the percentage of people read the product information Leaflet.

Methods: A questionnaire on interview basis is prepared. It has the fields for age, sex, designation and two questions with Yes /No answers. Then the questionnaires are collected and the results tabulated and the No. of Yes and No are calculated. Percentage of Reader, occasional Reader, and those who do not read the Leaflet calculated and the results obtained.

Results: Out of 500 people interviewed 376 (75.2%) people do not read the leaflet at all, 108(21.6%) people read occasionally, and only 16(3.2%) people read the leaflet for all the drug they purchase.It clearly points out only few people read the PIL.

Conclusion: Many countries have their own guidelines for drafting the Patient information leaflet for the manufacturing authority to make it easy for general public to easily understand and for better readability with proper font size, signs and symbols to educate and warn about Adverse Drug Reaction. In India many people dont read the Patient information leaflet even for the medicines which they are supposed to take for lifelong like anti diabetic & anti hypertensive drugs. Many read the instruction on cosmetic preparation available. It is time to educate the people to read the Patient information leaflet to avert or minimize the ADR caused by it. It is on the part of the Government Authority to draft guidelines for manufacturing authority to prepare Patient information Leaflet that is easy to read and understand for the general public.

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## A Randomized Open label Active Control Study comparing safety and efficacy of Levetiracetam and Oxcarbazepine as monotherapy in newly diagnosed Partial Onset Seizures

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Abstract

Objectives: To compare the efficacy and tolerability of levetiracetam with that of oxcarbazepine as monotherapy in newly diagnosed partial onset seizures

Methods: Newly diagnosed partial seizure patients attending the neurology outpatient department in a tertiary care center were randomized into Oxacrbazepine and Leviteracetam group (30 patients each). These patients were followed up for a 6 week period of stabilization (with step wise increase in dose) and 26 weeks after stabilization for seizure control and adverse effects

Results: In Oxcarbazepine group, most of the patients (70%), achieved seizure freedom at 6 months with Dose level 1(150mg BD) itself. 2 patients(6.66%) achieved seizure freedom at Dose Level 2 (300mg BD) and 2 patients (6.66%) at Dose Level 3 (600mg BD). In 2 patients, seizures were not controlled inspite of maximum dose. These patients were started on alternative drugs.In Leviteracetam group also, most of the patients (63.33%) had seizure control at 6 months with Dose level 1 (250mg BD) itself. 5 patients (16.67%) had control on Dose Level 2 (500mg BD). 2 patients(6.67%) had seizure control at maximum Dose Level 3(1500mg BD). In1 patient, seizures were not controlled inspite of maximum dose. This patient was started on alternative drugs.In Oxcarbazepine group, 26 patients (86.66%) were seizure free, at the final evaluation at 26th week after 6 weeks of dose stabilization.In Leviteracetam group, 25 patients (83.33%) were seizure free at the final evaluation. Adverse effect profiles were comparable between the 2 groups. Only 1 patient in each group had to discontinue treatment owing to adverse drug reaction (cutaneous rashes)

Conclusion: In this study, Leviteracetam has been proven non-inferior to Oxcarbazepine in treatment of new onset partial seizures, both in terms of efficacy and tolerability.

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## BIOSIMILAR DRUGS : CURRENT STATUS.

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ABSTRACT

CONTEXT: Biologic products developed over the past thee decades. The expiry of patent protection for many biological medicines has led to the development of biosimilars in UK or follow on biologics ( FOB) in USA. Biosimilars differ from generic drugs in many ways also legal and regulatory principals applicable to generic drugs cannot be applied to biosimilars . Experience with biosimilar drugs has been very limited and long term safety data are not available. There is need for appropriate regulatory guidelines and pharmacovigilance programs .

OBJECTIVE: To systematically review the literature on biosimilar drugs that cover the therapeutic status and regulatory guidelines.

METHOD / SEARCH STRATEGIES: Appraisal of published articles from peer reviewed journals for English language publications , search from Pubmed and guidelines from Europian Medicines Agency (EMA) .

RESULTS : Literature suggest that biosimilars are similar biological products i.e. comparable but not identical to reference product, are not generic version of innovator product and do not ensure therapeutic equivalence. Biosimilars present more challenges than conventional generics and market approval is also more complicated. To improve access US Congress passed the Biologics Price Competition and Innovation (BPCI) act 2009 and U.S FDA allowed @abbreviated pathway@ for their approval. U.S law has defined new standards and terms and EMA scientific guidelines have also set detailed approval standards.

CONCLUSION: Biosimilars are not identical to reference product. The US and EMA have set regulatory guidelines to ensure safety of such products . India being one of the most preferred manufacturing destinations of Biosimilars there is a need for stringent safety and regulatory guidelines.

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## ALLERGIC DRUG REACTION OF LEVOCETRIZINE: A CASE REPORT.

Dr. UmaShanker Pd Keshri*, **Dr. Anuj Pathak****, Dr. J. Sharma*****

Abstract

Objective: To report a case of allergic reaction resulting from the use of levocetrizine.

Method (Case report) : A 55 years old female patient was suffering from common cold. She had mild fever headache and running nose. She was advised tab. levocetrizine 5mg.once daily and tab paracetamol 500mg as and when required. Running nose was troublesome to the patient and headache was tolerable, so she took tab of levocetrizine and avoided tab paracetamol. It was noted that when this drug was taken by the patient; she had fever and developed rash on her limbs. Subsequently rashes appeared also on her face, trunk and upper and lower extremity. Rashes increased in severity. A levocetrizine induced drug reaction was suspected. Patient was properly examined to exclude other pathological condition and complete investigation was done. She was treated by antihistaminic drug and avoiding offending drug. Patient was kept under observation. Erythamatous rashes increased in severity in next few days and then started becoming faded up and turning dry. Skin peeled and new skin take place in place of old skin. It fully subsided in next one week. We therefore concluded that this was a case of levocetrizine induced allergic reaction. Further rechallenge with oral levocetrizine was not done in the interest of the patient and due to ethical constraints.

Conclusion: Levocetrizine is an antihistaminic drug and is used for this purpose. Although this is a safe drug but occasionally may cause serum sickness like allergic reaction. It is advocated that use of this drug should be carefully monitored.

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## ADVERSE DRUG REACTIONS & IEC INTERVENTIONS AT COMMUNITY SETUP: A WAY FORWARD IN PATIENT SAFETY.

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ABSTRACT

Community pharmacists are most easily accessible healthcare professional to an individual belonging to any socio-economic strata. Hence community pharmacist have got wide compass to play better and active role in pharmacovigilance.

OBJECTIVE: To study impact of the IEC (Information, Education and Communication) interventions focused on adverse

drug reactions (ADRs) among practicing pharmacists at community setup.

METHOD Community pharmacists were administered Knowledge, Attitude and Practicing (KAP) questionnaire pre and post sessions conducted for study purpose.

RESULTS: Among 60 consented community pharmacists, 40 attended training programme. Out of 40, 35 (87.5%) were interested in reporting ADR and 38 (95%) said that training is required in order to report an ADR. Pre session, 34 pharmacists (85%) were in opinion that pharmacist should be involved actively in ADR reporting, post session 39 (97.5%) were in favor. Twenty one pharmacists (52.5%) knew definition of ADR pre session on contrary 38 (95%) answered correctly post session Among 40 pharmacists, 25 (62.5%) had came across situation wherein they were sure that it was an ADR but have not reported because they were not sure how to report it. Pre session 26 pharmacists (65%) said ADR reporting will add value to service they offer, after training number was 36 (90%). Lack of knowledge about ADR and its reporting, uncertainty about which reactions to be reported are some factors for non-reporting of ADRs.

CONCLUSION: Continuous pharmacy education programme remain mainstay to sensitize and encourage community pharmacists to report ADR frequently.

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## MILTEFOSINE & ADR:- RISK MANAGEMENT

Dr. Arshad Hasan, Katihar

Visceral Leishmaniasis is a life threatening disease. Most of the cases specially found in the region of North Bihar, Orissa, & U.P. Traditional treatment contains Antimonial group. 2nd group contains antifungals.These group has also good result in eradicating the protozoa. Knowing the side effects of the drug & resistance makes these drugs less effective. Inconvenient to this drug is the parenteral route also makes this drug for its withdrawal. In this evolving era, lot of drugs are invented & more yet to come, in a holistic queue to a rational use for V.L. Allopurinol, Ketoconazole, Fluconazole & Atovaquone are the drugs which was made attempts to develop oral drug but was failed. The agent commonly used now days is Miltefosine & Edelfosine. These drugs are commonly used because of its advantage of Oral route. It is an alkyl phospholipids compound was initially intended for breast cancer & other solid tumours'. Common side effect includes G.I. Kidney & liver toxicity with Thrombocytopenia etc. No wonder, with all the knowing side effects still this drug being used. Data showing of use of Miltefosine and its effect, but unfortunately we have no data about its side effect. So we have to carry a jute box for ADR, especially for the drugs which are commonly used.

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## ATTITUDE AND PERCEPTION TOWARDS ADVERSE DRUG REACTION REPORTING AMONG DOCTORS OF MEDICAL COLLEGES IN PATNA

Dr Marya Ahsan,

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Objectives : Adverse drug reaction (ADRs) are of global concern as it affects many patients and adds up to their morbidity and mortality. It has a major impact on public health care system by increasing the effective cost of treatment and causing further distress to the patients WHO defines pharmacovigilance as the science and activities relating to the detection assessment, understanding and prevention of adverse effects or any other drug related problems As the state of Bihar does not have any ADR reporting and monitoring centres, many cases of ADR reporting and factors that influence the reporting of ADR cases.

Materials and methods : A suitable self-administered survey questionnaire is designed and will be randomly circulated to 50 doctors in two medical colleges in Patna. The obtained data will be collected and statistical analysis will be done

using SPSS software.

Observation and conclusion : As this study is still under progress, the observation and results will be presented during the conference.

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## VACCINE PHARMACOVIGILANCE-AN ISSUE OF CONCERN

Dr Priyanka Singh, pg student, dept.of PSM, Nalanda Medical College, Patna

Dr.(Prof) Mrs Geeta Singh, Professor, dept of PSM, Nalanda Medical College, Patna

Introduction- Vaccine pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, prevention and communication of adverse event following immunisation, as of any other vaccine or immunisation related issues.

Aim and objective of vaccine pharmacovigilance is to detect early unknown safety problems related to vaccine or immunisation,identify increase in the frequency of unknown adverse reactions,assess and communicate the risk and benefit of vaccines and promote safe and more cost effective use of vaccine. As for several reasons vaccine pharmacovigilance is different from pharmacovigilance of other drugs .

Method- from available literature.

Result- Vaccines are often administered to healthy children.This implies particularly to vaccine used within a national immunisation programme.In many countries,those exposed to a particular vaccine represents the entire birth cohort and therefore a sizeable part of the entire population.People' s expectation is high and even a small incidence of adverse event may result in loss of confidence and a consequent resurgence in morbidity and mortality of vaccine preventable disease.It is essential that there should be adequate safety surveillance supporting immunisation programmes.The skills and infrastucture to deal with genuine adverse event are essential in preventing or managing misplaced fear caused by false or unproven signals from patients and health workers that might adversely affect immunization coverage,for eg concerns about the safety of whole cell pertussis resulted in dramatic reduction in vaccine coverage and and a resurgence of pertussis in many countries.

Conclusion- It is now high time that vaccine pharmacovigilance should also receive their due attention.

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## Drug prescribing pattern among pediatricians in an out-patient and PICU, NICU department of teaching hospital in Rajasthan

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**Objective:** This study was carried out to find the drug prescribing pattern in children registered in department of pediatrics of a teaching hospital in Rajasthan.

**Methods:** A prospective, interventional follow up study was carried out at the pediatric department of the Rajasthan in 150 pediatric patients. The study consists of

(i) Average number of drugs per Prescription,

(ii) Percentage of category of drugs prescribed.

**Results:** The average number of drugs per patient was 5 1out of these antibiotics were 2 1. They were prescribed bronchodilators 40%, Analgesics and Antipyretics 33.03%, Anti histamines13.03%, corticosteroids 6.06%, Multi

vitamins13.03%, Diuretics 13.01%, Anti cholinergic 6.06% and Antibiotics 93% of prescriptions. Among these more than 60% of the neonatal patients were exposed to at least two or three antibiotics per prescription.

Conclusion: The fact that children below 1 year or infants are at special risk of receiving multiple courses of antibiotics, which have interactions with each other. By considering this enthusiastic poly pharmacy, we suggest that strategies to control antibiotic use should focus on these pediatric patients populations.

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## PRESCRIBING PATTERN OF DRUGS IN THE DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY IN EXPECTED MOTHERS IN RAJASTHAN

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Aim: To assess the pattern of prescriptions of drugs in obstetrics and gynaecology department in patients at different hospitals in Rajasthan.

Introduction: Irrational use of drugs is a huge worldwide problem and extra care should be taken especially in pregnancy. Pregnancy is one of the most important phase of women's life. In pregnancy irrational use of drugs may cause teratogenicity. To avoid the adverse effect to any extent minimum number of drugs should be prescribed in pregnancy. The study was carried out to determine the possible irrational use of drugs and drug- drug interactions among the prescribed drugs.

Method:

Prescriptions of 112 patients of obstetrics and gynecology were collected and studied through and analyzed for the following:

- Average number of drugs per prescription
- Possible drug interactions
- Duration of treatment (recorded or not)
- Frequency of administration (recorded or not)
- Percentage of types of drugs prescribed to individual patients

Results: Prescription analysis showed that the

- Average number of drugs per prescription was 5.9
- Duration of treatment was recorded for only 40% of the drugs prescribed.
- Frequency of administration was recorded for 90% of the drugs prescribed.
- Percentage of different types of drugs prescribed to individual patients were-

  Antibiotics @ 60%, diuretics- 10%, $Ca^{2+}$ containing products- 40%, Iron preparation- 70%,Anti-spasmodic-40%,Folic-acid- 20%, Hormones-20%, B -complex-40%, Multi-vitamins - 10%, anti-emetics-30%, and Anti-ulcer-40%.

Some other classes of drugs like Lovastatin, Neutraceuticals were also prescribed which accounts only 10% of the prescription.

Conclusion: The results obtained from the above study indicates poly-pharmacy and a high incidence of common prescription writing errors such as not recording the duration of therapy, frequency of administration and drug-drug interaction. On the basis of above study we have concluded that some drugs used in pregnant women were irrational and were not safe.

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## Prescription Audit of anti-psychotics drugs in the department of Psychiatry

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Department of Pharmacology, NIMS Institute of Pharmacy, NIMS University, Jaipur

Objective: To analyze the prescribing pattern of anti-psychotic drugs for the treatment of psychosis in a multi-specialty hospital in jaipur.

Introduction: Therapeutic jungle is increasing day by day & new moieties are being introduced. It may lead to poly pharmacy due to enthusiastic use of new moieties by the prescribers. This may lead to ADR's and other interactions. This study was done to measure awareness of prescriber and to develop intervention for improving patient care by rational use of drugs.

Material and Methods: Total 103 prescriptions were randomly selected from Outpatient department & Inpatient department of multispecialty hospital in jaipur. They were assessed and analyzed for

- Drug-drug Interactions,
- Adverse effects
- Type (Brand/ generic)
- Number of drugs prescribed
- Commonly prescribed drugs in the department
- Precautions enlisted in prescriptions

Result: We observed that most of the doctor's prescribed all anti-psychotics drugs according to the symptoms of the patients. Commonly prescribed drugs were pharagar inj. (55.33%), neogadine (44.14), sodium valproate (42.8%) , clonotril (32.37%) , and duloxetine (23.37%).

Conclusion: It was clear from the survey that the drugs which were prescribed may enhanced adverse effect & reduced therapeutic effect. All the prescribers responded very well so it is request from the prescribers that they prescribe safer drugs.

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## Prescription Audit of medical college and associated hospital of Jaipur

Srivastava DP*, Mandloi A*, Kulshreshtra S, Mohan G*

Department of Pharmacology NIMS Medical College *NIMS Institute of Pharmacy(NIMS University, Jaipur)

Objective: To assess prescribing pattern and trend of prescribing doctor in teaching Hospital.

Introduction: Inappropriate drug prescribing is a global problem. Good prescribing practice is a science and an art as it conveys message from doctor to patient. This study was done to measure awareness of prescriber and to develop intervention for improving patient care by rational use of drug.

Material and Method: Total 300 prescription were recorded from OPD and they were assessed and analyzed for-

- Prescribing pattern - quality, adequacy (Patient detail etc.),clarity.
- Rationality
- Type (Brand and generic)
- No of drugs prescribed by doctor- poly pharmacy

Results: The prescriptions were analyzed and it was foundthat name of patient, age, sex were present in all prescriptions, but 5.5% prescriptions were incomplete in address.Diagnosis was incomplete in 3.3% of prescriptions. In about 1.66%prescriptions,signature of prescriberwasnotpresent. Dose and duration of drugs was clear except in 7.8% of cases. 9% drugs were prescribed by generic nameand 18.7 % were in combination. About 55.5% of prescription contained atleast one antimicrobial agent and 18.7%of prescription contained nutraceuticals. In about 31% of prescription were having atleast three drugs and 16% of prescription contained more than 3 drugs. Poly pharmacy may lead to increase in drug interaction, cost of treatment & medication errors.

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## The prescribing pattern of non-steroidal anti-inflammatory drugs (NSAIDs) in 900 bedded multispecialty hospital.

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Department of Pharmacology, NIMS Institute of Pharmacy, NIMS University, Jaipur

OBJECTIVE: The prescribing pattern of non-steroidal anti-inflammatory drugs (NSAIDs) in 900 bedded hospital surrounded by many pharmacies in Jaipur.

METHODS: The decade has passed since Felix Hoffman reported the successful synthesis of acetyl salicylic acid and its common name was aspirin. Now NSAIDs are used so casually that their adverse drug reaction (ADRs) should be well studied. The data were collected by obtaining different prescriptions from patients and they were jotted down. Prescriptions containing NSAIDs were randomly taken from different departments of hospital and also from pharmacies. NSAIDs show a mild gastro-intestinal irritation (GI) as ADR. Aspirin cause (GI) irritation to some extent. The much common combined Prescription was found to be of paracetomol + ibuprofen.

RESULT : Commonly prescribed NSAIDs were

- Ibuprofen (6%)
- Aspirin (9%)
- Diclofenac (12%)
- Paracetomol (23%)
- Piroxicam (6%)
- Paracetomol + Ibuprofen (38%)
- Diclofenac + Serratiopeptidase (10%)

This should be avoided because they can cause certain ADR as well as unnecessary financial burden on patent. Above percentage showed that how commonly these NSAIDs are being prescribed.

CONCLUSION: It was observed that some time prolonged use of paracetomol causes hepatic toxicity that was treated by prescribing lactic acid bacilli. Diclofenac and other NSAIDs well prescribed in prolonged used causes GI irritations. Children may be more susceptible to a particular ADR, for aspirin causing Reye's syndrome. This study has shown that there exist significant differences in the usage pattern and preferences of NSAIDs among different practice categories in Jaipur. The data have also revealed that there is a need for awareness programmes on rational prescribing of NSAIDs towards optimal therapeutics and improved patient care in Jaipur.

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## PHARMACOVIGILLANCE STUDY OF ANTI-INFLAMMATORY DRUGS IN ORTHOPEDICS DEPARTMENT AT A MULTISPECIALTY HOSPITAL

**Selkari Rohit, Sharma Rohit,** Ahamad Ayaz, Gupta Nakul, Deb Binayak, Mohan Govind Department of

Pharmacology, Nims Institute of Pharmacy, NIMS University, Jaipur

OBJECTIVE: The current study is designed to investigate the prescribing pattern of anti inflammatory drugs and their adverse drugs reactions prescribed in orthopedics at a university hospital in Rajasthan.

INTRODUCTION: Prescription practice is an act of establishing official rules, laws or directions about drugs conveyed to patients from prescribers. By this study we can sensitize the prescriber which may help to develop intervention for improving patient care by rational use of drugs.

METHODS: Study was conducted on 105 patients in the orthopedics dept. of a 700-bedded multispecialty hospital in Jaipur. Data are recorded by observing the prescription on following parameters-

- Prescribing pattern (clarity, patient detail, quality)
- Commonly prescribed drugs
- Name of brand and generic drugs
- Adverse events
- Drug-drug interactions

RESULTS: We found that most of the orthopedic practioners prescribes all NSAIDs according to the diagnosis of the patients. Mostly the drugs which are prescribed by doctors in combination with NSAIDs are amoxicillin, calcium carbonate etc. which results in washing away the therapeutic effect of the same. Commonly prescribed drugs are Diclofenac sodium(42.8%), Ibuprofen(28.5%), Piroxicam(39.2%), Mefanamic acid(23.9%).

CONCLUSION: All the prescribers responded very well. This study shows the additional evidence that the combination which are prescribed having serious adverse effect and drug interaction. If this situation will go on like this, then imagination of healthy future will be in a great trouble.

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## Prescription Auditin a medical College associated hospital of Rajasthan

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Objective: To assess prescribing pattern of antibiotics in a medical College associated hospital of Rajasthan.

Introduction: In last one decade antibiotics has been prescribed for treatment of almost all diseases due to which the problem of antibiotic resistance increased. Antibiotic resistance is a global problem. Beside antimicrobial resistance the problem of drug interaction is also major consideration. Antibiotic now a day are frequently used and they lead to certain interaction as well as causes ADR.

Method and material: Total 100 prescriptions were recorded from OPD and pharmacy at Hospitals in Jaipur and they were assessed for -

- Prescribing pattern - quality, adequacy (Patient detail etc.), clarity.
- Rationality
- Type (Brand and generic)
- No of Medicine prescribed by doctor- poly pharmacy

Results: Total 100 prescriptions were analyzed. About 25.3% of prescriptions contained at least one fluoroquinolones

antibiotics and 17.6% of prescriptions contained macrolides. In about 15.4%prescriptions were having at least one beta lactam antibiotics. Dose and duration of medicine was clear except in 6.6% of cases. 12.1% medicines were prescribed by generic name. About 22% prescriptions contain at least two drugs, 6.32% prescriptions contain at least 3 antibiotics and 2% contains more than 3 antibiotics. Poly pharmacy may lead to increase in drug interaction, cost of treatment& medication errors.

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## Prescription Audit of Antacids and PPIs

Moyal Urmila, Khan Hina, Mohan Govind, Gupta Nakul, Ahamad Ayaz.

Department of Pharmacology, NIMS Institute of Pharmacy, NIMS University, Jaipur

Aim: A study on the use of Antacids and Proton Pump Inhibitors in a Multi Specialty Hospital of Rajasthan.

Introduction: Irrational prescribing pattern of drugs is major problem Worldwide. A study was conducted on the use of Antacids and Proton Pump Inhibitors in a wide range of patient's .In our study of prescription of different patients using Antacids and Proton Pump Inhibitors, we found that there is irrational use of these drugs, which may result in reduced effect adverse drug reaction, drug@drug interaction like chelating with metal ions. This study was conducted for improving patient care by rational use of Antacids and Proton Pump Inhibitors which include medical patients suffering from critical illness which requires immediate and accurate prescribing of drugs.

Material and methods: About 120 prescriptions were recorded from Medicine & Medical. I.C.U of hospital in Jaipur and they were assessed for-

- Prescribing pattern - quality, clarity, adequacy (Patient detail etc).
- Drug Interaction
- Adverse effects
- Type (Brand and generic)
- No. of drugs prescribed by doctor.
- Commonly prescribed drugs of Antacids and Proton Pump Inhibitors.
- Precautions.

Result: We found that most of the doctor's prescribes all antacids and Proton Pump Inhibitors according to the symptoms of the patients. Most of the drugs which were prescribed by doctors in combination like Pentaprazole, Domperidone, Ranitidine. Commonly prescribed medicines are Rantac (ranitidine) (42.50%),Pan-40 (pentaprazole and Domperidone) (38.50%), Pentocid (pentaprazole) (12.80%), Sucralfate (4.10%) Norflox (norfloxacin) (2.10%), Injection Emeset(ondansetrone) (1%)

Conclusion: It was clear from the survey that the combinations which were prescribed by the doctor are having adverse effects and drug interaction. Therefore these combinations should be avoided in future.

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## A STUDY ON THE USE OF DRUGS IN I.C.U OF MULTI SPECIALITY HOSPITAL

Sonkar A, Yadav J, Gupta N, Ahmad A, MohanG

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Objectives: To study the use of drugs in I.C.U Of Multi Specialty Hospital in Rajasthan.

Introduction: Irrational prescribing pattern of drugs is a major problem leading to adverse drug reaction. As estimate that cost of treating adverse drug reaction is more than the cost of treatment. This is especially true in I.C.U as the

patient is critical and polypharmacy may be required. A study was conducted on the use of medicine of different category for the patient of medical and surgical I.C.U. This study was conducted for improving patient care by rational use of drugs in I.C.U which include medical and surgical patients suffering from critical illness which require immediate and accurate prescribing of drugs.

Material and Method : Total 150 prescriptions were recorded from surgical& medical I.C.U of the hospital in Jaipur as they were assessed for

- Prescribing pattern - quality, adequacy ,Patient details ,clarity etc.
- Drug - drug Interaction
- Adverse effects
- Types (Brand / generic)
- No of Medicine prescribed .
- Commonly prescribed medication in I.C.U
- Precautions enlisted.

Results: The data showed that the 10% patient received no antibiotics,20%-1 antibiotic,50%-2 antibiotics and 20%-3 antibiotics. The 10% patient received no antacids,70% - 1 antacid,10%-2 antacids and 10%-3 antacids. The 30% patient received no anti-emetic,60%- 1 anti-emetic,10%-2 anti-emetics. The 10% patient received no NSAID,60%- 1 NSAID,30%-2 NSAIDs

Conclusion: It was clear from the survey that the combination which were prescribed by the doctor's having adverse effects and drug interactions. If this situation is continued and there is no awareness program for irrational use of these drugs, this may result in resistance, drug-drug interactions and adverse drug reactions. This is not a situation for GOOD PRESCRIBING PRACTICES.

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## Zauberkugeln-Paul Ehrlich's quest for specific medication

Riemke de Boer
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Ronald Meyboom
Dept. of pharmacoepidemiology ad clinical pharmacology, University of Utrecht, The Netherlands

The foundations of medical science and practice, as we know them today, have largely been established in the second half of the 19th century. While up till then chemicals had mainly been used topically for their antiseptic actions, a therapeutic breakthrough was reached through the first generation of biopharmaceuticals: antitoxins (for instance against diphtheria), vaccines and serologic tests. Through comparing and combining advances in pathology and histology, chemistry, physiology, bacteriology and immunology, Ehrlich and colleagues came to the idea of designing molecules that were well-tolerated by the body and had two side chains: one ensuring attachment to the relevant structures of the cells ('receptors') and one exerting the actual action on the cells (e.g. cytolysis). Ehrlich named these molecules „magic bullets□. The major historical example of a drug designed this way is arsphenamine (Salvarsan), the first drug to cure the devastating disease syphilis. Arsphenamine was created through planned exhaustive experimental testing of hundreds of compounds; experiments that covered drug development, clinical efficacy as well as pharmacovigilance, and have shown the way to the pharmacotherapeutic revolution of the 20th century.

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Abstract

## COMPARATIVE STUDY OF ADVERSE EFFECTS OF I.V. AMPHOTERICIN B AND ORAL MILTEFOSINE IN CASES OF VISCERAL LEISHMANIASIS

Manish Kumar[1], J.R. Keshari[2], Prof. (Dr.) Harihar Dikshit[3], Dr.(Mrs.) Ranjana[4]

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[2] Senior Resident, Department of Biochemistry, IGIMS, Patna

[3] Prof. And Head, Department of Pharmacology, IGIMS, Patna

[4] Associate Professor, Department of Pharmacology, PMCH, Patna

Objectives : To compare the adverse effects of i.v. Amphotericin B and oral Miltefosine. Parameters studied are: Hemoglobin, Total leukocyte count, Liver function test, Renal function test, Serum Potassium level and Other toxicities seen during treatment.

Methods : Total 100 patients were the subject of study. They were randomly divided into two groups of 50 each. I.V. Amphotericin B was given to Group A and oral Miltefosine to Group B. The present study was conducted in Department of Medicine and Pharmacology, Patna Medical College and Hospital, Patna.

Results : Group A patient shows fever and chills, anorexia, nausea and vomiting, headache, thrombophlebitis, rise of BUN, mild increase in serum creatinine, fall in serum potassium and rise in SGPT and SGOT. Group B patient shows nausea, vomiting, diarrhoea, rise in SGPT and SGOT. Rate of spleen and liver regression, response on fever were faster in Group A patients. Rise in Haemoglobin and Total leukocyte count were faster in Group B patients.

Conclusions : The final conclusion derived from this study is that no sufficient toxicity developed which warrant the withdrawal of drug in both groups. Both the drugs are equally efficacious. In terms of safety oral Miltefosine are safer despite of small rise of SGPT and SGOT. Miltefosine shows faster rise in Hb concentration and Total Leukocyte count. Also Miltefosine is more compliant to patients due to its oral route. Hence, Miltefosine is effective, safe and more compliant drug in comparison with Amphotericin B.

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ABSTRACT

## ASSOCIATION OF HOMOCYSTEINE AND OXIDATIVE STRESS IN PATIENTS OF PREECLAMPSIA.

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Preeclampsia is a complex multisystem disorder characterized by hypertension and proteinuria. It is one of the most common and potentially fatal complications of pregnancy. A case control study as carried out to assess the levels of homocysteine, lipid peroxidation and antioxidant status in patients with preeclampsia. Fasting venous samples were collected during antepartum period and serum levels of homocysteine (Hcy), malondialdehyde (MDA), ascorbic acid (vitamin C) and uric acid were measured. In the preeclamptic group, Hcy and MDA levels were significantly raised while antioxidant ascorbic acid level was significantly reduced ($p < 0.01$) and uric acid concentration was increased significantly ($p < 0.01$). These findings suggest that Hcy and lipid peroxidation are associated with preeclampsia. In preeclampsia, antioxidants are extensively utilized to counter act the cellular changes and endothelial dysfunction mediated by oxidative stress. Placental oxidative stress which results from the ischemic reperfusion injury is reported to be involved in the etiopathogenesis of preeclampsia.

Keywords: preeclampsia, Homocysteine, lipid peroxidation, antioxidants.

मुहिम स्वस्थ बिहार के अन्तर्गत

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**लोक स्वास्थ्य अभियान के अन्तर्गत:-**

- लोक स्वास्थ्य के मुद्दों पर ग्राम स्वास्थ्य एवं स्वच्छता समिति को सक्रिय किया जाएगा।
- मासिक ग्राम स्तरीय स्वास्थ्य स्वच्छता एवं पोषाहार दिवस को एक ''सामाजिक त्योहार'' के रूप में मनाया जायेगा।
- लोक स्वास्थ्य अभियान को आशा, ममता, ए.एन.एम, आंगनबाड़ी सेविका, ग्राम पंचायत एवं महिला समूह के माध्यम से घर-घर तक पहुंचाया जायेगा।

**इस चरण निम्नांकित संवादों को अंगीकार करने का प्रयास होगा :-**

- 0-14 वर्ष के बालकों तथा 0-18 वर्ष की बालिकाओं को अनिवार्य रूप से नयी पीढ़ी स्वास्थ्य गारण्टी कार्यक्रम के अन्तर्गत स्वास्थ्य परीक्षण कर स्वास्थ्य कार्ड का आवंटन तथा बीमारियों को दूर करने का प्रयास किया जायेगा।
- 18 वर्ष की आयु से कम में बालिकाओं की शादी नहीं हो।
- तम्बाकु, गुटका और शराब का सेवन करना जानलेवा है, इनसे दूर रहें।
- कुपोषण दूर करने हेतु 0-3 वर्ष के बच्चे, 10-19 वर्ष की बालिकाएं तथा गर्भवती महिलाओं की पूरी देखभाल हो।
- छोटा परिवार ही सुख एवं स्वस्थता का आधार है, बच्चे दो से अधिक न हो।
- दो बच्चों के जन्म के बीच कम-से-कम तीन वर्ष का फासला रखें।
- लड़की अनमोल है - उसे दोरंगी रीति का शिकार नहीं बनायें, भ्रूण हत्या कानूनी अपराध एवं सामाजिक बुराई है।
- आम जन-जन को भोजन के अभाव से बचायें।
- स्वच्छ पानी का ही प्रयोग करें, पानी को उबाल कर पीयें। गन्दा पानी भी साफ किया जा सकता है, क्लोरीन की गोली का प्रयोग करें। कई बीमारियों से बचने के लिए यह आवश्यक है।
- घर का कूड़ा इधर-उधर न फेंके, कूड़े को सही एवं सुरक्षित जगह पर ही निष्पादित करें व बीमारी से बचें।
- खुले में शौच बीमारी को बढ़ावा है, शौचालय निर्माण कर उसका ही प्रयोग करें। भोजन से पूर्व एवं शौच के बाद साबुन से हाथ अवश्य धोयें।

**आइये**
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