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Editor-in-Chief
Dr. Anurag Tomar

DIPSAR

NATIONAL CONFERENCE ON PHARMACOVIGILANCE, PHARMACOECONOMICS AND OUTCOMES RESEARCH

Incorporating

17th ANNUAL CONFERENCE OF SOCIEITY OF PHARMACOVIGILANCE INDIA

AND

7th INTERNATIONAL CONFERENCE OF ISPOR INDIA

October 9th – 10th, 2018

PROCEEDINGS

Organised by

Delhi Institute of Pharmaceutical Sciences and Research (DIPSAR)

Venue

Dr. G.K. Narayanan Auditorium

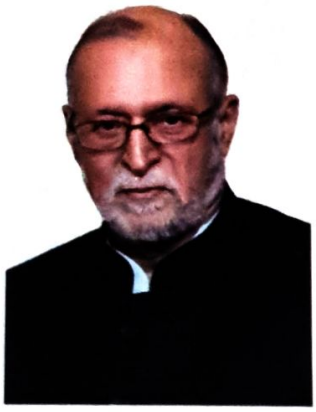
DIPSAR, M.B. Road, Pushp Vihar Sector- III, Opp. Sainik Farm Gate No:1, New Delhi, INDIA

ISPOR INDIA CHAPTER

www.dipsar.ac.in www.sopi.net.in www.ispor.org www.dpsru.edu.in

उपराज्यपाल
दिल्ली
LIEUTENANT GOVERNOR
DELHI

राज निवास
दिल्ली-११००५४
RAJ NIWAS
DELHI-110054



MESSAGE

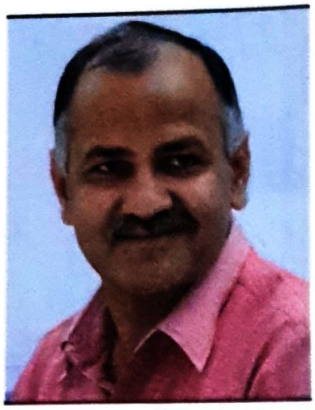
I am pleased to learn that Delhi Institute of Pharmaceutical Sciences and Research, New Delhi is organizing the **"National Conference on Pharmacovigilance, Pharmacoeconomics and Outcomes Research"** from 08th to 10th October, 2018.

It is heartening to note that constant efforts are being made to position India as one of the leading centres of pharmacy teaching, research and skill development. The need of the hour is to provide safe and effective drugs and medical devices at an affordable cost and boost the physical and mental health of the society. I am confident that the deliberations in the conference would contribute to this goal.

I extend my best wishes to all the stakeholders for this upcoming Conference.

(Anil Baijal)

MANISH SISODIA
मनीष सिसोदिया



सत्यमेव जयते

DEPUTY CHIEF MINISTER
GOVT. OF NCT OF DELH
उप मुख्यमंत्री, दिल्ली सरकार
DELHI SECTT, I.P. ESTATE
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NEW DELHI-110002
नई दिल्ली-110002
Email : msisodia.delhi@gov.in

D.O. No. DYCM/2018/666
Date : 26/9/18

Message

I am glad to know that the Delhi Institute of Pharmaceutical Sciences and Research is organizing "National Conference on Pharmacovigilance, Pharmacoeconomics and Outcomes Research" from 9th to 10th October, 2018.

I appreciate that this interaction will provide a training platform to the healthcare professionals, especially the pharmacists and open new career opportunities for them. I wish that the organization continues to shine by producing talented and competent pharmaceutical professionals who will contribute positively to the health sector.

I wish all the best to the delegates and organizers of the conference.

(MANISH SISODIA)

देविन्द्र सिंह भा.प्र.से.
सचिव (प्रशिक्षण एवं तकनीकी शिक्षा)

DEVINDER SINGH, IAS
Secretary (TTE)

सत्यमेव जयते

राष्ट्रीय राजधानी क्षेत्र, दिल्ली सरकार
Govt. of National Capital Territory of Delhi
प्रशिक्षण एवं तकनीकी शिक्षा विभाग
Department of Training & Technical Education
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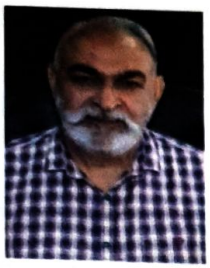
D.O. No. : PS|SECY|TTE|2018|272

दिनांक
Date.: 20|09|2018



MESSAGE

I am delighted to know that Delhi Institute of Pharmaceutical Sciences and Research is organizing "National Conference on Pharmacovigilance, Pharmacoeconomics and Outcomes Research" from October 9th to 10th, 2018. It is heartening to know that a pre-conference workshop is also planned for 8th Oct, 2018.

I am sure that the event will be instrumental in enhancing both the skills and knowledge of the participants. This initiative by DIPSAR is an important academic achievement and reflects its commitment to nation building.

My best wishes to the organizing team, participants and to the student fraternity for all success in the endeavour.

20/9/18
(DEVINDER SINGH)

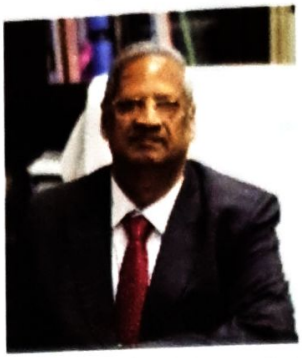
Govt. of NCT of Delhi

DELHI PHARMACEUTICAL SCIENCES AND RESEARCH UNIVERSITY

(Established Under Act 07 of 2008, Govt. of NCT of Delhi)

DIPSAR Campus, Pushp Vihar, Sector-III, Near Khanpur Bus Terminal, M.B. Road, New Delhi-110 017

Prof. Ramesh K. Goyal, Ph.D.
FIC, FIACS, FAMS, FNASc, FIPS, FICN, FSCH
Vice Chancellor



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Welcome to the Unique Event of Pharmacovigilance

It gives me immense pleasure to note that the premier institute DIPSAR, a constituent institution of Delhi Pharmaceutical Sciences and Research University is organizing the 17th Annual Conference of Society of Pharmacovigilance-India (SOPI) along with the 17th International Conference of International Society of Pharmacoeconomics and Outcome Research (ISPOR) in collaboration with Indian Pharmacopoeia Commission of CDSCO which has played a pivotal role in Pharmacovigilance in India with WHO and other bodies for over a decade. This is a unique event since, three pioneering personalities pharmacovigilance Prof. S. K. Gupta who established the first centre in India at AIIMS, New Delhi and Prof. K. C. Singhal who established the first society of pharmacovigilance in India and Dr G. N. Singh, Secretary IPC who established National Coordinator Centre of India when he was the DCGI of Central Drugs Standard Control Organization, with WHO reporting centre have joined hands to have this event in the first University of Pharmacy in India. I take this opportunity to welcome distinguished scientists, faculty, regulatory authorities and policy makers coming from various sectors of healthcare to participate in this event for not only interaction with each other but also to come up with appropriate recommendations to be taken to the regulatory authorities to convert into National policies.

Our university with its strong legacy for over 50 years is committed to contribute efficient and cost effective health care services including drugs, and medical devices to common man. Our University with Prof. S. S. Agrawal and Prof. D. P.Pathak have organized not only several networking events as a part of Global Network for ISPOR, but also given several students and scholars who are working for the cause of ISPOR in different parts of the country and world.

The theme of program this conference is Skill development in Pharmacovigilance, Pharmacoeconomics & Outcome research to the students, faculties, scientists and regulators. It is very apt to achieve the global challenge of affordable cost effective health care services including drugs, and medical devices to common man by evaluating the effect of health care interventions on patient well-being with clinical, economic, and patient-centered studies. The dynamic program has included not only lectures by experts in the field from industry as well as regulatory authorities but patient centric discussions with experts and a workshop on clinical trials and bioethics thus encompassing all the essential components of pharmacoeconomics and outcome research.

I am sure this conference will not only enrich the participants with current developments in the field but also provide guidelines to the regulatory authorities in drugs and pharmaceuticals and community at large to develop necessary policies.

(Ramesh K. Goyal)

दिल्ली भेषज विज्ञान एवं अनुसंधान संस्थान (दिप्सार)
दिल्ली सरकार
(दप्सरू का घटक कॉलेज
पुष्प विहार (एम.बी.रोड)
नई दिल्ली - 110 017

सत्यमेव जयते

Delhi Institute of Pharmaceutical Sciences & Research (DIPSAR)
Govt. of N.C.T. of Delhi
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Pushp Vihar, M.B. Road
New Delhi-110017

PROF D. P. PATHAK, Ph.D.
Professor of Pharmaceutical Chemistry
Director
Delhi Institute of Pharmaceutical Sciences & Research *(DIPSAR)*
Pushp Vihar, Sector-III, New Delhi-110017

Date .....

MESSAGE

It is a matter of great pride that the Delhi Institute of Pharmaceutical Sciences and Research and Delhi Pharmaceutical Sciences and Research University are jointly organizing the "National Conference on Pharmacovigilance, Pharmacoeconomics and Outcomes Research" from 9th to 10th October, 2018. This is an important academic highlight and achievement that is bound to contribute positively to the health care sector. I hope it will be an enriching experience for the delegates as well as the speakers.

My best wishes to the organizing committee for successful completion of the conference.

D P Pathak

Prof. (Dr.) D.P.Pathak
Director, DIPSAR

Phone: 29554327, 29554649, 29553771, 09818567796 (Mob.), Fax: 91-11-29554503
E-mail: drdppathak@gmail.com

Professor S K Gupta
President, ISPOR India

ISPOR INDIA CHAPTER

On behalf of the organizing committee of the Society for Pharmacoeconomics and Outcomes Research India (SPOR)-India Chapter. I welcome you to the National conference on Pharmacovigilance, Pharmacoeconomics & Outcomes Research, incorporating 17th Annual Conference of the Society of Pharmacovigilance India & 7th International Conference of ISPOR India. The conference is being organized with a mission to provide an environment for knowledge sharing among researchers, healthcare practitioners and decision-makers interested in the field of Pharmacoeconomics and Outcomes Research.

Moving forward, innovation, speed to market, cost effectiveness and long term safety will remain key factors in the lifecycle management of pharmaceuticals, medical devices, biotechnology and related products. SPOR will look forward to further hone these areas by providing a comprehensive portfolio of educational opportunities and knowledge exchange, bringing together industry, academia, government, policy makers and people from the community or across the globe.

SPOR-India is making efforts to bring together Indian researchers, healthcare practitioners, decision makers and members of pharmaceutical industry, healthcare organizations and academia using this global platform. It is a resource at a local level for the individuals including students interested in Pharmacoeconomics and Outcomes research. It provides an opportunity for India Chapter members to become more familiar with all the activities of ISPOR as well as participate in its various activities. A special session has been kept for the students to present their research work during Podium and Poster presentations.

We are looking forward for your active participation in making this conference a great success.

Professor S.K. Gupta

President, ISPOR India Chapter

Message

Patient safety is constantly moving target of almost infinite variations and complexities. The individual reaction to medicines is affected not only by age, sex, genetic make-up but, also by lifestyle, food we eat, environmental factors and other tiny disparities. Issues around safety of drugs are often debated by journalists and other people with lesser knowledge about them. Priorities of scientists, manufacturers, regulators, physicians and patients often differ and may lead to controversies and misunderstandings.

There was little understanding of Adverse Drug Reaction monitoring and reporting in India till early 1980^s.The efforts were made by a group of individuals with small financial support from agencies like ICMR to initiate and thereafter establishing the culture of reporting Adverse drug Reactions of medicines. Concerted efforts also brought fruitful results by initiating and establishing national centre for monitoring of drugs of Indian Systems of medicine. My unique and long lasting relationship with Uppsala Monitoring Centre (UMC), its dedicated team and experts of pharmacovigilance from world over prompted me to establish Society of Pharmacovigilance India (SOPI) with the uninhibited support from Prof. R K Goyal Prof. Govind Mohan and Dr Sandeep Agarwal to name a few.

Today SOPI is celebrating its seventeenth Annual Conference under the dynamic leadership of Prof R K Goyal and Dr Rajani Mathur. I hope and wish that the conference will strengthen the science, art and culture of Pharmacovigilance in India.

Prof. K C Singhal
M.D.Ph.D(medicine).DSc,
FRCP(Edin),FIAN,FIAMS,FIPS
Founder President
Society of Pharmacovigilance India

SYED ZIAUR RAHMAN
(MD, PhD, FIMSA, MAMS, CMCL-FAIMER Fellow)
Professor, Department of Pharmacology &
Deputy Medical Superintendent
Jawaharlal Nehru Medical College Hospital
Aligarh Muslim University
Aligarh 202002, India

National Secretary, Society of Pharmacovigilance India (SoPI)

SoPI Secretary says...

It is very enriching that first time the two important associations of India that is the Society of Pharmacovigilance India (SoPI) and International Society for Pharmacoeconomics and Outcome Research-India (ISPOR India) are going to jointly organize the 17th Annual Conference of Society of Pharmacovigilance India (SoPICON-2018) and 7th International Conference of International Society for Pharmacoeconomics and Outcome Research-India Chapter at Delhi Pharmaceutical Sciences and Research University (DPSRU), New Delhi, from 8-10 October 2018.

The theme of the present conference is "Pharmacovigilance, Pharmacoeconomics and Outcome Research" is to seek and explore the ever-changing discipline of science and medicine and to delve on recent advances and its applications to quality medical education and patient care for healthy nation.

The proposed academic and scientific conglomeration would give the right impetus and nidus to the evolving realms of National Pharmacovigilance Program (PvPI) and provide an opportunity to address new horizons. The time for introspection has come to make this specialty of Pharmacology more transparent, more accountable to the needs of the society and nation! Similarly, the time has also come when we need to think and look for a paradigm shift being sensitive to the demands of the society and nation in terms of evidence based medicine. The Outcome Research and Pharmacoeconomics Studies in India would help in generating data and consequently help in policy making for various health-related national programs.

In addition, a one-day pre-conference workshop on "Present Status and Future Challenges of Pharmacovigilance Program of India – Ensuring Safety of Medicines & Medical Devices" is arranged in partnership with National Coordinating Centre for PvPI and WHO Collaborating Centre for Pharmacovigilance for young scientists and students. Hope our participants would take maximum advantage from this national workshop!

No academic program could be successful if we don't have a whole-hearted cooperation from all sides. Firstly, I appreciate the hard work of the Organizing Secretary Dr. Rajani Mathur of DIPSAR. She had the support of all her colleagues. The SoPI is thankful to all of them particularly Prof. R. K. Goyal, Vice Chancellor of DPSRU, Prof. D. P. Pathak, Organizing Chairman and Prof. S. K. Gupta, Chairman Scientific Committee.

Residence: Tijara House, Dodhpur, Aligarh 202002
Tel. +91-8266001772 (Mobile); E-mail: rahmansz@yahoo.com

SYED ZIAUR RAHMAN
(MD, PhD, FIMSA, MAMS, CMCL-FAIMER Fellow)
Professor, Department of Pharmacology &
Deputy Medical Superintendent
Jawaharlal Nehru Medical College Hospital
Aligarh Muslim University
Aligarh 202002, India

National Secretary, Society of Pharmacovigilance India (SoPI)

SOPI is always grateful to all the participants and members who take pain in attending annual meetings and participating in all deliberations. SoPI would always remember the contribution of few of its founding members such as Prof. K. C. Singhal, Prof. Govind Mohan, Dr. Sandeep Agarwal for their constant guidance in improving the activities of SoPI at national and international level.

A warm reception now awaits for all delegates and I eagerly look forward to welcoming delegates in the event. I on behalf of organizing committee promise all delegates an academically beneficial and socially enriching experience during the joint conference. Hope delegates would enjoy the scientific, cultural and social programs during the whole program.

Syed Ziaur Rahman
National Secretary, SoPI

Residence: Tijara House, Dodhpur, Aligarh 202002
Tel. +91-8266001772 (Mobile); E-mail: rahmansz@yahoo.com

INDIAN PHARMACOPOEIA COMMISSION
(MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA)
SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.
Tel No: 0120- 2783392, 2783400, 2783401; Fax: 2783311
E-mail: ipclab@vsnl.net, Web: www.ipc.gov.in

Date: 25.09.2018

Message

Dear participants,

It is a matter of great pleasure that the National Conference on Pharmacovigilance, Pharmacoeconomics and Outcomes Research is being organized from 9-10 Oct 2018 in collaboration with Indian Pharmacopoeia Commission at Delhi Pharmaceutical Sciences & Research University Campus, New Delhi. A preconference workshop is also planned on 8th Oct 2018 on "Present Status and Future Challenges of Pharmacovigilance Program of India: Ensuring Safety of Medicines & Medical Devices". The safety profile of medicines need to be assessed on continuous basis for making available the drugs of assured quality & safety at affordable price to the masses. The timely identification of the need for organizing such an important event will give an opportunity to all participants to discuss the relevant issues in the area of Pharmacovigilance and Pharmacoeconomics.

I congratulate the members of the Organizing Committee for hosting this event. I am sure that both the above event will benefit all the participants and it will be a great experience sharing events in overall interest of patient safety.

(Dr. G.N. Singh)
Secretary-cum-Scientific Director

DELHI PHARMACEUTICAL SCIENCES AND RESEARCH UNIVERSITY
(Established Under Act 07 of 2008, Govt. of NCT of Delhi)
Pushp Vihar, Sector-III, M.B. Road, New Delhi - 110 017

सत्यमेव जयते

DPSRU/Pharmacology/2018/7642 Date: 25/9/2018

PROF. S. S. AGRAWAL
Ph.D. (AIIMS), D.Sc. (R.G.P.V.), FIC, FIPS, FISHR
National Research Professor of Pharmacology

Founder Vice Chancellor
Delhi Pharmaceutical Sciences & Research University, New Delhi

Former DG, PVC & Gp. Dy. PVC
Amity Group Universities, Noida

Founder Director
Delhi Institute of Pharmaceutical Sciences & Research, New Delhi

Former Dean
Faculty of Science & Head, Department of Pharmacy, University of Delhi, Delhi

Elected President
Indian Pharmacological Society – 2005

Former National Coordinator
QIP, Pharmacy, (AICTE)
GOVT. OF INDIA

MESSAGE

I am glad to know that DIPSAR is going to organize "**National conference on Pharmacovigilance, Pharmacoeconomics and Outcome Research**".

The topics cover the global health care interest and other issues indigenous to our nation. The economic aspects of medicine are likely to be discussed besides, pharmacovigilance programme of India.

It is a matter of privilege that Indian Pharmacopeia Commission is collaborating the event.

Pharmacovigilance is of paramount importance as the actual efficacy and side effects are only seen when the drug is marketed extensively. The cosmetovigilance is a branch of pharmacovigilance which deals with the toxicity/side effects caused by cosmetics as almost everybody is using cosmetics on day to day basis while drugs are used only when we are sick.

I wish all success.

(Prof. (Dr.) S. S. Agrawal)
National Research Professor, DPSRU
Founder Vice Chancellor, DPSRU

Prof. S.S. AGRAWAL
Ph.D, DSc, FIPS, FIC, FISHR
NATIONAL PROFESSOR
(Founder Vice Chancellor, DPSRU)
Delhi Pharmaceutical Sciences & Research University
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DIPSAR

NATIONAL CONFERENCE ON PHARMACOVIGILANCE, PHARMACOECONOMICS AND OUTCOMES RESEARCH

Incorporating

17th ANNUAL CONFERENCE OF SOCIEITY OF PHARMACOVIGILANCE INDIA

AND

7th INTERNATIONAL CONFERENCE OF ISPOR INDIA

October 9th – 10th, 2018

SCIENTIFIC PROGRAM

VENUE

DELHI INSTITUTE OF PHARMACEUTICAL SCIENCES AND RESEARCH, NEW DELHI

ISPOR INDIA CHAPTER

Ministry of Health & Family Welfare Government of India

9TH OCTOBER 2018

PHARMAECONOMICS & OUTCOMES RESEARCH

8:00 am – 9:30am Registration

	09:30am	**Key Note Address** **Chairpersons: SK Gupta, RK Goyal** **HTA in Asia: Where are we today?** Seema Haider, Senior Director, Group Lead PEH HEOR, Pfizer Inc. USA
10:15 am - 11: 00 am		**OPENING CEREMONY**
11:00 am - 11: 30 am		**HIGH TEA**

PLENARY SESSION -I

Health Technology Assessment for Better Healthcare

Chairpersons: Seema Haider, Jitendar Sharma, Manisha Sridhar

	11:30am	**Innovation – Assessment - Manufacturing Ecosystem in India** Dr. Jitendar Sharma, Exe. Director, Kalam Institute for Health Technology
	11: 50am	**How HTA can demonstrate Value for money in Healthcare?** Devarshi Bhattacharyya, Asst. Director, Kalam Institute for Health Technology
	12: 10 pm	**Value of Health Technology Assessment (HTA) in Ayushman Bharat** Denny Jon, Evidence Synthesis Specialist, Campbell Collaboration
	12: 30 pm	**Health Technology Assessments : Focuson Indian Scenario** Paranjoy Saharia, Senior Consultant- RWI, Global Scientific Services, IQVIA
01:00 pm – 1:40pm		**NETWORKING LUNCH**

PLENARY SESSION -II

Pharmacoeconomics and Outcomes Research

Chairpersons: Ahmed Shelbaya, PC Dandiya, Jai Prakash

	01:40pm	**Introductions to Real world Data and Informatics in Health Care** Mahendra Rai, Head- RWI, Global Scientific Services, IQVIA
	02:00pm	**Role of HEOR in drug development process** Sheily Kamra, Consultant Advisory Kinapse –a Syneos Health Company
	02:20pm	**Utilization of patient reported outcomes in regulatory & reimbursement approvals** Vinayak Jamdade, Senior Analyst, Advisory Kinapse – a Syneos Health Company
	02:40pm	**Biosimilars & HealthCare Delivery.. Opportunities & Challenges** Wing Yu Tang, HEOR Lead, Pfizer Essential Health
3:00 pm – 3:20 pm		**TEA BREAK**

PLENARY SESSION -III

Pharmacoeconomics and Outcomes Research

Chairpersons: Mahendra Rai, JS Bapna, Denny Jon

	03:20pm	**Usefulness of Meta-Analysis in Real World: the true need** Richa Goyal, Engagement Manager, HEOR, RWI, Global Scientific Affairs IQVIA
	03:40pm	**Value/Outcome Based Pricing –Current State & What Next** Mou Chatterjee, Engagement Manager, RWI, Global Scientific Affairs IQVIA
	04:00pm	**Economic Evaluation Alongside Clinical Trials** Loveleen Taneja, Principal, RWI, Global Scientific Affairs IQVA
	04: 20pm	**Pharmacoeconomics of methadone maintenance therapy as a harm reduction strategy** Abu Baker Abdul Majeed, Faculty of Pharmacy, Universiti Teknologi, Malaysia

3:00pm – 5:00pm

PODIUM/ POSTERS PRESENTATION

Theme: Pharmacoeconomics and Outcomes Research and Health Technology Assessment

Chairperson: T Velpandian & Sushma Srivastava

10th OCTOBER 2018

PHARMACOVIGILANCE

9:30am — **JOHN AUTIAN ORATION**

Chairpersons: KC Singhal, GN Singh

RK Goyal

10:00 am — **KC SINGHAL ORATION**

Chairpersons : Moin Don, GN Singh

Vivek Ahuja

10:30 am – 10:45am — **HIGH TEA**

PLENARY SESSION -IV
PHARMACOVIGILANCE

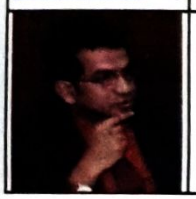
Chairpersons: Shridhar Dwivedi, GN Singh, Kalaiselvan

	10: 45am	**Key Note Address** **A Holistic Overview of Pharmacovigilance** Moin Don, CEO & Founder, PVCON Consulting Services
	11: 30 am	**Signals in Drug Safety** Naveen Chhabra, Manager Pharmacovigilance, TATA Consultancy Services
	11:50am	**Risk Benefit Assessment: Key Parameter & Considerations** Manoj Sharma, Sr. Manager-Global Pharmacovigilance Department, Win-Medicare
	12:10pm	**Opportunities for Pharmacy Professionals in Pharmacovigilance** Jamal Baig, Anwar, Global Safety Country Leader MSD-India
	12: 30 pm	**Drug Safety Status, a comparative analysis of European Union, Arab League, Eurasean Commisssion & India** Wasif Khan, Senior Professional PV & Regulatory Affairs, Trainer & ISO certified lead auditor

01:00 pm – 2:00pm — **NETWORKING LUNCH**

PLENARY SESSION -V
PHARMACOVIGILANCE

Chairpersons : D P Pathak, Govind Mohan, Syed Ziaur Rahman

	2:00 pm	**Pharmaceutical care for Patients with Tuberculosis and Diabetes Mellitus: a Malaysian Experience** Shubashini Gnanasan, Senior Lecturer, Faculty of Pharmacy University Teknologi, Malaysia
	2:20 pm	**Road to safety evaluation of drugs of Indian systems of medicine** Dr.K.C.Singhal, Founder Vice Chancellor, NIMS University
	2:40 pm	**Importance of Pharmacovigilance in Traditional System of Medicine** Syed Ziaur Rahman, Professor, Dept. of Pharmacology, Aligarh Muslim University
	3:00 pm	**Herbal Medicines & Phytopharmaceuticals Regulation, Quality and Safety Standards in India: Current Perspectives and way forward** V. Kalaiselvan, Principal Scientific Officer, IPC Gaziabad

2:00pm – 4:00pm

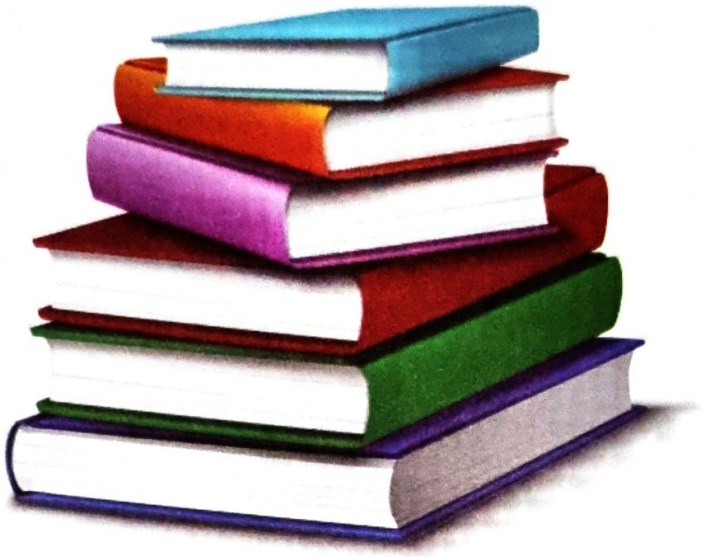
PODIUM/ POSTERS PRESENTATION

Theme: PHARMACOVIGILANCE

Chairperson: V. Kalaiselvan, Shubashini Gnanasan

4:00pm-5:00 pm AWARD DISTRIBUTION, VALEDICTORY FUNCTION AND HIGH TEA

With best compliments from :



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Orations

Prof. John Autian Oration

Prof. Ramesh K. Goyal. Ph.D.

Vice Chancellor, Delhi Pharmaceutical Sciences and Research University, New Delhi 110017, INDIA

Pharmacovigilance Beyond the Adverse Drug Reaction Monitoring for Pharmacoeconomics and Outcome Research

Prof. John Autian, USA in 1954 mentioned in one of the American meetings of pharmaceutical sciences that 'Pharmacists are overeducated and underutilized. This led to starting of the clinical pharmacy concept: a change from industry and commercial oriented profession to the hospital and service-based profession. **Iatrogenic diseases** caused by medical intervention including anything ranging from damage caused by an ill-fitting plaster cast to drug side-effects or long-term results of drug overuse were very well known from decades. Side-effects of drugs, misuse of drugs, harmful drug combinations, medical negligence, medical error or misjudgement, contravention of contra-indications and nosocomial disease constitute iatrogenic disease. It was reported that in United States, an estimated 44,000 to 98,000 deaths per year may be attributed in some part to iatrogenic iseases, 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. **Pharmacovigilance** emerged as a strategy and a 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 in the form of post-market surveillance studies. Pharmacovigilance is now a part of 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.

Importance of pharmacovigilance was recognized well by Prof. John Autian and he motivated Prof. K. C. Singhal and many others to start ADR data from India. In India, the first multicentric study for monitoring ADR was initiated in 1989 by 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. Prof. S. K. Gupta who established the first centre of pharmacovigilance with 24-hour Drugs and Poison information centre in India at AIIMS, New Delhi. 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.

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.

In spite of such weaknesses, the impacts 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 Prof. 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 after pharmacotherapy. For pharmacovigilance herbal drugs the concept of '**Herboviglance**' came up. Similar is

the case with medical device ad its vigilance.

It is interesting that data collected through pharmacovigilance is now being utilized by pharmaceutical companies like quintiles and many others to obtain newer targets and understanding of disease processes. This has given rise to what is now called as **Pharmacoeconomics and Outcome Research**.

Providing efficient cost-effective health care services including drugs, and medical devices to common man is a global challenge. **National Health policy (NHP) 2017** has considered seriously the problem of non-communication disorders and given impetus on affordability and accessibility. The NHP2017 has shifted the focus from "sick-care" to "wellness" and thereby promotion of prevention of these diseases. 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.

International Society of Pharmacoeconomics & Outcome Research (ISPOR) has 9,500 individual and student members from 114 countries and over 8,700 affiliate members from various regional Chapters representing the entire field including research, academia, decision and policy makers, consultants, payers and patients. It carries out activities to spread awareness and developing strategies for teaching and research activity with ultimate objective of making effective and safe drugs and medical devices available to the common man at affordable cost. DPSRU, the first university of India dedicated to pharmaceutical sciences is involved for more than a decade in pharmacovigilance, health economics and research has joined hands with ISPOR along with industry and regulatory authorities and hold discussion with students, researchers and faculty keeping patient centric approach for pharmacoeconomics and outcome research.

Thus, Pharmacovigilance has expanded into several sub-specializations like Herbovigilance, Pharmacoeconomics & Outcome research to the students, faculties, scientists and regulators. It is very apt to achieve the global challenge of affordable cost-effective health care services including drugs, and medical devices to common man by understanding better the expanding horizons of this dynamic subject of pharmacovigilance especially by pharmacists walking with medical doctors.

Prof. K. C. Singhal Oration

Dr. Vivek Ahuja

Dr. Ahuja earned a Bachelor of Medicine and Bachelor of Surgery Degree from Government Medical College, Chandigarh, India and subsequently did his MD from AIIMS New Delhi. Dr. Vivek Ahuja is currently Regional Director for Asia Pacific for Baxter Healthcare. In his industry career spanning ten years, he has held various positions both in CROs and pharmaceutical companies managing global pharmacovigilance compliance, operations and training. Dr. Ahuja has overseen audits, successfully undergone pharmacovigilance regulatory inspections by the USFDA, MHRA and other global agencies.His experience also encompasses implementation and validation of global safety database and overseeing updation and maintenance of various incremental modules. Prior to joining Baxter, he headed the Global Pharmacovigilance at Ranbaxy and was subsequently the Director for Clinical Operations, Data Management & Pharmacovigilance at GVK Biosciences. He is very passionate about pharmacovigilance as a science and subject and is eager to contribute to the development of this area both in India and internationally.

Pharmacovigilance: Exciting Times for India and Beyond

The world of pharmacovigilance is rapidly evolving and there are new ways and means that are emerging to 'crunch' patient safety data, understand that data and draw meaningful conclusions from it that can help prevent adverse events, make safer medicines, and thereby protect patient safety. The regulations on this subject have evolved greatly over the years, and the fundamental basis for the evolution is to ensure more accountability for the marketing authorization holders and a higher answerability to public health issues.

Increasingly, the practitioners of this science are realizing that 'data' is the new currency. Like in every other walk of life today, the more data you have - the more power you get to unearth some meaningful information that can be useful to the very people whose data you collected in the first place. Technologies are emerging to make the processing of patient adverse event data easier and more efficient. The culture of reporting adverse events is improving amongst the healthcare professionals, and patients are becoming more aware about the benefits of medicines and the risks that come along with it.

It is estimated that more than half of the world's adverse event data gets processed in the offshore outsourcing capital of pharmacovigilance – i.e., India. Pharmacovigilance has become a career choice for young graduates emerging from prestigious institutions every year. However, the skills expected are now much different from what they were ten years ago. This science is evolving as an advanced amalgamate of the knowledge of medicines and technology. Exciting times await the practitioners of this art and science of pharmacovigilance.

Invited Speakers

Jitendar Sharma

Advisor, Govt. of Andhra Pardesh, Managing Director & CEO, AP Med Tech Zone, Executive Director, KIHT, AMTZ Campus, VisakhapatnamAshish Goel, PhD

Known in policy forums as the "Med Tech Man of India", Dr. Jitendar Sharma is the Managing Director & CEO of Andhra Pradesh MedTech Zone (AMTZ) which is Asia's first medical devices manufacturing city besides being the Adviser for Health to Govt. of Andhra Pradesh, India and Executive Director of Kalam Institute of Health Technology (KIHT)- a technology policy research body set up with the support of Govt. of India. He is adjunct faculty at University of Adelaide, Australia; and program Director for Health Technology Assessment (HTA) fellowships in India. He has been founder of 6 organizations and architect of Universal Health Coverage for the state of Andhra Pradesh- the first state in India with 50 million people to declare UHC. He is also the National Chairperson for Indian Bio-Medical Skill Consortium which is an active congregation of over 20 national academic institutions.

Awarded among the "100 most impactful healthcare leaders" in global listing by Health & Wellness Congress, Dr. Sharma served as the Founder Head of Healthcare Technology Division and Head of Health Financing Divisions at National Health Systems Resource Centre (NHSRC) under Ministry of Health & Family Welfare, Government of India. He was also the Founder Director of WHO Collaborating Centre for Medical Devices in India. His past experience includes that as Hospital Administrator at Sri Sathya Sai Medical Institutions-one of India's largest not for profit health organizations, as consultant to the World Bank for health financing, as Expert Consultant to the World Health Organization, Geneva and advisor to Health Technology Innovation Centre at Indian Institute of Technology (IIT).

Dr. Sharma has authored seven books, twenty research papers and six compendiums on technical specifications for medical technologies besides contributing to a number of WHO reports on health technologies, health financing and Non-Communicable Diseases. He has been a key designer and coordinator for several health programs in India and teaches courses on health policy & health technology in several countries.

ABSTRACT

Innovation-Assessment-Manufacturing ecosystem in India

India's import bill for medical devices is about ₹ 24,000 crores per year. To reduce import dependency and boost indigenous manufacturing, Andhra Med Tech Zone (AMTZ) has been set up. India's first indigenous high-end medical devices like CT Scan, MRI, Cathlab and Linear Accelerator (LINAC), used in the treatment of cancer, will all be rolled out of AMTZ. Housed inside AMTZ, Kalam Institute of Health Technology (KIHT) aims to facilitate focused research on critical components pertaining to medical devices by supporting institutions involved with R&D, industry, policy makers and knowledge repositories. Hundreds of prototypes, developed at IITs, IISC, universities and engineering colleges, and lying in the institutions, would be auctioned to the prospective manufacturers.

The institute works as facilitator between academic research and Industry by collaborating with the stakeholders for the benefit of the society. The goal is achieved by landscaping medical technologies, enabling technology transfer, providing one stop consultancy for the innovators who need technical support and market access. This is supported by guiding them on standards, testing, certification and performing health technology assessment to give them strong technical review of their product. Thus, creating affordable, sustainable healthcare solutions with high quality standards.

Seema Haider

Senior Director, Group Lead PEH HEOR, Pfizer Inc, USA Seema Haider, Senior Director, Group Lead PEH HEOR, Pfizer Inc, USA

Seema Haider has over twenty-three years of experience in leading and managing international, multidisciplinary teams for the lifetime management of developing and executing Outcomes Research (OR) and Access Product and Therapeutic Area Portfolio strategies, studies and publications. Seema received her MSc in Social and Preventive Medicine from University of Montreal in 1992. From 1993 through1995, Seema completed PhD course work in Social and Preventive Medicine, specializing in Pharmacoeconomics, led a prospective, multicenter, Pharmacoeconomics substudy in COPD patients at the Randomized Clinical trial Unit at McGill University and was Project Director at the Interdisciplinary Health Research Group, Heath economics Unit at the University of Montreal. From 1995 to 1998, Seema was Country Manager of Pharmacoeconomics and Quality of Life Research at Schering Plough Canada for all products. Seema joined Pfizer Inc., 20 years ago and with escalating leadership positions, she currently leads Health Economics and Outcomes Research, Patient & Health Impact, for the Pfizer Essential Health Business Unit. Her work has been extensively presented and featured at conferences worldwide and in publications in high impact peer reviewed journals. Currently, Seema has also contributed to several training initiatives worldwide including, the IFAPP-King's College London Medical Affairs in Medicines Development Professional Certification Program, several ISPOR Trainings/Webinars, is an International Advisor to the ISPOR India Chapter and is a visiting professor for a 3 year term (Dec 2017 – 2020) at Hebei University in China. Outside of work, Seema is passionate about the non-profit community work she does through Grace Cares in rural India. She currently resides in Boston, MA, USA with her family.

ABSTRACT

HTA in Asia: Where are we today?

The current healthcare landscape is changing globally with a growing population and increased spending on health. With these increasing costs, new health technology, and a demand for better health, there is greater pressure on scarce resources. As such, it is imperative to have a system that can manage budget and resources, but still instill an environment that fosters innovation and considers both cost and value. As a result, health technology assessments (HTA) have been developed as a way to assess health technologies and provide input into decision-making in policy and practice. This presentation gives an overview of the history of HTA, the role of HEOR, basic components of HTA, and an APAC-specific landscape analysis. Case studies from other countries and networks can serve as strong external support in sustaining HTA and documenting shared experiences. Ultimately, there is a need to bring greater attention to healthcare financing both globally and in the region; HTA can help to meet this need with proper data, assessment, transparency, monitoring and evaluation, and involvement of all stakeholders in defining value and making a decision on price and/or access.

Outline:

1. Background: Rising Costs of Health Care Globally
2. Target: The Healthcare Decision Makers Dilemma
3. Emergence: Birth and Establishment of HTA
4. Evaluation: HTA around the world
5. Data: HEOR utilization
6. Asia & India HTA Overview and Application

Devarshi Bhattacharyya

Assistant Director, KIHT, AMTZ Campus, Visakhapatnam

Dr Devarshi Bhattacharyya is an Assistant Director in Kalam Institute of Health Technology, leading the health technology assessment (HTA), market access and trade work there. An expert health economist, he had previous work experience in Novartis pharmaceuticals and National Health Mission. He is a British government's Chevening scholar and completed his health economics training in University of Birmingham. He has a number of publications in high impact journals and has presented papers in ISPOR Glasgow and ISPOR Tokyo. As a regional hub of Department of Health Research, he is involved in KIHT's mandate of setting up health economics guidelines for India.

ABSTRACT

How HTA can demonstrate value for money in Healthcare?

All health systems around the world have a common goal which is to improve the health and well-being of their populations. To achieve this target a health system initiates an array of activities, most prominently coming up with a framework to finance and deliver health services. This involves making decisions to try and make the most optimum use of scarce resources. A lot of decisions are made on the interventions that are provided to the population and how they should be offered so that one can maximise the health benefits with respect to the available resources. Those at the helm for making decisions require data about the possible options and the consequences of those interventions. With the proliferation of new technologies at a rapid pace, it is quite clear with closer scrutiny that some of the older interventions have no benefits compared to the resources spent. But the advent of technology in health care and its increased usage has also added to expanding costs of health care, and as such technology is sometimes considered as a "culprit" for the burgeoning costs. This awareness has been behind the concept of "evidence-based medicine" and "health technology assessment", which contends that policymakers must use rigorous scientific research to make their decisions. They also have to optimise their decisions to strike a balance between the most cutting-edge innovations and maximising access to healthcare to the entire population.

Denny Jon

Evidence Synthesis Specialist, Campbell Collaboration, Adjunct Scientist, ICMR-National Institute of Medical Statistics, New Delhi

Denny has over 14 years of experience across various domains; managing hospitals and health projects, economic evaluation, health financing, evidence synthesis, implementation research, teaching and advocacy. He has experience of working with research institutions, development organisations, and consulting companies for conducting economic evaluations, systematic reviews, and health financing projects. He has been the Principal Investigator/Co-Investigator for over 15 research studies conducted across various states in India and have been awarded research and project grants from national and international bodies, such as World Bank, Grand Challenges Canada, etc. He has published over 40 articles in peer-reviewed journals and presented in national and international forums in the field of systematic reviews, cost-effectiveness analysis, and health financing. He is an Associate Editor with Cost Effectiveness and Resource Allocation, International Journal of Technology Assessment in Health Care (IJTAHC), and BMC Public Health journals.

At Campbell Collaboration, since July 2017, he has led/co-led training programs on evidence synthesis for over 275 participants in India, Ghana and Nepal, and mentors over 15 researchers from LMICs for publishing their systematic reviews in Campbell library. He is on Board of Studies for Post Graduate Diploma in Bioscience Policy Research, starting mid-2019, initiated by Institute of Bioinformatics and Applied Biotechnology (IBAB), Bengaluru, for a module on 'Evidence informed policy'. He is a qualified physical therapist, with Master degrees in healthcare management and public health, and is an external PhD candidate in HTA at Maastricht University, Netherlands.

ABSTRACT

Value of Health Technology Assessment (HTA) in Ayushman Bharat

The Ayushman Bharat is National Health Protection Scheme that aims to cover 10 crore poor and vulnerable families (approximately 50 crore beneficiaries) providing coverage of INR 5 lakhs per family per year for secondary and tertiary care hospitalization. The main impact of the scheme is envisaged to be on reduction of out of pocket expenditure (OOPE), and access to quality healthcare thus improving health outcomes and quality of life in general. The Health Technology Assessment India (HTAIn) has been formed in 2017 focusing for evaluation, appropriateness, and cost effectiveness of the available and new Health Technologies in India. The main aim, through development of standardized cost-effective interventions is overall reduction in OOPE of patients and streamline the medical reimbursement procedures. However, the integration of HTA has been left out of the implementation strategy of Ayushman Bharat. An example of such an integration is the HITAP agency in Thailand's universal health coverage (UHC) scheme, where the HTA agency conducts assessments for the drug benefit package within the National List of Essential Medicines (NLEM), and health package plan for universal coverage of diagnosis, treatment, prevention, health promotion, and supplementary list of medicines. The WHO has also recommended the use of cost-effectiveness as one criteria for benefit package selection for low- and middle-income countries. The use of HTA principles and guidance would be useful for supporting the implementation and coverage of Ayushman Bharat scheme in the country.

Paranjoy Saharia

Senior Consultant – RWI, Global Scientific Services, IQVIA

Paranjoy's areas of expertise are Protocol writing, Study report development, CSRs, clinical trial submissions, Value Dossier development, manuscripts, conference proceedings, systematic literature reviews and Network meta-analysis.

Paranjoy has over 9 years of experience in developing clinical trial submissions such as protocols, clinical study reports, and informed consent forms for regulatory authorities in the US, Europe, and India. In addition, he has supported HTA submissions in key markets such as Europe, Canada, and Australia by developing systematic literature reviews that address clinical, humanistic, economic, and epidemiological needs of major pharmaceutical and biologics companies

Paranjoy holds a Master's degree in Biochemistry from Bangalore University, Bangalore (India) and an Advanced Post-Graduate Diploma in Clinical Research from CREMA, New Delhi (India)

ABSTRACT

Introduction to Health Technology Assessments (HTA)

Health technology assessment (HTA) has been defined as a form of policy research that systematically examines the short- and long-term consequences of health against the resources used for a set of health-related technologies. This influences the policymaking decision at patient level, health care provider level and at regional, national and international levels. Although HTA aims to guide formulation of safe and effective health policies through a patient focused approach, consequence of the health technologies does not always answer the unmet health needs and may often not be distributed fairly.

Developed markets, like US, UK, Canada, Australia and Germany have well established HTA bodies and evaluation framework to guide coverage decisions. However, for developing countries, where medicines can represent up to 60% of healthcare spending and a large majority of people pay out-of-pocket for prescription drugs, it is critical to develop customized assessment framework balancing clinical outcomes and economic considerations to facilitate universal access to innovative therapies. Indian government is committed to extend healthcare services to its 1.25 billion population as part of India's Universal Health Coverage (UHC) agenda to reduce calamitous out-of-pocket health expenditure. The Medical Technology Assessment Board (MTAB) aims to reduce the cost and variations in patient care, expenditure on medical equipment and reduction in out of pocket expenditure of patients, along with streamlining the medical reimbursement procedures for effective implementation of the universal coverage program. However, the complex and fragmented Indian health system architecture poses a significant challenge to the successful translation of MTAB recommendations for cost-effective service provision translation into practice.

Mahendra Kumar Rai

Head- Real World Insights RWI South Asia, IQVIA

Mahendra heads the Real World Insights vertical for IQVIA for South Asia. Mahendra's core responsibility is to provide actionable insights to Healthcare clients, based on real world data, in the process facilitating informed decision-making at both Strategic and Tactical levels. He has over 12 years of experience in outcomes research, health economics, real world insights and observational research spanning across the healthcare spectrum covering pharmaceuticals, medical devices and diagnostics and OTC categories. Mahendra has worked with leading Healthcare Consulting Agencies, handling a range of categories and has worked on a range of Outcomes Research requirements across different aspects of Business and Marketing. His area of expertise is Outcomes research, Health economics, Real world Insights & Observational research (Epidemiology – Longitudinal studies, Clinical studies, Public Health, Biostatistics, Statistical analysis plans, Clinical studies - Project Management). He is a M.Pharma from DIPSAR, University of Delhi.

ABSTRACT

Introduction to Real World Data and Informatics in Health Care

The real world evidence (RWE) is derived from data associated with outcomes from the care of heterogeneous patients and healthy populations as experienced in real world practice settings. The RWE is not restricted to the controlled constraints of conventional randomized clinical trials (RCTs) and evaluates the profile of a health technology in normal clinical practice. It can be considered as the holistic patient journey and observation of effects following the treatment decisions when there is no control over the medical management of the patient beyond observing outcomes. The RCTs are considered as the gold standard evidence. The market authorization approvals are solely being granted on the basis of efficacy, compliance and side effects derived from RCTs. However, they do not reflect the true picture/evidence as the outcomes of the trials are closely controlled and monitored. Owing to large amount of cost involved, RCTs cannot address the long-term effectiveness, safety and true value of these therapies. In contrast, RWE is collected from a heterogeneous population which reflects the realistic scenario as the treatment is administered as per physician discretion. Additionally, the non-adherent patients may switch treatments but are likely to remain included in the analysis. RWE consists of the generalized findings which are collected from the journeys and outcomes of millions of patients in the real world settings. Thus, RWE can play an incredible role in the fast-changing global healthcare market as it helps to generate insight, foresight and predictive findings on diseases, products and patient populations.

Sheily Kamra

Consultant Advisory, Kinapse - a Syneos Health Company

Sheily Kamra has more than eight years of work-experience in the life-science industry including Health Economics and Outcome Research and Medical writing. She has expertise in conducting systematic reviews, literature reviews, report writing, publication writing, product labels, clinical overviews, narrative writing, clinical trial disclosures, and handling enquiries as part of medical information system. She has worked across various therapeutic areas including oncology, CNS, CVS, and respiratory system, etc. She has eight publications in Journal of haematology and Oncology and ISPOR conferences.

ABSTRACT

Role of HEOR in drug development process

The emergent power of payers in healthcare decision-making has increased emphasis on health economics and outcomes research (HEOR). With this increasing demand of the HEOR work, pharmaceutical companies have increased their field-based HEOR personnel by 53% in 2016 as per Pharma Force International reports. HEOR is an interdisciplinary function within pharmaceutical and life science companies responsible for generating value evidence of new interventions for reimbursement

agencies and local health care payer; thus, guide decision makers regarding patient access to specific drugs and service.

Vinayak Jamdade

Senior Analyst, Advisory Kinapse – a Syneos Health Company

HEOR work begins simultaneously with the initiation of phase I of the drug development and continues throughout the post-approval product lifecycle. HEOR is a methodical approach that involves understanding the implication of the disease and the existing treatments; and assessing the requirements to develop specific QoL or patient-reported outcomes questionnaires. Further, it also involves development of comprehensive burden of illness studies to identify the biggest cost drivers, and the clinical and humanistic impact of the disease at a population level; incorporation of endpoints in pivotal registration trials and economic models; as well as the evaluation of real-world effectiveness and health economic implications. This session will cover various components of HEOR and its applications during the drug development process.

Vinayak has almost four years of work experience in the field of HEOR. He has worked across various areas, including literature reviews, meta-analysis, AMCP dossier, market access, protocol and report writing, patient centricity and epidemiology. He has hands-on experience in evaluating PROs and on various methods of economic analysis and critical appraisal of economic evaluation studies. He has worked on a wide range of disease areas including oncology, autoimmune diseases (rheumatoid arthritis, diabetes), CNS diseases, migraine, infectious diseases, and many others.

ABSTRACT

Utilization of patient reported outcomes in regulatory and reimbursement approvals

Patient-reported outcomes (PRO) measure is a report that comes directly from the patient about his/her health condition without amendment or interpretation of his/her response by a clinician or anyone else. The value gained through understanding health outcomes from the patient's perspective has been increasingly acknowledged in recent years. As commercial competition increases and payer demand rises, companies must offer more proof of their products' impact. PRO measures offer regulatory agencies a holistic view of drugs' effects and potential success. Incorporating the patients' voice to products value propositions is crucial for regulatory approval and reimbursement deliberations. Although PROs are being utilized in clinical development for long time, these measurements still have an untapped potential in market access. Data related to treatment compliance and drug effects as obtained from PRO instruments are influential in developing desired products and play instrumental role in product labelling. Further, this session will elaborate different kinds of PROs, their development and utilization during clinical development and reimbursement process of medicinal product.

Mou Chatterjee

Engagement Manager, RWI, Global Scientific Affairs IQVIA

Mou has extensive experience in scientific communication and strategy consulting (including Market insights and business intelligence) and worked with several clients from Fortune 50 global pharmaceutical companies. Her areas of expertise include, Value communication, Disease area Strategy, Go-to-Market (GTM) Strategy development, Product Differentiation and Brand Positioning, Pricing, Reimbursement and Market access. She has also worked as domain consultant with reference to market sizing, patient flow modeling, revenue potential estimation, PE modeling, Market access and GTM strategies, etc. In her current role, she is involved in supporting and leading Value Communication delivery including Scientific / medical writing (protocol development, Study report preparation, development of manuscripts, posters, conference proceedings, etc) preparation of value messages and value dossiers, HTA submission, pricing

strategies, etc. She also participates in developing regulatory landscapes across geographies, supporting pricing regulatory submissions, systematic literature review, etc.

Mou has 15+ years of experience across different aspects of Pharmaceutical industry from new drug discovery to evidence- based decision support. She has published in International peer-reviewed journals. She has worked with several organizations like National Brain Research Center (India), Ranbaxy, Daiichi Sankyo India Ltd. And SmartAnalyst. Mou holds Master's degree in Biotechnology from Jawaharlal Nehru University (JNU). She has extensive training in molecular biology from University of Calcutta – Indian Statistical Institute and University of Cincinnati (Graduate Program). She also participated in Executive Program in Project Management from IIT- Delhi.

ABSTRACT

Value / Outcome based pricing – current state and what next

With an unsustainable increase in drug pricing especially for specialty therapies and orphan drugs, payor pressures are pushing pharmaceutical companies towards value-based contracts – where drug prices are directly linked to its clinical and economic performance, rather than volume and unmet need. In this approach, pricing and reimbursement decisions are driven by evaluation of innovative therapies based on health outcomes, value to the patient, and their effectiveness in real world setting compared to other alternate treatment options. Performance / outcome-based price negotiations and / or coverage decisions are not a "new concept" and has been routinely used by single payer systems in Europe (e.g., NHS UK). In recent times, this approach is gaining increasing importance, even in fragmented multi-player markets like US and out-of-pocket markets in developing nations like India and China.

Despite the regulatory and financial pressures to adopt value-based pricing, assessing a therapy's "value", is a daunting task. Assumptions on treated population, unmet need, endpoints assessing effectiveness, treatment duration, etc adds to the complexity of models used to appraise "value of new drugs". The challenges are further complicated by the lack of globally standardized procedures for extensive data collection, patient privacy restrictions, and governmental pricing regulations. To standardize value assessments, ISPOR Special Task Force on Value assessment framework, has recently published guidelines (2018) on key considerations for value assessment including specificity about context and perspectives, consideration of incremental costs and benefits, and development of value thresholds and continues to refine the concepts with respect to multiple stakeholders, payors and patients.

Wing Yu Tang,

HEOR Lead, Pfizer Essential Health

Experienced outcomes research analytic and marketing lead with an eight-year portfolio in high profile academic, policy, and pharmaceutical arenas. Strong technical and communication has led to success in global health surveillance efforts, coordination and management of outcomes research strategic portfolios, and health economic evidence generation for market access in a variety of infectious and chronic diseases. High performance track record and proactive strategies has optimized product access, reimbursement, and commercialization efforts in global and local contexts.

Abstract

Biosimilars & HealthCare Delivery.. Opportunities & Challenges

Dr. Ahmed Shelbaya, Wing Yu Tang, HEOR Pfizer

A growing number of biologic medicines have been developed and approved over the past decade, improving the lives of patients worldwide. Patients suffering from Oncology, Auto-immune , Diabetic and Inflammatory disorders can be now be treated now with a innovative Biologics. The current market for Biologics is estimated to be around $277 billion in sales globally in 2017 and is projected to reach $452 billion by 2022. The availability of such innovative interventions does present a promise to many desperate patients, but due to the high price

tag associated with Biologics they also do present a big financial challenge and burden for payers including governments and definitely an access challenge to patients, especially in developing country settings. The loss of patent exclusivity for many Biologics offers a promise though. A promise not just in terms of increasing access to patients but a promise of capacity to sustain the Biologic markets in general. Loss of exclusivity of Biologics and accordingly opening up room for competition and therefore expanding access to Biologics while lowering treatment costs is the promise of Biosimilars. More than 45 biosimilar products (for 15 biologic medicines) are now available (differs from one region to another). In this presentation we provide an overview of the opportunities and challenges associated with the availability of Biosimilars and accordingly sustainability of these important interventions."

Richa Goyal

Engagement Manager, HEOR, RWI, Global Scientific Affairs IQVIA

Richa Goyal is an Engagement Manager, RWE projects from India. Her areas of expertise include HEOR, RWE, Evidence Based Medicine (EBM) and Scientific Communications. She also has good understanding of medical statistics and data interpretation. She has 11+ years of experience in HEOR, PE models and medical communications and has publications in many peer reviewed journals. She also holds position of Director ISPOR India, Mumbai Chapter. She holds a Master of Pharmacy in Pharmacology along with certifications in "Health Technology Assessment" from University of Sheffield and "Statistics in Medicine" and "Writing in Sciences" from Stanford University

ABSTRACT

Usefulness of Meta-Analysis in Real World: the true need?

With the World progressing towards the boom of Real World Evidence and the usefulness of it: the big question comes as need of Meta-analysis in Real World Setting. What is meta-analysis? Is it necessary for solutions to the Real World? Will the quantitative data obtained help in drawing clear solutions and will help in the launch of the relevant drug and its usefulness? The questions are many and with the help of analysis we are able to answer some. Meta-analysis is a technique where we can assess the results produced by various studies for assessment of various outcomes. The results come in the form of forest plots or rankograms which can help us in further analysis of the outcomes and the drugs. In the highly competitive world, where there are so many solutions present for a disease, meta-analysis can help us in giving an unbiased direction. But this also comes with its own perils as it is dependent on the data inputs which further depend on the robustness of study, sample size, heterogeneity, inconsistency; are many of the inter playing factors to it. With the evolution of new technologies and softwares where we say machine learning contributes towards more efficiency and reducing the bias in the systematic review we are still in the process and working towards it. Although there are many softwares to help in meta-analysis like Winbug's, R and R studio we are still exploring its need in Real World setting.

Loveleen Taneja

Principal, RWI, Global Scientific Affairs IQVIA

Dr. Loveleen Taneja has extensive experience in domain consulting, pharmaco-economics and pharmaco-epidemiology support. Her areas of expertise include pharmaco-economic modelling, scientific content writing, disease landscapes, clinical trial and pipeline analytics, revenue forecast, longitudinal data analysis, value messaging, pricing, reimbursement and market access.

Loveleen has 18+ years of experience across clinical work and industry. Loveleen holds a Master's degree in General Surgery from National Board of Examinations (NBE) and has worked for 6 years in general surgery and pediatric surgery. For past 12 years, she has worked in several companies in healthcare consulting and scientific communications.

ABSTRACT

Economic Evaluation alongside clinical trials

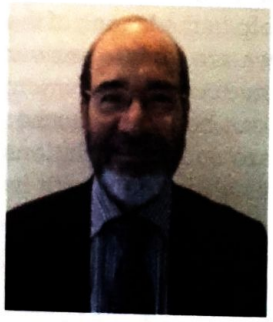
Economic evaluation is increasingly being used by various decision-making bodies to advise on reimbursement decisions for new drugs or devices. It is used by Payers to assess which drug represents the best value for money, and to make decision regarding its pricing negotiations, reimbursement, and by physicians to decide which drug to prescribe. Cost effectiveness (CE) analysis is a type of economic evaluation which compares the cost and effectiveness of a new intervention with other alternatives. This analysis is used by multiple countries including United Kingdom, for reimbursement decision.

Traditionally, the cost and effectiveness outcomes used for evaluation have been obtained from non-sampled secondary data. This includes searches from published literature (peer reviewed and non-peer-reviewed), insurance claims databases, published costs units by healthcare services and expert opinion. These sources have associated variability and uncertainty which needs to be addressed by use of sensitivity analysis.

Over the past two decades, there has been a thrust to include economic endpoints in large clinical trials. CE analysis is expected to more robust if based on outcomes from clinical trials, as the analysis would be based on actual patient-level data is available for both clinical outcomes and costs. However, challenges exist in designing the randomized controlled trial. These include need for the trial to reflect current clinical practice, ability to collect the costs for each alternate outcome for equal length of time, have sufficiently long follow-up period so that important costs and effects can be collected. To help in this, ISPOR Task Force on Good Research Practices developed and published guidelines for improvement in conduction and reporting of trial based economic evaluation in 2004-05 which were updated in 2015.

Moin Don

CEO & Founder, PVCON Consulting Services



Moin has about 40 years' experience in the pharmaceutical industry. Pharmacist by education, Moin is one of the most well-known 'Pharmacovigilance Professionals' in Asia Pacific. He has rich hands on experience of practically every facet of Industrial Pharmacovigilance, while serving reputed international pharma cos like Sanofi Aventis & his last assignment being, with Johnson & Johnson as Regional PV QA Director for Asia Pacific. Moin has undergone extensive training in U.S, Germany, France & Singapore and is a certified 'Lead Auditor'. He is closely associated with Govt. of India's National Pharmacovigilance Program as 'Advisor' and 'Trainer' for DCGI & PVPI staff & has also been a trainer for UMC's PV Workshop in Asia Pacific region. In addition Moin is Steering Committee member of DIA India & has been chairing DIA India PV flagship Conferences for last 5 years. He is a visiting faculty & international speaker & Course Director of PG Diploma in Pharmacovigilance conducted by Academy for Clinical Excellence in Mumbai. His many articles have been published in international journals of repute. As a distinguished PV consultant & auditor, Moin has conducted audits in India & rest of the world besides helping pharma companies in establishing PV systems. Recipient of 'Pharma Ratan 2016 ' Award for life time achievement and for his contribution to Drug Safety & PV in India.

ABSTRACT

A Holistic Overview of Pharmacovigilance

Pharmacovigilance has always been considered a critical activity by almost all the key stake holders, associated with drugs, and its high place in organizational priorities has never been questioned. From time to time, episodes like thalidomide tragedy (1962) and cardiovascular risks posed by COX 2 inhibitors (2005), only add emphasis to this ever evolving medico-regulatory discipline.

Traditionally speaking, the science of pharmacovigilance has been a discipline more focused on the post marketing or post authorization period. As a part of 'Risk Management Tool' it has not only an important role to play in patients' safety, but it has also assumed astronomical significance, to safeguard pharma industry against

possible loss of revenue through damaging litigations & declining share value. However, as biological sciences have evolved, pharmacovigilance has also become an integral part of new drug development process.

The new regulations (E2E Pharmacovigilance Planning) require that, the would be marketing authorization holders, submit, in the application dossier, a comprehensive review of the safety profile of the new drug, and how the potential risks will be further investigated and / or minimized during lifecycle of medicines.

Spontaneous reporting and Periodic Safety Update Reports (PSURs) for the marketed products, form the back bone of the traditional, post marketing surveillance activities throughout the pharma world. US FDA's MedWatch forms & MHRA's 'Yellow Cards' have almost become synonyms with spontaneous reporting. While US FDA recommends voluntary spontaneous reporting of all serious suspected ADRs through Form 3500A, for health care professionals, it makes such reporting mandatory for the Marketing Authorization Holders (MAHs) and draws very stringent timelines & reporting requirements.

From the latest amendment, to the Schedule Y of Drugs and Cosmetic Act 1945, the serious intentions of the Drug Controller General of India (DCGI) regarding stricter compliance relating to the reporting of adverse events from clinical trials are clearly palpable. The regulations clearly spell out the responsibilities of the stake-holders visà- vis safety reporting along with the timelines and a well defined format.

The stake holders must take cognizance of the tremendous challenges they are faced in order to realize the great growth potential and it's usefulness of this domain in India. Diligent compliance and adherence to GCP and GPVP principles can only be the right Direction to move forward.

Naveen Chhabra

Manager Pharmacovigilance, Tata Consultancy Services

Area of expertise: A gold medalist physician with an extensive experience in clinical trials and drug safety, authored and reviewed aggregate safety reports (pre-marketing and post-marketing reports, including periodic and adhoc/interim aggregate reports) and risk management plans. He has expertise in core areas includes trainings, ICH-GCP guidelines, medical writing, signal detection and assessment, designing risk management plans and label (core and regional) updates.

Current Profile: He is holding position of Manager- Drug safety, risk management and regulatory affairs at Tata Consultancy Services, Mumbai, India. Having excellent communication skills, he has proven his ability to work within regulatory & client specified framework. He has mentored many aspirants to achieve excellence in drug safety and medical writing. Dr Naveen has several publications in his credit in national and international journals.

ABSTRACT

Signals in Drug Safety

Signal management remains a cornerstone in the drug safety. A signal is defined as any information (arising from one or multiple sources, including observations and experiments) which suggests either a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action [1,2]. From the Uppsala Monitoring Centre, "reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information." A safety signal is not synonymous with a statistic of disproportionate reporting for a specific drug-event combination as a validation step is required. Signals may be qualitative (e.g., a pivotal individual case safety report, case series) or quantitative (e.g. a disproportionality score, findings of a clinical trial or epidemiological study). Signals may arise in the form of an information request or inquiry on a safety issue from a health authority [3]. The signal management process includes a set of activities performed to determine whether, based on an examination of

individual case safety reports (ICSRs), aggregated data from active surveillance systems or studies, scientific literature information or other data sources, there are new risks associated with an active substance or a medicinal product or whether known risks have changed, as well as any related recommendations, decisions, communications and tracking [2]. The EU signal management process includes the following activities: signal detection, signal validation, signal confirmation, signal analysis and prioritisation, signal assessment and recommendation for action. The release of the revised Good Pharmacovigilance Practices (GVP) Module IX – Signal Management [Oct 2017], brings further clarification and additional regulatory requirements for the marketing authorisation holder (MAH). From 22nd February 2018, the MAHs with an active substance on the EMA pilot additional monitoring list are obliged to monitor the EudraVigilance Data Analysis System (EVDAS) for new and existing signals with a frequency proportionate to the identified risk, potential risks and need for additional information.

Manoj Sharma

Sr. Manager - Global Pharmacovigilance Department, Win-Medicare Pvt. Limited

Dr Manoj SHARMA is a Ph.D. in Clinical Pharmacology with a Post-Doctoral Experience in Pharmacovigilance and Pharmacoepidemiology from University of Bordeaux-II, FRANCE. He is having more than 15 years of experience in Pharmacovigilance and Pharmacoepidemiology and Drug Discovery. He has developed Pharmacovigilance departments for global pharmacovigilance regulatory needs for countries in the European, North American, Latin American and Asian region and has also contributed to Pharmacovigilance Programme of India as an expert member in Quality Review Panel of National Coordination Center Pharmacovigilance Programme of India (NCC-PvPI), Ministry of Health &Family Welfare Govt. of India. He has assisted NCC-PvPI, Ministry of Health &Family Welfare Govt. of India in finalization of the "SUSPECTED ADVERSE DRUG REACTION REPORTING FORM" and reviewed "STANDARD OPERATING PROCEDURES" for Pharmacovigilance Programme of India. He has been awarded grants by the International Society of Pharmacoepidemiology, USA, Indian National Science Academy, and Deptt. of Science and Technology, Govt. of India, International Society of Pharmacovigilance for presentation of original research papers in international conferences. He has officially represented Developing Countries Vaccine Manufacturers network (DCVMN) in WHO Global Vaccine Safety Initiative (GVSI) meeting for implementing the vaccine safety strategy of the Global Vaccine Action Plan. He is also a Faculty / Trainer for Pharmacovigilance programme of India at Indian Pharmacopoeia Commission Commission, Ministry of Health &Family Welfare Govt. of India. His areas of interest include capacity building in Pharmacovigilance, Risk Evaluation and Mitigation Strategies, Vaccine Pharmacovigilance.

ABSTRACT

Risk Benefit Assessment: Key parameter & considerations

Pharmacovigilance is the science and activities related to the detection, assessment, prevention, recording and reporting of adverse drug reactions related to the pharmaceutical products. This includes the biological and medical devices as well. Global pharmacovigilance regulations require marketing authorisation holders (MAH) to continuously monitor and assess the benefit and risks in "real world clinical setting. The benefit risk assessment requires periodic monitoring of worldwide global medical and scientific literature, review of individual case safety reports of adverse events for lack of efficacy, drug-drug interaction drug-food interaction, overdoses, cases in special patient group including case series, safety findings from any ongoing and completed clinical trials, preparation and submission of periodic safety update reports at specified time intervals. The routine monitoring of benefits and risks of a product may generate new signals and safety concerns. It is imperative for MAH to prepare a Risk Management Plan for newly authorised products and already authorised with new therapeutic indications, dosage forms etc. The Risk Management Plan describes the important 'identified risks', 'potential risks' and 'missing information' for the product. On each occasion, the marketing authorisation holder needs to specify the methods of monitoring and the methods of risk minimisation for e.g. update of package insert, SmPC, warnings and precautions for use, any change in the dosage regimen etc. A critical integrated benefit risk evaluation requires compliance with the requirements of the guideline on Good Pharmacovigilance Practices.

Jamal Baig Anwar

Global Safety Country Leader MSD - India

In the past have been associated with Kasturba Medical College and Hospital a Regional Centre during for Pharmacovigilance and was responsible for reporting ADRs to the National PV center at AIIMS , this program later on became the PvPI in 2010. Have also held faculty position at the NIPER , Hajipur (Premier Institute of Pharmaceutical Education in India) teaching and supervising M. Pharm Students. Have worked at Wipro Ltd- setting up of Drug and Safety outsourced project in India for Pfizer Inc in India as Team Leader, Pharmacovigilance trainer and Subject Matter Expert for case intake, data entry , case processing and quality control of ICSRs.

Currently working in Merck Sharp and Dohme (MSD) Pharmaceuticals Pvt Lt as Global Safety (Pharmacovigilance and Clinical Risk Management) country leader, in the current role oversee the PV operations in India, Pakistan, Bangladesh, Nepal, Sri Lanka, Maldives and Bhutan, which includes the PV responsibilities in the area of Clinical Trials, PAAS, Aggregate reports , Patient support programs, Health agency engagements, PV vendor qualification, SDEAs and collaboration with business partners .
Invited trainer for NCC- IPC - PvPI PV workshops for AMCs
Invited trainer for NCC- IPC - PvPI PV workshops for AMCs and Short term courses on Pharmacovigilance and Regulatory affairs. Have been session chairs/ speaker at various national and international PV conferences in India and abroad. Included in the Hall of Fame 2018 by India Society for Clinical Research (ISCR) for contribution in the field of Pharmacovigilance .
2016-17 played a key leading role in the Industry collaboration with the Indian Pharmacopeia Commission (IPC) – Pharmacovigilance program of India (PvPI) and initiated the drafting of the Post Marketing Pharmacovigilance Guidelines in India, the guidelines were released in Sep 2017 and are now considered for implementation .

ABSTRACT

Opportunities for pharmacy professionals in Pharmacovigilance

What is Pharmacovigilance?

- Pharmakon (Greek) = Medicinal Substances Vigilia (Latin) = To keep watch

Why do we need Pharmacovigilance?

Humanitarian concern insufficient evidence of safety from clinical trials, Animal experiments & Phase 1 – 3 studies prior to marketing authorization Limitations of clinical trials, Small number of patients studied, Restricted populations (age, sex, ethnicity) Narrow indications ,Short duration of drug exposure

Common terminologies in Pharmacovigilance

- Side effects, ADRs, Adverse Events ,SAEs, NSAEs, SUSARs, AEFI, Listed/Unlisted SAE (Expected/ Unexpected) Follow up letters, Spontaneous report , Solicited report, PSPs, Literature reports , Social media reports , ICSR, PSURs, DSURs, QSRs, Line listings ,MedDRA ,Event term coding, Drug Coding, Narrative writing/Case narrative, Medical review , Causality , Dechallenge , Rechallenge Signal detection , Distribution – E2B (Regulatory submission), Case processing, ,PASS,PMS, Phase IV, CIOMS ,Medwatch – US ,CSDCO /PvPI AE reporting form , Data base, Eudra vigilance , Vigibase, AER-US, VAERS-US.

Career Opportunities

- Pharmacovigilance (PV) market is expanding globally at a very high speed , In the year 2013, it was estimated to be a USD 2,408.0 million market globally; expected to grow at 14.20% CAGR between 2014 and 2020,As per a report by Transparency Market Research the PV market is expected to reach US$6.1 bn by 2020. The main reasons for the proliferation of the PV market are the strict drug safety regulations and policies by the governments of most developed and developing countries

Global Pharmaceutical Industries have outsourced major PV activities to CRO's based in India .

Combined set of activities performed by above individuals is called case processing.

India has the highest number of PV professionals involved in case processing activities Job opportunities in Industry and Government , Contract Research Organizations: Quintiles-IMS (IQVIA) , Paraxel, Pharm-Olam, Siro Clinpharm, Sciformix , Kynapse, Covance, etc, IT/BPOs/KPOs: TCS, Cognizant, Accenture, Wipro, All Pharma/Device, Biologics companies, IPC-PvPI employs a large number PV associates in AMCs (ADR monitoring centers), Drug Inspector (temporary and permanent) at CDSCO and state FDAs – role is to collate and co-ordinate SAEs submitted by Sponsor, EC and Sites with SAE expert committee members, higher officials of CDSCO and Industry.

Wasif Khan

Senior Professional in Pharmacovigilance & Regulatory affairs. Trainer & ISO certified lead auditor

A healthcare professional with more than a decade of experience in Pharmacovigilance, Regulatory Affairs and drug development.

(M. Pharm. PhD) Pharmacist by qualification, one of the well-known 'Pharmacovigilance Professionals', has rich hands-on experience of practically every facet of Pharmacovigilance and Regulatory Affairs, while handling projects of leading regulatory agencies like European Medicines Agency (EMA) and reputed international pharma companies.

EMA accredited ICSR quality reviewer, manual drug recoder and xEVMPD expert for EudraVigilance. Shared review feedback with over 500 Pharma companies.

Has visited multiple Europan and Asian countries being trainer and keynote speaker.

Closely associated with Govt. of India's National Pharmacovigilance Program as part of a committee who has drafted pharmacovigilance guidelines for Pharmacovigilance Program of India (PvPI) & also been a trainer for skill India PV Workshops conducted by PvPI.

ISO certified 'Lead Auditor' and facilitated as Pharma Ratan 2016 for contribution in drug safety.

As a young and enthusiastic PV professional, exhibits interest and excitement in assisting pharma companies in establishing PV systems, performing system audits and ensuring regulatory compliance in Europe, Asia Pacific, Arab league & CIS region.

ABSTRACT

Drug Safety Status, a comparative analysis of European Union, Arab League, Eurasean Commission & India

Access to medicine has significantly improved during last decade worldwide, thanks to the efforts of global health initiatives and also to the commitment of national governments. Medicines are required to be safe, effective, and of good quality to achieve their intended purpose. However several incidences of harm from poor quality or unsafe products have been recorded. The primary objective of pharmaceutical regulation is to safeguard the public from unsafe medical products. Countries can achieve that by establishing a comprehensive pharmacovigilance (PV) system. While major advancements of the discipline of pharmacovigilance have taken place in the West (US & EU), not much has been achieved in low and middle income countries (LMICs), though several attempts have been taken. However, with more clinical research activities being conducted in these countries, there is an immense need to understand and implement PV. For this to happen, the mind set of people working in regulatory agencies, the Pharmaceutical companies, prescribers and patients/consumers need to

change. WHO has a major role in supporting and coordinating these developments.

In the past 20 years, many LMICs have created national PV systems and joined the WHO's global PV network. However, very few of them have fully functional systems. Legislation and regulatory framework as well as financial support to build sustainable PV systems are needed. Public health programs need to integrate PV to monitor new vaccines and medicines introduced through these programs. Signal analysis should focus on high-burden preventable adverse drug problems.

Shubashini Gnanasan

Senior Lecturer, Faculty of Pharmacy, Universiti Teknologi, Mara Selangor, Malaysia

Dr. Shubashini Gnanasan graduated with a Bachelor Degree in Pharmacy from Universiti Sains Malaysia in the year 2003 and a Master's Degree in the field of Clinical Pharmacy from the same university in the year 2005. She was selected to receive a scholarship in the year 2007 to pursue her PhD studies in the field of Clinical Pharmacy in United Kingdom. In 2012, she was successfully awarded with a PhD by the School of Pharmacy, University of Nottingham, UK. She joined the Department of Pharmacy Practice, Faculty of Pharmacy, Universiti Teknologi Mara, Malaysia in 2005 and has been working in the same university for the past 13 years. She is a senior lecturer, supervises PhD and masters student by research and give lectures to pharmacy undergraduate and postgraduate students who are pursuing their Master in Clinical Pharmacy and Master in Pharmacy Practice. Her research interests are in the field of pharmacy practice, social pharmacy and clinical pharmacy research such as co-morbid disease management of tuberculosis and diabetes mellitus, pharmaceutical care and health services research, exploring patient experiences of using medicines, qualitative research, action research, pharmacy education, and complementary and alternative medicine. She has communicated her research findings in many international and national conferences, published a few research articles and has been invited to speak at conferences. She has also conducted a workshop to train pharmacists in mixed-method research. She was honoured to be given the opportunity to be the organising chairperson of the International Conference of Pharmacy Practice which was recently held in Malaysia. She is currently working on non-pharmacological management in dementia care as she has been awarded a fundamental research grant for the project.

ABSTRACT

Pharmaceutical care for patients with Tuberculosis and Diabetes Mellitus: a Malaysian experience

Diabetes mellitus (DM) is one of the most common co-morbidity in patients with tuberculosis (TB) with prevalence as high as 15-30% in Malaysia. The convergence of these two diseases is linked to poorer TB treatment outcomes, increased chances of relapse and recurrence within two years, increased risk of multi drug resistant-TB, reactivation of latent TB infection and higher risk of death during TB treatment. Although, directly-observed treatment (DOT) has been shown to be a good strategy to enforce adherence to TB treatment, pharmacists are underutilized. However, many pharmacists run diabetes medication therapy adherence clinic (MTAC) in many public hospitals. Despite the fact that DOT and MTACs are good strategies in promoting adherence to TB and DM treatment respectively, there is a lack of clinical guideline on the co-management of TB and DM patients. A collaborative effort from all stakeholders including pharmacists is needed in order to combat the dual jeopardy. Hence, a qualitative enquiry (phase 1) was carried out in a public tertiary hospital in order to explore the pharmaceutical care needs of patients with TB and DM. Concerns about medication and issues related to the management of TB and DM were the two main themes that emerged. Concerns about medication include the negative consequences of medicine taking (adverse effects of medication, burden of multiple medication, drug interactions and medication confusion) and the perceived positive effect of medication which were expressed in terms of necessity and efficacy of medication. Issues related to the management of TB and DM patients include longer duration of TB treatment in DM patients, delayed initiation of TB and DM treatment, poor record keeping, communication barriers between patients and physicians, the ambiguity of DM management in TB patients, DOT and the burden of attending multiple clinics, and self-management and incorporation of traditional remedies. Phase 2 study employed action research methods to assess the feasibility of providing a pharmaceutical care service for patients with TB and DM in the same hospital. Action research comprised both quantitative and qualitative data and a variety of 'real-life' experiences were captured. Pharmacists played an important role in managing DM in TB patients by: raising the awareness

that DM is a risk factor for TB; emphasising the importance of adherence to DM medication as well as to dietary recommendations; advocating the importance of regular monitoring of blood sugar level; addressing patients' concerns about their medication; and referring patients to physicians and recommending treatment modifications. Nevertheless, there were other issues which could be regarded as barriers to pharmaceutical care management such as communication barriers; delays in initiating DM treatment in newly-diagnosed DM patients; infrequent monitoring of blood glucose level; absence of certain clinical and laboratory data; and nurses' reluctance to conduct finger-prick blood glucose monitoring if it was not a physician's order at the chest clinic. In spite of the need to address logistic barriers and the need for more collaborative practices between pharmacists and physicians, the provision of the pharmaceutical care service for TB and DM patients was a feasible conclusion.

K. C. Singhal

Former Vice Chancellor, NIMS university, Jaipur

Professor Krishan Chandra Singhal earned both his Bachelor of Medicine and Bachelor of Surgery (M.B.B.S) in 1964 and his Doctor of Medicine (M.D.) in 1968 from King George's Medical College Lucknow. His Doctor of Philosophy (Ph.D.) degree in 1976 from Rajasthan university and Doctor of science D.Sc.) in 2001 from Aligarh Muslim University, Aligarh, India. Dr Singhal has been elected Fellow of Royal College of Physicians Edinburg, FRCP (Edin) Dr. Singhal's major areas of research are Pharmacovigilance, Clinical Pharmacology and Chemotherapy. He has established a new method for screening potential anti-filarial agents using Setaria cervi as test organism. He was Professor and Chairman Department of Pharmacology, Jawahar Lal Nehru Medical College, AMU Aligarh. He joined as Vice Chancellor, NIMS University Jaipur, India in February, 2008 and was there till 31st May 2015..

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, Indo-US workshop on Problem Based learning, Workshop on Pharmacovigilance of Drugs of Indian Systems of Medicine,Chaiman organizing committee and co-chai scientific committee joint conference of International Society of Pharmacovigilance and Society of Pharmacovigilance India at Agra in 2016. He was Coordinator and Principal Investigator of multi-centric Indian Council of Medical Research sponsored task force on "Monitoring of Epidemiological profile and factors responsible for Adverse Drug Reaction in India". He was coordinator 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 papers/lectures at National and International conferences.

Prof. Singhal is a founder fellow of IMA Academy of Medical Specialities,(FIAMS) Founder fellow of Indian Pharmacological Society (FIPS), Founder fellow of Indian Academy of Neurosciences (FIAN) and Founder of Society of Pharmacovigilance India (FIPS). He has been consultant with WHO centre for International Drug Monitoring Uppsala, Sweden for eight years He has participated and represented India in National Centre Meetings of WHO in different parts of the world. Prof Singhal has been honoured by B C Sarma Memorial Research Award of Indian Medical Association, S S Parmar Foundation Award of Indian Academe of Neurosciences, B MukherjeePrize of Indian Pharmacological Society, Major General S L Bhatia Oration Award of Association of Physiologists abd Pharmacologists of India, Cl. R N Chopra Oration Award of Indian Pharmacological Society.Platinum Jubilee Oration Award of Indian Science Congress Association, G Achari Oration Award of Indian Pharmacological Society,John Autian Oration Award of Society of Pharmacovigilance India, Life Time Achievement Award of Association of Physiologists and Pharmacologists of India, Prof S B Pandey Oration Award of Indian Pharmacological Society .

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.Dr Singhal has been awarded many prizes, oration awards,and honors.

Presently Dr singhal is working as physician at Dr K C Singhal Hospital and research centre, Kwarsi, Ramghat Road Aligarh.

ABSTRACT

Road to safety evaluation of drugs of Indian systems of medicine

Indian systems of medicine (ISM) namely Ayurveda, Siddha and Unani are holistic systems which aim to integrate body, mind and spirit to help prevent illness and promote wellness. With greater acceptance and popularity, the production and sale of these drugs has been formalized into thriving industry covered by Drugs and Cosmetic Act Government of India. In Ayurveda ancient text Charak Samhita describes adverse reaction to many drugs and also host related factors which can influence the intensity of adverse reactions.

However, many physicians of ISM are not inclined to accept that the drugs of these systems of medicine can cause adverse reactions. Ayurvedic literature provide methods to detoxify metallic as well as plant preparations and claim that the method of Shodhana removes the toxic component and the drug becomes free from adverse reactions. However, such claims are required to be verified with scientific and clinical evidences. On the recommendation of a joint meeting of ISM at the behest of Government of India in 2008 ,it was decided to establish ADR monitoring program for drugs of ISM with headquarter at Gujrat Ayurved University, Jamnagar. Countrywide training programs were organised and ADR monitoring centres including regional and peripheral centres were established. More than 2000 physicians and paramedics have been trained .Reports of ADRs are pouring in but are not frequent. Substitution of drugs is one major issue. In Ayurveda the substitution is permitted only for additives and exipients whereas, in Unani system the drug with main pharmacological action can be substituted too. The practice is old. Abu Bakar Mohammad Bin Zakariyya al Razi (Rhazes) (865-925 AD) compiled all substitutions used in a book Maqala Fi Abdal al-Adwiya al Mustamala Fi al-Tib Wa al-Alaj popularly known as Kitab-al-Abdal and laid down the principles for substitution. Al-Razes has listed 122 drug substitutions in practice till then. In Indian pharmacopeia 50 more plant drugs were added to this list, thus making the total number of permitted substitutions to 172 in practice in India. A pharmaceutical house can market its drugs without disclosing the name of the substitute used as they claim to have prepared the drug according to the Unani text,

The substitution of components of an Ayurvedic or Siddha systems of medicine are confined to exipients and additives and the drug responsible for the pharmacological actions are not changed. This makes it easier to monitor drugs of these systems of medicine Efforts are on to reach a large number of ISM practitioners with workshops and training programs. Recently a joint training program was organized for ISM physicians from Sri Lanka and more concerted efforts are required to prove safety of drugs of India systems of medicine.

Syed Ziaur Rahman

Professor, Department of Pharmacology, Aligarh Muslim University

Professor Syed Ziaur Rahman is working in the field of Pharmacology for the last 21 years. As a scholar, he has to his credit 7 published books, 12 chapters and more than 165 articles/research papers/case-reports/editorials in both national and international journals. He edited 11 periodicals and has been invited to deliver hundreds of lectures both as guest speaker and as resource person. He participated in 62 Workshops/ Training Programs and presented papers during 46 International Conferences and 64 National Conferences. He himself organized two international conferences and many national conferences/symposiums and handled 7 academic projects. He works in the field of Traditional medicine with special reference to Unani medicine. While working on morphine de-addiction properties of medicinal plants, he proposed a modified method for moderately and severely induced morphine dependent rats. He specifically screened Delphinium denudatum for its protective activity in morphine induced physical dependence. Two of his MD candidates expanded the same work. In the field of Pharmacovigilance,

he gave the concept of Environmental Pharmacovigilance and coined the term 'Pharmacoenvironmentology' for the study of drugs at therapeutic doses and its impact on environment. He further differentiated the earlier terminology 'Ecopharmacology' from 'Pharmacoenvironmentology'. In addition, he is closely associated with Society of Pharmacovigilance, India (SoPI) and currently serving as National Secretary. He started as editor-in-chief, the official journal of the SoPI in 2003 'Journal of Pharmacovigilance & Drug Safety' (ISSN 0972-8899) and edited its first 2 numbers. He organized 15th Annual Conference of SoPI (SOPICON 2014) at JNMC.

He is involved with and/or member of 33 learned educational bodies including International Medical Sciences Academy (FIMSA), National Academy of Medical Sciences (MAMS), International Brain Research Organization, International Society for Neurochemistry (ISN), South African Pharmacological Society, Indian Science Congress Association (ISCA), Indian Medical Association (IMA), Safety Pharmacology Society (SPS), Australian and New Zealand Society of the History of Medicine (ANZSHM), Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT), IndiaCLEN (Regional network of INCLEN), Indian Science News Association (Science and Culture), Association of Physiologists and Pharmacologists of India (APPI) and Indian Pharmacological Society (IPS). He was entrusted to organise the 9th Annual Meeting of Indian Society of Rational Pharmacotherapeutics (ISRPTCON 2017) at JNMC, AMU, Aligarh during 19-21 November 2017 He is the founder trustee and treasurer of Ibn Sina Academy of Medieval Medicine & Sciences, Aligarh and an Associate Editor of its quarterly newsletter (NISA). He coordinated in the establishment of the Library, Museum on History of Medicine & Sciences, Centre for Safety & Rational Use of Indian Systems of Medicine & AIDS Cell as corpus body of the Academy. The Academy is designated as 'Centre of Excellence' by Ministry of AYUSH, Govt. of India and listed in the Directory of History of Medicine Collections, US Department of Health and Human Services, National Library of Medicine, NIH, USA. He arranged many medical camps on the occasion of World AIDS Day, World Health Day and World Tuberculosis Day. Many scholars and institutions have cited his works including in few Pharmacology books. Under his supervision and co-supervision, 17 candidates have either completed or are completing their thesis/dissertation works. He is invited as external examiner to several medical and pharmacy colleges for BDS, MBBS, MD, PhD, M. Pharm and MSc (Pharmacology) examination and also served as expert for various selection committees for the post of Senior Residents, Assistant Professors and Associate Professors. He was awarded with International Alumni Leadership Award 2018 (Western Sydney University), Pharma Ratan Award 2017, Servier Young Investigator Award of International Union of Pharmacology (1999), Junior Scientist Award of Safety Pharmacological Society of USA (2006), The African Institute of Biomedical Science and Technology (AiBST) Scholarship for Kenya, 2003, WHO Fellowships to attend the 2nd Asian Course on ED & RDU in Kuala Lumpur (Malaysia) and Second International Conference on Improving Use of Medicines (ICIUM 2004) in Chiang Mai (Thailand). He is also recipient of APSN Fellowship and ISN Fellowship for 6th Biennial Meeting of the Asia Pacific Society for Neurochemistry, 2004, Hong Kong and 20th Biennial Meeting of the ISN-European Society for Neurochemistry (ESN), Austria, 2005 and First Special Neurochemistry Conference, International Society for Neurochemistry (ISN), France, 2004, respectively. He also got International Postgraduate Research Scholarship (IPRS) to pursue PhD from University of Western Sydney, Australia (2010-2012). He visited USA (thrice), Holland, Germany, UAE, Malaysia, Iran, Kenya, Hong Kong, Thailand, France, Norway, Sweden, Switzerland, Nepal, Pakistan, Australia, Czech Republic and Austria for academic purpose.

ABSTRACT

Importance of Pharmacovigilance in Traditional System of Medicine

No medicine is safe whether it is of streamline medicine or belongs to traditional system of medicine. Any medicine, no matter how common its clinical uses, has the potential to cause harm. It is true that adverse reactions are a cost of modern medical therapy, but then indigenous drugs used in traditional system of medicines especially minerals and herbs (phytomedicines) are also not safe in true sense. These herbal medicines are in fact widely used in health-care in both developed and developing countries. Medicines used and prescribed by traditional practitioners argue that their medicine does not need any clinical testing as they are being used since ages. They claim if the medicines are prepared as per their traditional formularies, then they won't pose any harm. But in reality, all medicines are not prepared as per standard format. In this era of competition and also unavailability of unfinished quality raw material, all medicines are not manufactured as per standardization levied by drug regulatory agencies. Any deviation from the official pharmacopoeias, may lead to cause adverse reactions. In addition, in recent years, there have been several other high-profile herbal safety concerns that have had an impact on the public health, and there is increasing recognition of the need to develop Pharmacovigilance systems for herbal medicines. Pharmacovigilance for herbal medicines or monitoring the safety of herbal medicines presents unique challenges. This lecture aims to provide a

comprehensive and critical overview of the current state of Pharmacovigilance activities for herbal medicines at the national and global levels. The lecture will explore in depth the challenges that Pharmacovigilance of herbal medicines presents, consider relevant emerging issues and what steps could and should be taken to improve the safety monitoring for herbal medicines in the future.

V. Kalaiselvan

Principal Scientific Officer, IPC, Ghaziabad

Dr. Kalaiselvan, completed his B. Pharm and M. Pharm in Tamil Nadu Dr. M G R Medical University, Chennai and Ph. D in DIPSAR, University of Delhi Played a crucial role in establishing a Pharmacovigilance Programme of India (PvPI), at National Coordination Centre (NCC)-Indian Pharmacopoeia commission. He is working with different partners of Pharmacovigilance at national and international levels. He has been instrumental in establishing systems and procedures, capacity building and implementing the technical and operational activities of PvPI

He is serving as member/member secretary in various committees of PvPI, CDSCO, Revised National TB Control Progam, and Universal Immunization Program to provide inputs/recommendations to the Ministry of Health & Family Welfare, Government of India on the policy level matters related to drug and vaccines safety, regulation etc. He has published 60 research and review articles in national and international journals; contributed chapters in 3 books and also a patent on 'synergistic herbal ophthalmic composition for the prevention of cataract' for his credit. His scientific contribution also reflected in bringing out Indian Pharmacopoeia 2010 & 2014 and National Formulary of India 2011 He also received fellowship from AICTE and DST to pursue the research In his 18 years of progressive experience in the academic and pharmaceutical research and currently, is being involved in policy formulation, management, research & development and implementation of PvPI for better patients care.

ABSTRACT

Herbal medicines and Phytopharmaceuticals regulation, quality and safety standards in India: Current perspectives and way forward

As per the recent amendment in Drugs & Cosmetics Act 1940, rules thereunder 1945, Phytopharmaceuticals are considered to be a drug. Therefore, Indian Pharmacopoeia Commission (IPC) shall play a pivotal role in setting the standards for herbal drugs and Phytopharmaceuticals in Indian Pharmacopoeia (IPC). The current edition of IP i.e. 2018 prescribes standards for 165 herbal drugs/formulations/processed herbs. The IPC, through the existing Pharmacovigilance Programme of India (PvPI) envisages the reporting of adverse events related to herbal drugs to monitor their safety; several adverse events associated with the of herbal medicines have been reported to IPC. Since quality and safety of herbal drugs are equally important, IPC is continuously striving for the mission accomplishment; Phytopharmaceutical/herbal drug industries, healthcare professionals and consumers must be educated to ensure the quality and safe use of herbal medicines.

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Oral Presentations

O1

STUDY ON VARIATION IN THE PRICES OF SELECTED STATINS IN THE COUNTRY

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Risk of CVD and hypercholesterolemia is increasing at an alarming rate in all age groups with rapid epidemiological transitions in India. The availability of large number of branded and generic statins and other antihyperlipidemic combinations is the driver for this work.

The objective of this study was to estimate the variation in price of selected statins and their combinations over the last 15 years.

Cost of oral antihyperlipidemic drugs manufactured by different pharmaceutical companies, in the same strength and dosage forms was obtained from "Current Index of Medical Specialties" for the years 2003, 2008, 2013 & 2018. The percentage variation among minimum and maximum cost (per 10 tablets) of atorvastatin, simvastatin, lovastatin, rosuvastatin and combinations was calculated.

Percentage variation in cost for antihyperlipidemic drugs marketed in India was found to be as high as 1400% for atorvastatin (10mg), 800% for lovastatin (20mg), 308% for rosuvastatin (40 mg).

Among the combination therapy, variation in cost was as high as 351% atorvastatin + fenofibrate (10/160 mg), 109% atorvastatin + ezetimibe (10/10 mg), 128% rosuvastatin + fenofibrate (10/160 mg).

These results reflect that the cost of statins have fluctuated widely in last 15 years in India. Such variation in the cost of statins and combinations largely influence the expenditure towards the cost of treatment of dyslipidaemia.

O2

A RETROSPECTIVE STUDY OF PATTERN AND OUTCOME OF POISONING CASES ATTENDING EMERGENCY MEDICINE DEPARTMENT OF A TERTIARY CARE TEACHING HOSPITAL IN UTTARAKHAND

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Poisoning is a common medical emergency with social and legal implications all over the world. It consumes valuable health service resources and causes considerable morbidity and mortality. The incidence, nature, aetiology, age group affected and outcome of poisoning in our country is different from that of the western world and there may be region-wise variation as well.

Management of patients with poisoning will greatly improve if the causes are properly defined and physicians become sensitised to the common substances involved in poisoning in this region. Therefore, we wanted to analyse the pattern of poisoning and treatment outcomes in patients attending the Emergency department of our institution.

Our aims and objectives were to analyse the pattern of poisoning and treatment outcomes of patients diagnosed with poisoning in our institute.

After IEC approval, we performed this retrospective observational study of clinical case records of Emergency and patient referral departments of patients with exposure to poison or drug/substance overdose in VCSGGIMSR between January to December 2017. We recorded demographic and clinical data, analysed them using descriptive statistics and any age/gender variations, using Chi Square/Fischer's exact test ($P<0.05$ for statistical significance at 95% Confidence interval). The analysis is ongoing analysis and we will present after analysis of results.

O3

COMBINED EFFECT OF METFORMIN AND FENUGREEK ON THE LIPID PROFILE OF THE TYPE 2 DIABETES MELLITUS PATIENTS

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Type 2 Diabetes Mellitus (DM) patients are characterized by Dylipidemia. Metformin has beneficial effect in improving lipid metabolism in Type 2 Diabetics. Fenugreek (Trigonella foenum graceum) is one of the oldest herb used for medicinal purposes in India also possess the similar properties. The objective of the present study was to evaluate the lipid lowering effect when metformin and fenugreek were given concomitantly in Type 2 DM patients.

An open-labelled comparative study of 12 weeks duration was conducted on patients (randomly divided in 2 groups of 30 each) of Type 2 DM. Group 1 was given metformin 500 mg twice a day while group 2 was given 500 mg of metformin along with fenugreek seed powder capsule,1 gm thrice a day. The patients were investigated for lipid profile were done at the beginning of the study and at the end of the study. Student's t-test (paired and unpaired) was applied for statistical analysis

After 12 weeks of treatment, there was significant improvement in the lipid profile in group 1 and group 2. However this improvement was statistically more significant in group 2 when compared to group 1.

This study shows the beneficial hypolipedemic effects of fenugreek seeds on lipid profile in patients of Type 2 DM when used

04

CHANGES IN HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH CHRONIC HEPATITIS C DURING THE CLINICAL COURSE OF DACLATASVIR/ VELPATASVIR THERAPY: A PROSPECTIVE OBSERVATIONAL STUDY

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Interferon-free direct-acting antiviral agent (DAA) therapy is preferred for the treatment of chronic hepatitis C (CHC) patients as it exhibits a higher rate of sustained virologic response (SVR), along with reduction in treatment related adverse drug reactions (ADR), which elevates the quality of life (QOL) of patients. The study aims to evaluate the health-related quality of life (HRQOL) in patients with CHC, receiving daclatasvir or velpatasvir (DCV/VEL) therapy, using Short Form-36 (SF-36) as a tool.

The study involves 50 CHC patients receiving DCV/VEL, who's HRQOL was measured using SF-36. Laboratory investigational data and SVR was recorded, and SF-36 was filled by the patient at baseline (prior to therapy), week 12 (post initiation of therapy), end of treatment (EOT), and week 24 (post initiation of therapy). SVR12 and HRQOL were analyzed at week 24. The association between laboratory data and HRQOL was also evaluated.

In regard to HRQOL, statistically significant changes were observed in physical functioning, general health, and emotional role functioning in the period between baseline to week 12 and week 24, respectively. A considerable change was observed in laboratory parameters such as aminotranferases, platelet count, and Fibrosis-4 (Fib-4) index at each time point of study as compared to baseline. 47 out of 50 (94%) patients achieved SVR12.

It was found that HRQOL of patients with CHC improved significantly along with hepatic functions during the clinical course of interferon-free DAA therapy (DCV/VEL).

Keywords: chronic hepatitis C, daclatasvir, velpatasvir, sustained virologic response, health-related quality of life, short form-36.

O5

CHANGES IN LIVER STIFFNESS AND STEATOSIS IN PATIENTS WITH CHRONIC HEPATITIS C DURING THE CLINICAL COURSE OF DACLATASVIR/ VELPATASVIR THERAPY: A PROSPECTIVE OBSERVATIONAL STUDY

Megha Garg[1], Divyanshi Rastogi[2], Vibhor Aggarwal[3], Dr. Amit Mishra[4]
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The mechanism behind reduction of liver fibrosis and steatosis is chronic hepatitis C (CHC) patients receiving interferon-free direct acting antiviral agent (DAA) therapy is still unclear. Non-invasive techniques such as transient elastography (TE) and TE-based controlled attenuation parameter (CAP) are used to evaluate the chronological changes in liver stiffness and steatosis, respectively, in CHC patients receiving DAA therapy.

The study involves 50 CHC patients receiving daclatasvir or velpatasvir (DCV/VEL) in whom liver stiffness and steatosis was measured using TE and CAP, respectively. Laboratory investigational data and SVR was recorded at baseline (prior to therapy), week 12 (post initiation of therapy), end of treatment (EOT), and week 24 (post initiation of therapy). Analysis was performed at week 24.

Median liver stiffness at baseline, week12, EOT, and week24 were 8.4, 5.8, 5.5, and 5.4 kPa, respectively. A statistically significant change was observed between baseline and week12 liver stiffness values ($P<0.05$). 17 patients with fatty liver exhibited CAP≥ 238 dB/m, and CAP at baseline and SVR12 was 251 and 227 dB/m, respectively. Overall, a considerable change was observed in laboratory parameters such as aminotranferases, platelet count, and Fibrosis-4 (Fib-4) index at each time point of study as compared to baseline. 47 out of 50 (94%) patients achieved SVR12. Liver stiffness value was indicative of fibrosis at SVR12 in patients receiving DAA therapy, although they achieved SVR. Similar cohort with fatty liver exhibited reduction in steatosis.

Keywords: chronic hepatitis C, daclatasvir, velpatasvir, liver stiffness, sustained virologic response, transient elastography.

O6

SAFETY AND TOLERABILITY OF FIXED DOSE COMBINATIONS OF SELECTIVE A_1-BLOCKERS WITH DUTASTERIDE AND ITS EFFECT ON QUALITY OF LIFE IN PATIENTS OF LOWER URINARY TRACT SYMPTOMS (LUTS) WITH BENIGN PROSTATIC HYPERPLASIA (BPH)

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The fixed dose combinations (FDCs) of α-1 adrenergic antagonists and 5α-reductase inhibitors are currently the mainstay of medical management of LUTS with BPH but have potential for causing adverse drug reactions (ADRs). The present study compared the safety and tolerability of FDC's of tamsulosin, alfuzosin and silodosin with dutasteride and their effect on quality of life (QoL).

Ninety six male patients diagnosed with LUTS and BPH were randomized to receive FDC's of dutasteride with tamsulosin (Group 1), alfuzosin (Group 2) and silodosin (Group 3) over a period of 16 weeks. Safety assessment was carried out by doing an active ADR monitoring as and when these happened during the course of study and specifically at 4, 8, 12 and 16 weeks post-treatment. Severity of ADRs was evaluated by Divison of AIDS scale and causality by WHO-UMC Scale. QoL was assessed using international prostate symptom score (IPSS) question 8th, BPH impact index and modified PPSM questionnaire.

Total 49 patients showed ADRs. Retrograde ejaculation and dizziness with tamsulosin, retrograde ejaculation, dizziness and palpitation with alfuzosin and retrograde ejaculation with silodosin were the common ADRs. All ADRs were graded mild and possible with regard to causality. QoL improved significantly in all groups. IPSS 8th question score improved by 61.68%, 57.63% and 63.4% and BPH Impact Index score improved by 62.95%, 60.13% and 61.82% in group 1, 2 and 3 respectively. Majority of patients were satisfied with their treatment and wanted to continue with their medication.

All FDCs though have potential to cause ADRs yet relatively safe with good tolerability profile and also an improvement in QoL and either can be used as per physician preference.

O7

ANALYSIS OF VARIATION IN PRICES OF ANTIHYPERTENSIVE DRUGS IN NLEM 2015

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Hypertension is a major risk factor for cardiovascular diseases. National List of Essential Medicines, 2015 includes nine antihypertensive drugs.

The objective of the study was to analyse variation in prices of antihypertensive drugs included in NLEM 2015 over the last ten years. The prices of nine antihypertensive drugs included in NLEM 2015 in 2008, 2015 and 2018 years was obtained from CIMS, MIMS, Drug Monitor, IDR and by using other current online sources. Cost ratio and percentage cost variation was calculated for three different years 2008, 2015 and 2018.

Nine drugs in this study had 18 formulations.The cost ratio was more than 2 for ten, eleven and nine number of formulations in the years 2008, 2015 and 2018, respectively. Range of cost ratio varied 1.19-11.29, 1.06-11.41 and 1.10-8.83 in years 2008, 2015 and 2018, respectively. The prices of tablets of Amlodipine 10mg, Atenolol 50mg and Telmisartan 20mg had increased from 2008 to 2018.

The prices of other 15 formulations had shown a decrease over the same time period. The price of Amlodipine 5mg tablet decreased by 3.99 folds. However, the prices of 5 formulations decreased by half and the remaining 9 formulations showed insignificant decrease.

This study has concluded that the prices of a large number of antihypertensive agents listed in NLEM 2015 have decreased over the last ten years. In view of the fact that antihypertensive agents are used over a long-term, the decrease in prices shall ease the out-of-pocket expenditure for many patients.

O8

DESIGN, SYNTHESES, MOLECULAR DOCKING AND BIOLOGICAL EVALUATION OF 1,2,4-OXADIAZOLE DERIVATIVES OF 2-(3-BENZOYLPHENYL) PROPANOIC ACID IN SEARCH OF SAFER NON-STEROIDAL ANTI- INFLAMMATORY AGENTS

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Enhancing the gastrointestinal safety profile of Non-Steroidal Anti- Inflammatory Drugs (NSAIDs) is a critical goal. So, approach to improve NSAIDs with minimal Gastrointestinal (GI) toxicity by targeting the COX-2 with selective inhibitor. In this study we selected 2-(3-benzoylphenyl)-propionic acid as a lead NSAID for development into safer agents. 1, 2, 4-Oxadiazole moiety was employed to mask the free acid group of the 2-(3-benzoylphenyl)-propionic acid to get six different derivatives hypothesized to have minimal GI irritation. In Vivo anti-inflammatory and analgesic activities of these six synthesized derivatives were tested and compared to equivalent dose of the parent drug.

Three compounds indicated superior anti-inflammatory activity (76.29%, 80.45% &79.06% inhibition) compared to the parent drug (72.71% inhibition), in a carrageenan induced paw edema model (peak at 4h). One compound, 3d also showed moderate analgesic activity (51.14%), in comparison to 2-(3-benzoylphenyl)-propionic acid (63.97%) in an acetic acid

induced writhing model. Their unique selectivity toward the COX-2 enzyme was investigated using molecular modelling techniques.

Results of compound 3d which showed highest anti-inflammatory and analgesic activities with much reduced ulcerogenic potential compared to the parent NSAID, are highly encouraging and may serve as new COX-2 selective lead and merits further investigation.

O9

COST EFFECTIVE ANALYSIS OF LINAGLIPTIN VS TENEGLIPTIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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Diabetes is and metabolic disorder characterized by disturbance in protein, carbohydrate and fat metabolism. Burden of diabetes increasing day by day, 62 million people are suffering from type two diabetes mellitus consisting of more than 7.1 percent of adult population. There is need of assessment of drug therapy used for treatment of type 2 diabetes mellitus to get optimum cost and benefit.

A prospective observational study was conducted for period of 9 months to compare the cost effectiveness of Linagliptin and Tenegliptin, DPP IV inhibitors. Inclusion criteria was patient diagnosed with type 2 diabetes mellitus, who were newly prescribed with Linagliptin and Teneglpitin. Patients were followed for glycated hemoglobin (HbA1C) levels from baseline to 3rd month and 6th month. Cost per day and treatment for sixth month was calculated. Demographics were presented in the form of descriptive statistics. For both the drugs, ICER (Incremental Cost effective Ratio) was calculated.

One twenty patients participated in the study. Male patients (61) were more as compared to female (59). Mean age of patients was found to be 58.3 year. Most of the patients were from rural area. Mean reduction of HbA1c for Tenegliptin was found to be 2.07 and for Linagliptin it was found to be 3.69 Mean difference in reduction of Hb1c was found to be 1.62. Linagliptin proved to be more effective in reducing HbA1c as compared to Tenegliptin. ICER was calculated Linagliptin was found to be more effective with P value of < 0.001.

Linagliptin was found to be more cost effective as compared to Tenegliptin. Economic burden for treating diabetes is rising day by day. There are no as such reimbursement policies for health care expenditure so there is need of conducting such pharmacoeconomics analysis so that we can reduce the cost of treatment and provide maximum therapeutic outcomes to the patients.

Keywords: DPP4 inhibitors, Cost Effective Analysis, Tenegliptin, Linagliptin, Diabetes Mellitus

O10

EVALUATION OF EFFECT OF METOPROLOL ON CARDIAC BIOMARKERS IN PATIENTS HAVING HEART FAILURE WITH PRESERVED EJECTION FRACTION

Niti Mittal, Nusrat Shafiq, S Reddy, Samir Malhotra, Savita Kumari
Pgims, Rohtak, Haryana

There is a lack of evidence-based therapies for the treatment of heart failure (HF) with preserved ejection fraction (HFpEF). Beta blockers may provide some benefit in HFpEF due to their proven role in HF with reduced ejection fraction. NT-proBNP has been characterized as a surrogate marker of LV dysfunction, NYHA class, and prognosis. A linear relationship between PICP levels and indices of diastolic function and filling pressure has also been proposed. This was an investigator-initiated, randomized, double-blind, placebo-controlled, 14-week pilot study with metoprolol succinate as a study drug. The biochemical end points included N-terminal pro-B-type natriuretic peptide and serum carboxy-terminal propeptide of procollagen type I.

Twenty patients were enrolled in each of the treatment arms. No statistically significant difference was observed for mean change in NT-proBNP levels between two groups. In the metoprolol group, the levels of PICP decreased at 12 weeks from baseline indicating reversal of myocardial fibrosis, but the changes cannot be deemed important in the absence of statistical significance (113.32 ± 24.95; $P = 0.43$).

A significant increase in NT-proBNP levels and a trend towards reduction in serum procollagen propeptide levels was seen in the metoprolol group. Hence, this pilot study showed that metoprolol succinate possibly can have some beneficial role in HFpEF as reflected by improvement in biochemical parameters.

O11

COMPARISON OF DRUG COST IN CONVENTIONAL AND NON-CONVENTIONAL TREATMENT OF GT-3 HEPATITIS C IN INDIA

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Hepatitis C virus (HCV) infection is a blood borne and transfusion-transmitted infection. In India, around 12-18 million people are reported to be infected with HCV and is a major cause of healthcare burden in India.

Among six unique genotype of hepatitis C, genotype 3 is predominant in Indian patients. Conventional treatment of hepatitis C includes Interferon and Ribavirin whereas newer non-conventional treatment uses the directly acting antiviral agents (DAAAs).

To estimate and compare the drug cost in conventional and non-conventional treatment of GT-3 Hepatitis C in India.

The drug cost of conventional therapy in 2014 was compared with drug cost of non-conventional therapy in 2018. The prices of DAAAs available in India (2018) were obtained from online CIMS. If it was not available with this, the costs were obtained from the retailers. The prices of Interferon and Ribavirin was obtained from CIMS hard copy, 2014. Drug cost were calculated based upon the standard treatment guidelines for Hepatitis C from "Indian National Association for Study of the Liver (INASL)".

The drug cost of conventional therapy of Ribavirin + Interferon α2a, for a six month period, in 2014 was found to range between Rs.2.65-3.43lakhs; whereas, it was Rs.2.69-5.55lakhs with Ribavirin + Interferon α2b.

The drug cost of non-conventional therapy with Sofosbuvir + Daclatasvir in 2018 was in the range of Rs.0.57-0.85 lakhs. The ratio of drug costs of the conventional therapy to the non-conventional (at the minimum) was 4.61. Likewise, at the higher end, this ratio ranged from 4.03- 6.5. The non-conventional therapy is less expensive compared to conventional therapy for the treatment of hepatitis C in India. The correlation with effectiveness of the non-conventional treatment in Indian patients shall be interesting to examine.

O12

ANALYSIS OF COLLECTED ADRs IN A SOUTHERN TEACHING MEDICAL INSTITUTION: A PROSPECTIVE OBSERVATIONAL STUDY OF ADR MONITORING UNDER PvPI

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Adverse Drug Reaction [ADR] is defined as "reaction which is noxious and unintended and which occurs at dosages normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function". India is a country where many generic drugs are available in the market and presently the data regarding the ADRs in India is in infancy stage. It has been reported that 1.06 lakhs of people dies per year because of ADRs in USA according to 1998 report. ADR monitoring is crucial in current era of medical practice as there is introduction of more and more toxic drugs in the market especially in the last 20 to 30 years.

After obtaining the approval of research proposal from the IRB, the study was conducted in strict compliance with the ICMR bioethics guidelines related to the human study participants. The ADRs were collected from the different departments of the tertiary care hospital and were recorded in standard ADR form designed by the CDSCO. The recorded data on CDSCO ADR forms was subjected for causality assessment using WHO, Naranjo Algorithm, Schumock & Thornton and Modified Hartwig and Siegel scales and data was expressed in frequency and percentage.

During the entire study period, ninety one ADRs were collected. When subjected for assessment it was found that, WHO scale showed, maximum number of ADRs were possible 65 [71.43%] followed by probable/likely 17 [18.68%], unlikely 5 [5.49%], unclassifiable as 3 [3.3%] and conditional/unclassified 1 [1.1%]. It was observed in Naranjo algorithm scale that ADRs were possible in 78 [85.71%] of cases, followed by probable 9

[9.89%] and definite 4 [4.4%]. Modified Hartwig and Siegel scale revealed 69 [75.82%] of ADRs were mild in nature, followed by moderate 19 [20.88%] and severe 3 [3.3%] cases. The Schumock & Thornton preventability scale detected 53 [58.24%] of all ADRs were definitely preventable, followed by 25 [27.47%] as probably preventable and rest as not preventable in nature.

This study confirmed that, antimicrobial class of drugs [beta lactam group] was responsible for highest number of ADRs followed by drugs acting on skin, respiratory system and ANS were the least likely causes for occurrence of ADRs. ADR assessment scale revealed maximum number of the ADRs was possible in both the WHO and Naranjo scales with mild in nature on Modified Hartwig and Siegel; and definitely preventable on Schumock & Thornton ADR preventability scales.

O13

ACETAZOLAMIDE INDUCED HORMONAL IMBALANCE : AN UNTOUCHED AREA

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Diamox: acetazolamide; an inhibitor of carbonic anhydrase, used as diuretic, anticonvulsant, in ophthalmic practice, also in acute mountain sickness and idiopathic intracranial hypertension. It has many side effects like paresthesia and GIT disturbances, occasionally transient myopia, photosensitivity, metabolic acidosis and rarely can cause hormonal imbalance also. We report a rare case of 32 year old female patient presented with changes in menstruation, acne, weight gain. She was on diamox 250 mg QID since 6 months for treatment of idiopathic intracranial hypertension. She was referred to gynaecologist by treating neurologist. After blood tests and USG, with elevated testosterone levels (82.54 ng/ml) and PCOD like changes in ovaries (well defined cystic lesion in left ovary, few follicles in right ovary), a diagnosis of hormonal imbalance was made. She had completely regular menstrual cycle with a 4 year old child before start of acetazolamide. After ruling out other causes of hormonal imbalance, acetazolamide was identified as culprit. She was put on dose tapering and after 3 months diamox was stopped completely. She is on low dose OCPs and her menstrual cycle is normal now. Carbonic anhydrase is widely present in reproductive system and its inhibition may affect reproductive physiology. Our case is rare and untouched area of concern due to chronic use of acetazolamide.

Keywords: Idiopathic Intracranial Hypertension, Acetazolamide, Hormonal Imbalance.

O14

FLUCONAZOLE INDUCED SJS-TEN OVERLAP IN 37 YEARS HIV MALE: A CASE REPORT IN GGH KAKINADA,ANDHRA PRADESH

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Fluconazole is an antifungal agent used for treatment of onychomycosis, vaginal candidiasis, oral candidiasis. To report a case of SJS-TEN overlap induced by fluconazole in HIV infected person.

This is a case report of 37 years HIV male came to dermatology opd with complaints of erythematous rash all over body and oral lesions with erythematous base present over lips and oral mucosa. One week back he was prescribed Tab. fluconazole for complaint of oral thrush by local physician. He developed SJS-TEN overlap syndrome after 5 days of medication and came to opd on 6th day. Dechallenge was done on 7th day and he was on treatment with injection decadron, moxifloxacin eye drops, candid mouth paint. He was diagnosed as HIV positive one month back and not on HAART. Causality assessment was done using WHO scale.

The erythematous rash due to fluconazole was considered as a probable ADR . Reaction subsided over time. Rechallenge was not done. ADR is reported to ADR monitoring center and entered into vigiflow. As patient showed positive response after dechallenge. Fluconazole can be contributor to this ADR. So physicians should monitor HIV patients on fluconazole therapy.

Keywords: SJS- Steven Johnson syndrome, TEN- toxic epidermal necrolysis, HAART- highly active antiretroviral treatment.

O15

A PHARMACOECONOMIC STUDY OF EPILEPSY TREATMENT AT A GOVERNMENT TERTIARY CARE TEACHING HOSPITAL

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Epilepsy is the second most common neurological condition worldwide which causes increases in health care costs. The currently available data regarding cost of treatment of epilepsy is sparse and most of the financial burden of epilepsy is carried by developing countries. The study assessed economic outcome of epilepsy treatment using the principles of Pharmacoeconomics.

To assess the direct and indirect costs of epilepsy treatment among inpatients diagnosed with epilepsy at a government tertiary care hospital. A prospective observational study was done over a period of 12 months among 165 inpatients over the age of 18 years admitted to the Department of Medicine, MIMS, Mandya. After obtaining informed consent from the patients, sociodemographic data, clinical data about epilepsy and data on costs incurred towards treatment were collected and expenditure was measured as direct and indirect costs.

The total annual cost of epilepsy treatment per patient is INR 4957.41. The total direct cost per patient is INR 3973.00 and total indirect cost per patient is INR 984.36. The direct and indirect costs represent 80.14 % and 19.86 % of the total cost of epilepsy treatment respectively. Cost of drugs accounts for 27.22 % and cost of investigations 71.05 % of the total direct costs. The economic burden due to epilepsy is not adequately examined in developing countries. Since cost estimates are very important in health care planning and delivery of services, this study has estimated the direct and some of the indirect costs of epilepsy treatment among patients diagnosed with epilepsy on treatment.

Keywords: Direct Cost, Indirect Cost, Epilepsy.

O16

PREVALENCE OF METABOLIC SYNDROME IN ADULT PATIENTS OF GENERALISED TONIC CLONIC EPILEPSY STABILIZED ON ANTICONVULSANT DRUGS: A COMPARATIVE STUDY

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Anticonvulsant drugs used for epilepsy treatment have many adverse effects including metabolic syndrome (MetS). The present study was undertaken to compare the effect of first generation vs second generation anticonvulsants drugs on MetS in adult patients of generalized tonic clonic epilepsy(GTCS).

An observational cross sectional study was conducted on 160 adult patients of GTCS who were stabilized on anticonvulsants for at least 3 months. First generation AEDs prescribed were valproate(VPA), phenytoin(PHT) and carbamazepine(CBZ) and second generation AEDs were levetiracetam(LEV), lamotrigine(LTG) and oxcarbazepine(OXC). The Adult Treatment Panel III(National Institutes of Health, 2004) criteria for MetS modified for Asian Indian population was used for the measurement of MetS. MetS is defined as presence of any three out of the five parameters (central obesity, hypertension, triglycerides, HDL and fasting blood glucose(FBG)). Data was expressed as number and percentages. Chi-square(x2) test was used to analyse differences between the values of MetS along with its parameters.

First generation anticonvulsants had significantly more prevalence of MetS in comparison to second generation anticonvulsants (35.7% vs 13.5%, p=0.02). MetS was found to be significantly more with VPA as compared to LEV (36.7% vs 12.9%, p=0.03). On analysis of individual parameters, 2nd generation anticonvulsants fared clinically better as compared to 1st generation anticonvulsants. 2nd generation anticonvulsants like Levetiracetam, oxcarbazepine, lamotrigine cause lesser derangement of metabolic parameters and MetS. Since long term treatment has to be given, so preference maybe given to 2nd generation anticonvulsants in patients prone to develop MetS.

O17

ANTIMICROBIAL UTILIZATION PATTERN IN POST-OPERATIVE PATIENTS AT TERTIARY CARE HOSPITAL

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Antibiotics are prescribed most frequently and accounted for majority of drug costs. A useful strategy for achieving cost efficient healthcare is drug utilisation research as it forms the basis for making amendments in drug policies and helps in rational drug use. The objective of the study was to evaluate the antimicrobial utilization pattern in post-operative patients at tertiary care hospital in Rohtak.

This was a prospective analysis of the case records of 150 post-operative patients admitted in surgery ward. WHO Anatomical Therapeutic Chemical/Defined Daily Dose methodology was used to assess drug utilisation data and drug prescriptions were analysed by WHO core drug indicators.

The total number of DDDs consumed were maximum for ceftriaxone sulbactam (288), amoxicillin clavulanic acid (161). The comparison of number of PDDs and DDDs of various antibacterials showed that for β-lactams, the average PDD was similar to or higher than that of WHO DDD Index. The reason of higher PDD of β-lactams might be its broad-spectrum use, easy availability and affordability. While for aminoglycosides, PDD was lower than DDD, which might be due to safety profiles of aminoglycosides. Overall, correspondence was observed between PDD and DDD for most antibiotics reflecting adherence to international recommendations. overprescribing of antibiotics leads to resistance & to overcome such scenarios, hospital should develop recommendations & policies for use of antibiotics depending on prevailing resistance patterns and costs.

O18

IMMUNOSUPPRESSANTS INDUCED DYSLIPIDEMIA IN RENAL TRANSPLANT RECIPIENTS- A RETROSPECTIVE OBSERVATIONAL STUDY

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Dyslipidemia is a common complication of renal transplantation. Immune suppressants, particularly cyclosporine, the calcineurin inhibitor and others are known to cause dyslipidemia through non-competitive inhibition of sterol 27-dehydroxylase (CYP27A1). On the other hand, dyslipidemia has been found to be associated with higher graft rejection due to decrease in immune suppressant activity and direct graft destruction. Hence the study was designed to analyze the effect of dyslipidemia on chronic allograft rejection.

Retrospective observational study was carried out in the nephrology department of a multispecialty hospital for a period of two months. Clinical and biochemistry reports of 142 renal transplant recipients were collected in designed case report forms. All statistical analysis was carried out using IBM SPSS Statistics 17 and Graphpad Prism 6.0.

Renal transplant recipients of both genders, which 67.6% patients were male and 32.3% female patients. 61.27% of patients were treated with cyclosporine, 33.80% of patients were treated with Tacrolimus, followed by Sirolimus (5.63%), Azathioprine (1.41%) and Rituximab (4.23%). The serum lipid levels were found to be high in cyclosporine treated patients compared to other immunosuppresants. However significant difference was observed only in the levels of total cholesterol, LDL-C and triglycerides ($P<0.001$).

Cyclosporine induces dyslipidemia in renal transplant recepients. Thus monoclonal antibodies such as rituximab or basiliximab should be preferred over conventional immune suppressants. Hence tacrolimus should be considered as first line immunosuppresent regimen.

O19

EFFICACY AND SAFETY PROFILE OF DENOSUMAB AS NEOADJUVANT THERAPY IN ADVANCED OSTEOCLASTOMA

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GCT (Osteoclastoma) is a primary,osteolytic,aggressive,RANK –L +ve tumor of long bones. Denosumab, is a fully humanized monoclonal antibody and a RANK-L inhibitor that is approved by FDA as an adjunct for adults and skeletally mature adolescents with advanced unresectable GCTB. To evaluate efficacy of Denosumab in GCT in Indian patients .2. To access the safety profile of Denosumab.

A prospective, observational study of 8mn duration was carried out in the Dept .of Orthopedics, S.C.B.M.C.H, Cuttack. 8 no.of patients with biopsy proven and having radiological features of GCTB affecting long bones were enrolled . Inj Denosumab 120 mg given s.c every 4 wks till 24wks.VAS and MSTS score were done to evaluate efficacy. Adverse events noted at the end of every month. Demographic profile, clinical data ,histological and radiological tests done and recorded in proper format.

3 Men and 5 women were enrolled for the above study. Mean age of presentation was 34.8 yrs.50% tumor was in femur,75% tumor was of Campannacigrade3.After 24wks efficacy was evaluated. There was 61% decrease in VAS score and 52%increase in MSTS score. There was 90% decrease in giant cells histologically. Majority of the patients (75%) complained extremity pain, backache and myalgia and only 1 patient reported mild hypocalcaemia. Denosumab proves to be highly efficacious in patients having GCT of long bones with acceptable toxic profile.

Keywords: GCT, DENOSUMAB, ADR

O20

IN SILICO PREDICTION OF POTENTIAL SIDE EFFECTS

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In silico is an expression which means "performed on computer or via computer simulation." In silico prediction of drug side-effects in early stage of drug development is becoming more popular now days, which not only reduces the time for drug design but also reduces the drug development costs. In silico tools include data such as protein-protein interactions, pathways of drugs, drug chemical profiles, signalling pathways, drug action pathways and metabolism information.

Till date various ADE(Adverse Drug Event)-associated databases have been constructed: Kuhn et al. developed a computer-readable side effect resource (SIDER) that connects 888 drugs to 1450 side effect items. Davis et al. developed the comparative toxico-genomics database (CTD) which is a public resource of expanded chemical gene disease associations data. Tatonetti et al. presented a comprehensive database of drug side effects (OFFSIDES) and a database of drug-drug interaction side effects (TWOSIDES). A database (namely MetaADEDB), which included more than 520,000 drug-ADE associations among 3059 unique compounds (including 1330 drugs) and 13,200 ADE items by data integration and text mining. Pharmacophore based virtual screening plays a very major role in prediction of potential side effects. This approach includes the prediction of potential side-effect profiles of drug candidate molecules based on their 3D chemical structures and structural-activity relationship. Evaluation of side effect profile is done by nearest neighbour (NN), support vector machine (SVM), ordinary canonical correlation analysis(OCCA), and sparse canonical correlation analysis(SCCA). By gathering the information from various databases and by analysing the 3D chemical structures of potent compounds in their initial stages of development, the side effect profile of that particular compound can be studied.

Keywords: In Silico, Adverse Drug Event, Database, Drug Design, Chemical Structure

O21

AWARENESS OF RESEARCH PRINCIPLES AMONG DENTAL POSTGRADUATES IN A SOUTHERN TEACHING TERTIARY CARE CENTRE: A CROSS-SECTIONAL SURVEY

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Training in research is highly essential during the postgraduate period to impart the good research practices in future. This study was aimed to assess the awareness of research principles among dental postgraduates in a southern teaching tertiary care centre and hospital.

The study proposal was approval by the Institutional Research Committee [IRC] and Institutional Human Ethics Committee [IHEC]. The study participants were informed about the study in detail and written consent was obtained from the participants before enrolling them into the study. This study was a cross-sectional questionnaire based survey conducted on postgraduate trainees of southern dental tertiary care centre and hospital over a period of one year. The obtained data was entered into the MS office excel sheet and the confidentiality of the study participants was maintained throughout the study period.

The study participants had good knowledge on medical research with correct response rate of more than 57% to the questions comprising on various sections of the biomedical research principles. It was also seen that, more than 90% of study participants willing to undergo training in the biomedical research to update their knowledge periodically. The practices towards the research were also found to be satisfactory among postgraduate trainees of southern dental tertiary care centre and hospital, with more than two-third of the study participants were involved in some kind of basic research with presentation of research work in various conferences either in the form of poster or oral. This study revealed, there was a good knowledge with positive attitude and fair practices towards the medical research principles among postgraduate trainees of southern dental tertiary care centre and hospital.

O22

PROTECTIVE ROLE OF ANTIOXIDANTS, CALCIUM AND EXERCISES IN POSTMENOPAUSAL WOMEN

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Menopausal symptoms like hot flushes, vaginal atrophy and other mental symptoms are very distressing. Women also suffer from osteoporosis, decreased immune function and weaking of muscles, connective tissue & collagen disorders and neurological problems. Menopausal women are vulnerable to the action of free radicals because of loss of the antioxidant effect of estrogen as well as the decreased competence of antioxidants defenses with ageing. Hence, there is need of antioxidants to reduce the enhanced oxidative stress and decrease the risk of diseases associated with ageing. Calcium supplementation and exercise have synergistic effect on bone density. Apart from this, exercise can improve self-esteem, reduce stress, elevate mood, enhance energy, reduces chances of cardiovascular disease, increase muscle mass and body metabolism thus resulting in weight loss and alteration of the muscle-fat ratio. Hence, the objective was to study the role of antioxidants, calcium and exercises in menopausal women.

50 postmenopausal women on HRT were selected and 25 women among them supplemented with antioxidants, calcium and advised weight bearing exercises for three months while other received placebo. Efficacy endpoints were improvement in menopausal symptoms, lipid profiles, bone marrow density and reduction in weight. Antioxidants, calcium and exercises reduced menopausal symptoms elevate mood and enhance energy. Exercise and calcium supplementation have synergistic effect on bone density

Adequate supplementation of antioxidants, calcium along with exercises improves lipid profile, alleviation of menopausal symptoms and improvement in bone health with any major adverse effects.

O23

COMPARISON OF EFFICACY AND SAFETY PROFILE BETWEEN PEGFILGRASTIM AND FILGRASTIM IN BREAST CANCER PATIENTS

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Granulocyte Colony Stimulating Factor (G-CSF) is a glycoprotein ,helps in producing cells from bone marrow. Pharmaceutical analogs of naturally occurring G-CSF are used in chemotherapy induced neutropenia to prevent infections and sepsis. This study compares the efficacy and safety of single fixed dose of pegfilgrastim(pegylated form of filgratim) versus daily administration of filgrastim in breast cancer patients

Patients (n=80) with confirmed diagnosis of breast cancer receiving chemotherapy regimen(cyclophosphamide +doxorubicin+paclitaxel)were randomised in 2 groups. One group received pegfilgrastim 6 mg subcutaneously & the other group received filgrastim 300 mcg consecutively for 3 days on day 2 of chemotherapy cycle.The primary end point was the occurrence of neutropenia (neutrophil count <4000 and fever on same day or the day after).The secondary end points were duration of hospitalizations, intravenous (IV) antibiotics required for neutropenia.Any adverse drug reaction(ADR) related to study drug were observed.

40 patient were analysed in each group (197 cycles in group 1 & 176 cycles in group 2). Neutropenia developed in 11.6% & 5.6%($p<0.0423$) ,mean duration of hospital stay were 5-6 days & 3- 4 days, i.v antibiotic usage was7% & 4% and requirement of blood products were 25% & 29% in each group respectively. Bone pain was the most common ADR found due to filgrastim.

Single dose of pegfilgrastim were significantly better than 3 doses of filgrastim for reducing Neutropenia rate in breast cancer patients receiving chemotherapy.

Keywords- G-CSF(Pegfilgrastim, filgrastim),Breast cancer,Neutropenia

O24

PHENYTOIN INDUCED STEVENS JOHNSON'S SYNDROME: A CASE REPORT

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Stevens-Johnson syndrome (SJS) is an uncommon, acute and potentially life-threatening adverse cutaneous drug reaction. It is considered as a hypersensitivity reaction and can be triggered by drugs, infections and malignancies. The drugs most often involved are Allopurinol, antibiotics including sulfonamides, cephalosporin's, anticonvulsants such as phenytoin, carbamazepine and NSAIDs. Phenytoin is the most commonly prescribed antiepileptic drug in adults. An 50 years old female patient on regular treatment with antiepileptic's (phenytoin) since 40 days came to dermatology OPD complaining of Maculopapular rashes and peeling of skin all over the body since one day, ulceration in oral cavity. She gave history of having taken phenytoin 100 mg po bid for 40 days. After taking the phenytoin, she had severe burning sensation over extremities, back, front of chest associated with itching and redness. Gradually blisters developed over extremities, abdomen and face, Ulcerations in oral cavity since two days. There was a rise in body temperature associated with severe headache. On examination bullous eruptions and detachment of epidermis on face and extremities, crusts over lips and erosion of mucous membrane inside her mouth were seen, her lab reports revealed raised random blood sugar levels. All the on-going treatment was stopped. She was treated with injection dexamethasone, pantoprazole, tablet erythromycin, cetrizine and nutritional supplements, hydrated with normal saline and external application fudic cream, oral candid paste, mucopain gel, Serum chemistry revealed elevated RBS and decreased hemoglobin levels were observed. On causality assessment using WHO causality scale was probable.

Key words: Phenytoin, Hypersensitivity reactions, Stevens-Johnson syndrome

O25

ANTIPSYCHOTIC INDUCED EARLY FUNCTIONAL BRAIN CONNECTIVITY CHANGES IN SCHIZOPHRENIA

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Antipsychotic medications are the frontline treatment for schizophrenia. Functional magnetic resonance imaging (fMRI) informed large-scale resting state brain network changes with antipsychotic medications are not well studied. This not only enables us to identify the mechanistic basis of antipsychotic action, but also enables in identifying predictors of response to antipsychotic medications. In this study, we aimed to examine short-term (6-weeks) changes in resting state brain functional connectivity following antipsychotic treatment in never treated schizophrenia patients. 15 schizophrenia patients who were recently diagnosed according to the Diagnostic Statistical Manual IV criteria underwent resting state fMRI scans in a 3-tesla MRI scanner before and 6-weeks after treatment with risperidone – an atypical antipsychotic medication. After quality checks of structural and functional MRIs the scans were subject to registration, slice timing correction, spatial smoothing and motion correction. The FMRIB software laboratory (FSL) MELODIC toolbox was used to identify 15 resting state functional networks. Dual regression was applied in a paired samples design with 5000 permutations to identify changes in functional connectivity for two contrasts (a) baseline > follow-up and (b) follow-up > baseline to identify changes with risperidone.

In the first contrast, patients demonstrated significantly greater connectivity of the sensorimotor, visual, auditory and executive control networks with regions in the posterior temporo-occipital cortex on the right side. In the second contrast, patients demonstrated greater connectivity of the bilateral inferior frontal and premotor cortices with the default mode network. Risperidone decreases hyper-connectivity of the posterior temporo-occipital regions which are usually associated with the florid delusions and hallucinations of schizophrenia and improves connectivity of the default mode network, which is an important hub for social cognition and functioning.

Poster Presentations

P1

IMPACT OF UNIT BASED CLINICAL PHARMACISTS INTERVENTIONS IN PREVENTION OF MEDICATION ERRORS IN A MULTISPECIALTY HOSPITAL

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The main of the study was to assess the impact of clinical pharmacists interventions in the prevention of medication errors.

This retrospective study was carried out in Jaypee Hospital, Noida, Uttar Pradesh, India. All In-patients that were admitted in the hospital over the study duration were included in the study. During their hospital stay medication errors were intercepted by unit based clinical pharmacists through reviewing their prescription and intervention were made and then reported to clinical pharmacology department, this data of the past six months from January 2018 to June 2018 was obtained retrospectively and analyzed using IBM SPSS Version 25.

A total 17559 prescriptions were reviewed for medication errors in which 13361 medication errors were intercepted. Among these patients who experienced medications errors 59% were males and 41% were females. The mean age of patients was found to be 50.29 years. The majority of medication errors intercepted were 70.68% prescription error. On assessment of severity based on NCCMERP Index, it was found that most of the medication errors belonged to category B (62%). The unpaired t-test between six months data to assess the effectiveness of pharmacists interventions was found to be statistically significant $*P < 0.05$.

In this study male gender, age group of 50-70 years, medication error category B, prescribing error were found to be more prevalent. There was a 21% decrease in incidence of medication errors which clearly indicates the impact of unit-based clinical pharmacists interventions in minimizing medication errors.

P2

STUDY OF PRESCRIPTION PATTERN AND SWITCHING OVER TECHNIQUES OF ANTIPSYCHOTICS IN PSYCHOTIC PATIENTS IN A TERTIARY CARE HOSPITAL

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Psychiatric disorders are increasing with an incidence of 0.5 to 5 per 10,000 population. Atypical antipsychotics have selective receptor action with better safety profile. Psychosis is a chronic disorder requiring prolonged treatment, hence selection of drug should be emphasized on not only on efficacy but also on suitability , safety, compliance and cost. There are scanty reports available regarding the prescription patterns and the switching over patterns of antipsychotic drugs. Therefore, this study was undertaken to analyse the prescription pattern and switching over techniques adopted in patients of psychosis in our hospital.

This retrospective study was conducted in the department of pharmacology and psychiatry in SCB medical college and hospital, Cuttack from July 2017 to Sept. 2017. Prescription pattern was studied from the case sheets using WHO core prescribing indicators and switching between the drugs was studied under four headings: a) Titrated b) Immediate c) Gap d) Overlapping.

Case sheets of 72 patients were studied.60 patients used atypical antipsychotics (83.3%)while typical antipsychotics were used in 22 patients (30. 5%).The most commonly prescribed atypical antipsychotic was Olanzapine(51.3%),followed by Risperidone(31.9%).Most common switching over method observed was overlapping.

The above study revealed, Olanzapine was used in majority of psychotic patients and common method adopted for switching over technique was Overlapping.

Keywords: Atypical antipsychotics, switching over techniques, prescribing patterns

P3

AN OVERVIEW OF REPURPOSING DRUGS - THE ECONOMIC NEED OF THE HEALTHCARE SECTOR

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Drug repurposing studies whether a drug designed for one disease is safe and effective for another disease. The current study is done to signify its critical role, to identify the barriers and steps to promote it.

A literature search for articles on drug repurposing was carried out in the PubMed and ScienceDirect for the years 2016-2018.Publications were selected if they were in English language and the articles were analysed based on revelations of details regarding drug repurposing.

Repurposing reduces the cost and duration of clinical trials. Several barriers like economical (less funding by pharmaceutical companies on rare diseases treatment), patency (difficulty securing already disclosed patency for failed drug) , Legal and ethical(lack of seeking legal and ethical expertise opinions by clinicians) and profit to researchers(new research brings more profits than reviving the old) have been identified. Steps like infrastructure building , public awareness , collaborating government and private sectors for ideas and funding can help overcome the hurdles.

Drug repurposing have huge promises to generate more, faster, affordable, accessible and effective treatments for rare diseases and hence needs to be encouraged. Patients, researchers, government, pharmaceutical companies need to come together to support and promote it.

P4

A CROSS-SECTIONAL STUDY TO EVALUATE POTENTIAL DRUG-DRUG INTERACTIONS AMONG PATIENTS WITH ISCHEMIC HEART DISEASE AT A TERTIARY CARE HOSPITAL

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Effects of one drug changed by the presence of another drug, herbal medicine, food, drink or by some environmental chemical agent.DDI accounts for 27%ADR.

In IHD, the number of associated comorbidities are observed to be more, leading to increase in the number of drugs prescribed hence even the number of DDIs also increases.

Hence this study was undertaken to evaluate the potential drug-drug interactions of different classes of drugs in patients with Ischemic heart disease

This Cross-sectional observational study conducted between Feb 2018 – June 2018 among 250 Patients diagnosed with IHD among patients of medicine department of KIMS Hospital.Collected prescriptions were also analysed for DDIs using Lexicom software.

Among 250 patients males constituted the majority,results depicted in the form of graphs.DDIs were categorized according to their risk and were discussed with cardiologist for further management.

Our study showed that Antiplatelets and Statins constituted the majority and DDI can be avoided by careful monitoring.

P5

REVERSAL OF INTRACEREBROVENTRICULAR STREPTOZOTOCIN INDUCED NEUROBEHAVIORAL, NEUROINFLAMMATION AND OXIDATIVE STRESS BIOMARKERS ALTERATION BY BISPHOSPHONATE IN MICE MODEL OF ALZHEIMER'S DISEASE

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Alzheimer's disease is a neurodegenerative disorder manifested by progressive cognitive deficit and a number of complex neuropathologies, including neurofibrillary tangles, neuritic plaques and cholinergic dysfunction. The existing therapeutic treatment confer only symptomatic relief but not completely correct the pathological basis of AD. Therefore, several hypothesis have been tested for defining points of pharmacological interventions in AD. A nitrogen containing bisphosphonate, alendronate, is recommended for treatment of bone disorders like osteoporosis. Earlier reports cited its beneficial role in brain via inhibiting acetylcholinesterase enzyme and cholesterol synthesis which is involved in development of AD. So we hypothesized the role of alendronate in this disorder. Preliminary in silico modelling to investigate its affinity to beta and gamma secretase enzymes. Swiss albino mice (8 in each different groups) were administered with intracerebroventricular streptozotocin (3mg/kg) at 1st and 3rd day and alendronate (1.76mg/kg) and donepezil (5mg/kg) orally for 15 days. All mice were employed to different behavioral paradigms following biochemical assessment. Alendronate was found to reverse the cognitive deficit induced by intracerebroventricular administration of streptozotocin in mice as assessed by increased % alteration in spontaneous alteration behavior, prolonged step-through latencies in passive avoidance, reduced escape latency, path length and increased % dwell time in Morris water maze test. Furthermore, the enhanced levels of amyloid beta, BACE-1, acetylcholinesterase enzyme as well as pro-inflammatory cytokines and oxidative stress by streptozotocin were significantly attenuated by the alendronate. In histopathological analysis, alendronate was found to reduce the Aβ deposition in brain tissue. Taken together the observed results of the present study, alendronate may ameliorate streptozotocin induced dementia of AD type in mice.

Keywords: Alendronate, dementia, streptozotocin, Alzheimer's disease and molecular docking.

P6

ROLE OF LETROZOLE IN THE TREATMENT OF UTERINE MYOMAS

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Uterine myomas, the most common solid benign tumours, occur in 20 - 40% women in their reproductive years. Various medical and surgical therapeutic options are available but the search for an ideal medical option continues. Aromatase inhibitors have been reported to have a potential role in the treatment of oestrogen-dependent conditions like endometriosis and uterine myomas.

To evaluate the effect of letrozole on symptomatology and size of uterine myoma in reproductive age group women.Total number of 23 women aged between 20-50 years with menstrual or pressure symptoms and having a intrauterine myoma of size 2cm or more were enrolled. They received tablet letrozole 2.5 mg a day for 12 weeks and the effect of the drug on symptomatology was measured by using PBAC score (Pictorial Bleeding Assessment Chart) at baseline and then at 4, 8 and 12 weeks. Size of myoma was measured at baseline and then at 12 weeks. We also studied the adverse effect profile.

The symptomatology score showed a significant improvement from baseline i.e 268.34 ± 36.99 to 113.86 ± 56.37 ($p < 0.01$) at 3 months. The mean myoma size reduced from 4.40 ± 1.93 cm to 3.82 ± 1.83cm ($p< 0.05$) at the end of 3 months. Nausea and hot flushes were the main adverse effects observed. Letrozole not only improves the symptoms of myoma, significantly, but also its size, with tolerable side effects.

Keywords: Uterine myomas, PBAC, Letrozole

P7

CRITICAL APPRAISAL OF DRUG PROMOTIONAL LITERATURE USING WORLD HEALTH ORGANISATION GUIDELINES

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Pharmaceutical marketing using drug promotional literatures is an important strategy adopted by the companies to promote their drugs. The primary objective of the present study is to compare the drug promotional literature of different pharmaceutical companies on the basis of World Health Organization (WHO) guidelines on ethical drug promotion. This observational, cross sectional study was conducted at a tertiary care hospital, Delhi. The promotional literature was evaluated in accordance with WHO guidelines, nature of claims, pictorial content presented in it and for the cited references.

A total of 208 promotional brochures were analysed. Only few (5.8%) of the promotional literature fulfilled all the criteria as mentioned by the guidelines. Nutritional supplements (27.9%) were the most promoted group of drugs. Pharmaceutical companies were most reluctant to provide information regarding contraindications (9.6%), adjuvants (11.5), side effects (10.6%) and drug interactions (9.6%). Generic name, brand name, dosage form, therapeutic indications were outlined in most of the brochures. Exaggerated emotional claims were made in 47.1% brochures, followed by that of efficacy in 39.4% and safety in 25% of brochures. Pictures of medicinal products outnumbered others with 39.9% followed by pictures of women, children and doctors with 20.7%, 17.3% and 13.5% respectively.

Majority of the drug promotional literature did not comply with the ethical guidelines and was inadequate in terms of their adequacy, quality and reliability. Hence, it can be concluded that the majority of the promotional advertisements that are given to the prescribers are not able to spread awareness towards rational prescribing.

P8

COMBINATORIAL CHEMISTRY ON SOLID PHASE

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Combinatorial chemistry involves synthesis of compounds in mass instead of single compounds & it saves time and cost associated with drug discovery

Material & Methods:-Solid phase organic synthesis is a rapidly expanding area of synthetic chemistry which is being widely exploited in the research for new biologically active compound by combinatorial technique. In addition, to overcome some of the drawbacks of existing materials, several new resins and new methods of handling solid supports have been developed. New methodologies have also been introduced to simplify the preparation of solid supports. Combinatorial chemistry is especially common in CADD (Computer aided drug design) and can be done online with web based software such as Molinspiration.In the past, chemists have traditionally made one compound at a time. For example compound A would have been reacted with compound B to give product AB, which would have been isolated after reaction work up and purification through crystallization, distillation, or chromatography. In contrast to this approach, combinatorial chemistry offers the potential to make every combination of compound A1 to Am with compound B1 to Bn. Although investigating the solid-state synthesis of peptides.

Combinatorial chemistry assembles building blocks to make new molecule. Large libraries can be made by assembling all possible combinations of a set of building blocks & new molecule can be identified.

Most of the in this commentary has focused on the generation and examination small organic molecules but obviously combinatorial libraries of peptides, nucleic acids and oligosaccharides continue to be generated.

P9

OVER THE COUNTER (OTC) MEDICINES AMONG RURAL POPULATION: A CROSS SECTIONAL STUDY

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The main aim of the study was to assess the knowledge, attitude and practices of OTC drugs among rural population as well as which indications OTC drugs are used most of the time. A cross- Materials and methods: sectional study was carried out over a period of four months (November 2017 to February 2018) in Moga, Punjab, India using a self administered pre-validated questionnaire set which was prepared based on previous studies to collect the information pertaining to the pattern of OTC drugs use, reason and indication for OTC drugs use, list of drugs commonly used for self-medication. Among 70 study participants 69% knew about the OTC drugs. On an average 7 times in last one year they practiced self-medication and used OTC drugs. It was seen that reasons for taking OTC drugs were various majority of them 93 % people take it due to their low cost. Analgesics and antipyretics were the most common class of drugs self –medicated by the majority of the participants 100%, followed by Antacids 81%. Pain and fever were the most frequently reported indications for use of OTC drugs headache, were the second and third most common indications were cough & cold. While considering the attitude and practices of self-medication it was found that a majority of study participants occasionally 36% read the instructions given on the product label. In case of checking the expiry date of the drug before use 39% always check the expiry date before using the drug and 30% of participants never checks the expiry date. The main reason for consuming the OTC drugs majority of participants 91% agreed was whenever they feel sick. A majority of participants 61% immediately discard the drug when it shows change in shape, color and odour. Over 74% of the study participants consult to pharmacist before using OTC drugs.

Keywords: Over the counter drugs, Self medication, OTC drugs, Practices, Rural population.

P10

ASSESSMENT OF METHODOLOGICAL QUALITY OF SYSTEMATIC REVIEWS ON SUMATRIPTAN FOR THE TREATMENT OF MIGRAINE

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Systematic literature reviews (SLRs) pile up a well-defined objective, comprehensive literature searches, pre-determined inclusion and exclusion criteria for the study selection, critical appraisal, data extraction and finally synthesis of results from the available evidence on a particular topic. **ROBIS and AMSTAR are the tools for assessing the methodological quality or the risk of bias (RoB) in SLRs.**

We aimed to assess the methodological quality of SLRs conducted on the effect of Sumatriptan for the treatment of migraine using ROBIS and AMSTAR.

A literature search was conducted in PubMed on February 2018, and the references of all included reviews also searched for other relevant studies. No language or date restrictions were imposed. All the SLRs assessing the efficacy and safety of sumatriptan (by any route) for the treatment of migraine were included. Methodological quality of included reviews was assessed using the ROBIS and AMSTAR. Two authors were independently selected and assessed the quality of included reviews and disagreements were settled through discussion or by consulting a third reviewer.

A total of 16 out of 44 reviews were identified that met our inclusion criteria. Nine were Cochrane SLRs. Nine studies considered to be with low RoB, whereas, six studies graded as high and two studies considered as unclear RoB using the ROBIS tool. Six studies scored 8-10, which is considered to be high quality, whereas six studies scored 3-4, considered to be low quality and other six studies scored 8, which was considered to be moderate quality using AMSTAR tool. ROBIS assessment rates the Cochrane reviews better as the Cochrane

reviews have more detailed information on the review methods which makes it easier to apply on ROBIS.

Our research suggests that ROBIS is more rigorous and reliable tool than AMSTAR in assessing the methodological quality of the included SLRs. We found most of the reviews are good quality as they all were the Cochrane SLRs.

Keywords: ROBIS, AMSTAR, Sumatriptan, Migraine

P11

COST-EFFECTIVENESS OF PHARMACOTHERAPEUTIC INTERVENTION IN CHRONIC LOW BACK PAIN: AN EVIDENCE FROM SYSTEMATIC REVIEW

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Low Back pain is a common problem and a major cause of disability and health care utilization. Purpose. Pharmacotherapeutic interventions like Pregabalin and duloxetine and opioids are that have demonstrated benefit in chronic low back pain (CLBP). The specific aim of this study was to systematically review the cost-effectiveness of pharmacotherapeutic interventions in CLBP.

The search strategy was designed to identify peer-reviewed cost-effectiveness evaluations of pharmaceutical therapies for management of CLBP, accessing five key databases. All identified publications were reviewed and screened according to pre-defined eligibility criteria. Data extraction was designed to reflect key data challenges and approaches to modelling in CLBP pain and based on published guidelines. Quality of included studies were assessed by Drummonds criteria.

The search strategy identified 4 cost-effectiveness analyses meeting the inclusion criteria, of which 3 had original model structures using cohort-level state-transition (Markov) models and one discrete-state time-dependent semi-markov model. Studies identified in the review focused on antidepressants like duloxetine, amitriptyline Pregabalin and NSAIDS include naproxen, celecoxib and other opioids. On average, gabapentinoids was associated with lower costs and larger effects for quality-adjusted life-year (QALY) in comparison with usual care for chronic low back pain from a healthcare perspective (based on ICUR).

Pregabalin seems to be cost-effective compared with usual care for chronic low back pain. The authors further encourage transparent reporting of inputs used to inform cost-effectiveness models, with robust, comprehensive and clear uncertainty analysis and, where Feasible, open-source modelling is encouraged.

P12

HIDDEN ASPECTS OF MEDICATION ERROR

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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, has been defined by NCCMERP as Medication Errorr.

Use of internet & web search with respect to medication error.

ME can occur due to faulty prescription writing that is irrational, inappropriate, ineffective, underprescribing or overprescribing, or fault in manufacturing the formulation or wrong dispensing or wrongly administering the dose or failure to monitor therapy .These errors are classified as knowledge-based, rule-based ,action-based or memory-based error. In U.S , ME accounts for 28% of all medical mistakes. With respect to India, studies from Uttarakhand and Karnataka reported ME rate as high as 25.7% and 15.34%, respectively, in hospitalized patients. A study from Gujrat showed ME rate 45.90%. Another study from mysore reported ME incidence of 27.8% in general surgery wards. Example of faulty prescription - warfarin prescibed with erythromycin, oral

treatment in a patient with dysphagia , writing diazepam for diltiazem and illegible writing such that 'Panadol' (paracetamol) is dispensed instead of 'Priadel' (lithium). ME may result in adverse drug reactions, drug-drug interactions, reduced compliance and quality of life of patient, they may have significant health and economic consequences and can sometimes lead to death also.

Avoiding medication errors is extremely important so that appropriate medicine within the limits of therapeutic decisions in an optimal dose be prescribed to maximize the balance of benefit to harm to the patient.

Keywords: Medication Error, adverse events, drug drug interaction, faulty, prescription

P13

ADR CASE REPORT ON PREDNISOLONE INDUCED PERIORAL DERMATITIS

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Prednisolone is a glucocorticoid with many anti-inflammatory uses and prominent adverse effects.

Perioral dermatitis is a skin disorder resembling acne or rosacea. In most cases, it involves tiny red pimples with itching and burning on the lower half of the face, in folds of the nose and around the mouth.

A 29 years old male from Dehradun came to Dermatology department of VCSGGIMSR. He gave a history of genital itching for which he went to a private practitioner who prescribed tablet Prednisolone and Capsule Fluconazole. Two days after taking the drugs, he developed black coloured rash around the lips and eyes with itching.

We applied the WHO-UMC causality scale for the suspected drugs – Fluconazole and Prednisolone.

According to WHO-UMC causality scale, it can be concluded that the adverse reaction was possibly caused by Prednisolone as well as Fluconazole. Although according to the causality scale, the ADR can also possibly be caused by Fluconazole, previous literature reports mention steroid induced perioral dermatitis. Topical steroids are mostly involved in this type of ADR, as per a review by Mokos ZB, et al, but there have been reports of systemic steroids causing perioral dermatitis by Clementson B, et al.

Predisolone has possibly caused perioral dermatitis in the patient.

P14

PHENYTOIN INDUCED STEVENS JOHNSON SYNDROME: A CASE REPORT

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Stevens-Johnson syndrome (SJS) is a severe adverse cutaneous drug reaction that predominantly involve the skin and mucous membrane. Drugs have been implicated in most of the cases. Diagnosis relies mainly on clinical signs together with the histological analysis of a skin biopsy.

A 25-year-old male with history of seizure disorder (GTCS) was admitted in ICU with complaint of fever, widespread rash and stinging of eyes. Mucocutaneous examination revealed macular erythematous and purpuric lesions, predominantly over face, trunk and extremities. There was a presence of atypical flat targetoid lesions on extremities, haemorrhagic crusted lesions on lips along with buccal mucosal erosions and conjunctival injection. General physical and systemic examination were unyielding.

Laboratory investigations revealed mild leucocytosis and transaminitis. On enquiry, the patient was prescribed anticonvulsant drug (Phenytoin in a dose of 300 mg per day) 2 weeks back for GTCS. A clinical diagnosis of Stevens Johnson syndrome was contemplated. Patient recovered fully on withdrawal of the drug, supportive care and glucocorticoid therapy.

SJS is a rare disorder that has been described in all age groups and races. Genetic susceptibility, drugs and infections are implicated as the trigger in most cases. The reaction is idiosyncratic and independent of dose of drug. SJS is a potentially fatal condition with adverse sequels including death, if not intervened early. The physicians must have knowledge about the condition for early recognition and intervention.

P15

PATTERN OF CUTANEOUS ADVERSE DRUG REACTIONS IN TERTIARY CARE TEACHING HOSPITAL IN KUMAON REGION

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Adverse drug reaction is defined as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function." The incidence of adverse Cutaneous drug reactions (CADRs) among all adverse drug reaction may varies from 15 to 30%. It may be negligible, serious or even fatal. Serious and fatal adverse Cutaneous drug reaction is common causes of hospitalization or its prolongation.

This was a retrospective study conducted at the tertiary care centre at Dr.Sushila tiwari Government Medical College Hospital & Institute Haldwani Nainital. Data was collected during the period of one year from various department to the ADR monitoring centre attached to department of Pharmacology under the Pharmacovigilance Programme of India (PvPI) using suspected ADRs reporting forms. The reported ADRs were evaluated for causality and severity.

A total of 123 patients were included during our study period out of which 43 males (34.95%) and 80 females (65.04%) reported CADRs. Most common age group suffered from CADRs was 20-29 years (22.76%). Itching (30.68%) was the most common morphological pattern of ADR. The most common class of drug causing Cutaneous drug reaction was antitubercular drugs(26.51%).Amongst all reported cases 40.65 % were serious and 59.43% were non-serious. Hence, this study shows CADRs are common with widely used drugs and detection of similar will help to reduce suffering of mankind and can also strengthen the Indian Pharmacovigilance database.

Keywords: CADRs, PvPI, ADRs, ADR reporting form.

P16

DICLOFENAC INDUCED TOXIC EPIDERMAL NECROLYSIS IN 50 YRS FEMALE: A CASE REPORT IN A TERTIARY CARE HOSPITAL

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NSAID'S are drugs of choice for various inflammatory conditions and pain. Among them COX2 inhibitors and propionic acid derivatives are known to produce serious cutaneous adverse effects. It is a case report of Diclofenac induced TEN resulting in death. To report a case of TEN induced by diclofenac in a patient with joint pains and to emphasize its early diagnosis. A 50 year old woman was admitted with erosions all over the body (BSA >30%), after taking inj. diclofenac single dose for joint pains. No past history of drug allergy. Diagnosis was confirmed by skin biopsy. At the time of admission her electrolytes, RFT were deranged along with metabolic changes. Dechallenge was done & patient was put on Systemic Steroids, Cyclosporine, Insulin, Antibiotics & other supportive measures. Despite resuscitative measures patient landed up in AKI due to sepsis secondary to TEN & expired within 7 days of hospitalisation. Causality assessment was done using Naranjo & WHO scale.

Naranjo score 7 & WHO scale revealed ADR – Probable. Prognosis was done using SCORTEN criteria (score >5). Despite all resuscitative measures patient's condition deteriorated and resulted in death. It was reported to AMC and uploaded in Vigiflow. Since this serious ADR is proved to be caused by Diclofenac, we should be vigilant while administering it.

Keywords : TEN- Toxic Epidermal Necrolysis , SCORTEN criteria

P17

ADVERSE DRUG REACTION PATTERN IN PATIENTS ON ANTIRETROVIRAL THERAPY IN TERTIARY CARE HOSPITAL

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The human immunodeficiency virus (HIV) disease continues to be a serious global health issue. Antiretrovirals mainly suppress viral load, thus restoring the immune function.

Despite showing considerable efficacy in reducing mortality and morbidity, ART is associated with wide range of adverse effects which affects treatment adherence leading to treatment failure.

To monitor and explore the pattern of occurrence of ADRs to various ART regimens at ART centre in tertiary care hospital. A prospective, Observational clinical study was carried in OP settings of ART centre in Government General Hospital, Kakinada.

A total of 254 patients on various ART regimens were studied for suspected ADRs over 6 months (1st January 2018-31st March 2018). Adverse event history, medication history and other relevant details were noted. Causality & severity of reported ADRs were assessed.

Out of 254 patients, 52.75% patients presented with adverse drug reactions.70.17% & 47.71 % presented with ADRs with Zidovudine based regimens & Tenofovir based regimens respectively.

Tenofovir based regimens are found to have less ADRs when compared to Zidovudine based regimens. Monitoring of ADRs of ART regimens helps to reduce the occurrence of severe ADR & improve ART adherence.

Keywords: ADRs- Adverse drug reactions, ART- Antiretroviral therapy.

P18

ROLE OF PHARMACOVIGILANCE IN UNANI SYSTEM OF MEDICINE

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Unani Medicine includes totally the drugs of natural origin, comprising 70% of plant origin and rest from animal and mineral origin. Herbs used in Unani medicine have some plus point than allopathic medicines as they have very negligible side effects on human systems but more researches are needed to ensure their reliable, natural and therapeutic effects. Due to adulteration, faith in herbal drugs has declined.

Pharmacovigilance, also known as drug safety. According to WHO, "Pharmacovigilance activities are done to monitor detection, assessment, understanding and prevention of any obnoxious adverse reactions to drugs at therapeutic concentration that is used to modify or explore physiological system or pathological states for the benefit of recipient". ADR is common clinical problem. Pharmacovigilance, is the only best way to safeguard the public health. The medication security issues were globalized, fortify and systematized after the foundation of WHO program for international Drug Monitoring in 1968. Prevention of adverse drug reaction (ADRs) is the essence of Pharmacovigilance and its precise diagnosis is crucially a primary step, which still remains a challenge among specialists. Avicenna (980-1037 A.D) in the Unani classical literature (Al-Qanoon) has mentioned that Drug Monitoring starts from the day of collection of the drug till its use by the patient and follow -up the patient.

Treatment of patient with drugs through following rules: choice of drugs by their quality, selection of drugs by their quantity and this rule includes changes in weight, potency and properties as well as the time of drug administration. So, if follow the basics of Unani medicine we can safe from ADR in multi ways and this is the prime differentiation and safety measurement in Unani drugs.

Keywords: Pharmacovigilance, Unani system of medicine, Avicenna, WHO.

P19

SOLID LIPID NANOPARTICLES AS A DRUG DELIVERY SYSTEM FOR BRAIN TARGETING VIA NASAL ROUTE

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Certain mechanism like presence of highly complex structure *i.e.* blood brain barrier (BBB), P-glycoprotein (active efflux transporter) and certain enzymatic activity protect the brain in adverse conditions. These mechanisms especially BBB frustrate therapeutic interventions during the treatment. As a result most of the drug substances are fruitless in treating brain disorders, because they are not able to reach the brain in desired amount required for therapeutic activity. As a consequence, several invasive and non-invasive strategies are presently being used to increase the delivery of drugs across the BBB by opening it. However, opening the BBB by such strategies may allow the entry of certain undesirable substances to the brain. There are several drugs (especially peptides and proteins) which cannot cross the BBB or produce the systemic side effects when given orally. Solid lipid nanoparticles (SLNs) via intranasal route furnish a way out of these potential problems. It is an innovative, practically feasible and simple approach for delivery of certain categories of drug that cannot reach the brain due to above mentioned reasons. The drug administered through intranasal route bypasses the BBB and prevents the systemic exposure of drug and hence systemic side effects associated with drug molecules. This is due to the unique connection provided by olfactory and trigeminal nerves between the brain and external environment. SLNs are colloidal carrires made up of solid lipids, possessing exclusive benefits over other drug delivery carriers. The lipids used for the preparation of SLNs are usually biocompatible and biodegradable. SLNs hold great capabilities for nose to brain delivery and lured researchers to explore this field.

Keywords: Blood brain barrier, Brain targeting, Central nervous system, Nose to brain delivery, Solid lipid nanoparticles.

P20

CURRENT ASPECTS AND SAFETY OF PHARMACOVIGILANCE: A REVIEW

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Pharmacovigilance (PV) play a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst drug and their effects on human. Pharmaceutical and Biotechnological medicines are designed to cure, prevent or treat diseases; however, certain risks particularly adverse drug reactions (ADRs) are also associated which can cause serious harm to patients. Recently, pharmacovigilance has been confined, mainly to detect adverse drug event that were previously either unknown or poorly understood. Adverse events reported by PV system potentially benefit to the community due to their proximity to both population and public health practitioners, in terms of language and knowledge, enables easy contact with reports electronically. The PV team obtain valuable additional information, builds up the scientific data contained in the original report and makes it more informative. This review simply gives the knowledge about drug safety, worldwide pharmacovigilance centres and their role, benefit and challenges of pharmacovigilance and its future consideration in healthcare sectors.

Keywords : Pharmacovigilance, ADRs, Drug Safety, Healthcare.

P21

PHOSPHONIUM-FUNCTIONALIZED AMPHIPHILIC DIBLOCK COPOLYMERS FOR NUCLEIC ACIDS DELIVERY

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Intracellular delivery of nucleic acid drugs, such as DNA and siRNA (short interfering RNA), can either trigger or knockdown the expression of specific proteins that are linked to several diseases. However, the poor cellular uptake of genetic material, due to its overall negative charge and rapid degradation of DNA/RNA by nucleases in biological media, still represent major challenges toward their successful cellular delivery. Viral vectors have been used successfully to deliver genetic materials to cells, but have raised many safety concerns. On the other hand, nonviral vectors, deliver genetic materials intracellularly via electrostatic interactions with the negatively charged nucleic acids to form what so-called lipoplexes and polyplexes, respectively. These cationic complexes can then undergo endocytosis and ultimately release the genetic materials in the cytosol. Latest being the phosphonium cation which due to its efficient charge distribution (centered on the phosphorus atom, while distributed through adjacent carbons on the ammonium moiety) leads to stronger and more stable interactions with the negatively charged nucleic acids, providing biocompatible nanocarriers for therapeutic nucleic acid delivery.

P22

ANTIBIOTIC PRESCRIBING PRACTICES BY DENTISTS: A REVIEW

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Antibiotics are important in the prophylaxis and management of infection in patients at risk of experiencing microbial disease. Indications for the use of systemic antibiotics in dentistry are limited, since most dental and periodontal diseases are best managed by operative interventions and oral hygiene measures. However, the literature provides evidence of inadequate prescribing practices by dentists, due to a number of factors ranging from inadequate knowledge to social factors. Here we sought to review studies that investigated the pattern of antibiotic usage by dentists across the globe. We have genuinely attempted to outline the main lacunas in the knowledge of antibiotic prescription. The main conclusion is that, unfortunately, the prescribing practices of dentists are inadequate and this is manifested by over-prescribing practices. Recommendations to improve antibiotic prescribing practices are also presented in an endeavour to curb the increasing incidence of antibiotic resistance and other side effects of antibiotic abuse.

P23

ADRs –TYPE, PATTERN AND CAUSALITY ASESSMENT: A PHARMACOVIGILANCE STUDY

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Indian Pharmacopoeia Commission [IPC] is the current national co-ordinating centre for Pharmacovigilance Progamme of India [PvPI]. The major goal of this PvPI is to booster the safety medicines for better health care in India. It is important to monitor the ADRs continuously throughout the post-marketing period to detect any delayed or rare ADRs.

A prospective observational study was done in a Southern based medical institution, for a period of two months. The study protocol was cleared by the Institutional Human Ethics Committee [IHEC]. The collected ADRs from tertiary care centre and hospital were analysed using ADR causality assessment scales and represented in frequency and percentages. A total of eighty eight ADRs were reported during the study period. It was found that drugs related to the antimicrobial class [53.41%] were responsible for maximum causation of ADRs, followed by drugs related to the autacoids and CVS [12.5% each], endocrinal system [7.95%], CNS [5.68%], GIT [2.27%] and drugs acting on other/multiple systems [5.68%].

ADR causality assessment by WHO scale revealed, maximum number of ADRs were possible [60.23%] followed by probable/likely [23.86%] and unlikely [15.91%]. It was seen in Naranjo algorithm scale that ADRs were possible in 76.14%, probable in 13.64% and definite in 10.23% of cases. Modified Hartwig and Siegel scale found 69.32% of ADRs were mild in nature followed by 30.68% as moderate in nature and none as severe. The Schumock & Thornton preventability scale identified 55.68% of all ADRs were definitely preventable, 29.55% as probably preventable and rest as not preventable.

This study showed that antimicrobial class of drugs were responsible for maximum number of ADRs; drugs related to respiratory system, blood, ANS and skin contributed for least/none number of ADRs. Causality assessment of ADRs revealed that, maximum number of the ADRs were possible in both the WHO and Naranjo scales. It was also seen that, maximum number of ADRs were mild in nature on Modified Hartwig and Siegel scale; and definitely preventable on Schumock & Thornton ADR preventability assessment scale.

P24

COGNIZANCE OF BIOSTATISTICS PRINCIPLES AMONG FINAL YEAR UNDERGRADUATE STUDENTS: A CROSSSECTIONAL SURVEY FROM A SOUTHERN TEACHING MEDICAL INSTITUTION OF INDIA

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Biostatistics is important subject in the medical field to impart the better research practices among young budding doctors. It should be taught in early periods of medical training, to make the better physician cum good researcher in future. The awareness regarding the same varies from place to place and hence among institutions.

This is a cross-sectional observational study, done in a Southern based teaching tertiary care centre over a period of one and half year. Prevalidated questionnaire based on the application of biostatistics principles in biomedical research was distributed to the medical final year undergraduate students who formed the study population. A total of sixty two medical final year undergraduate students were recruited into the study, after obtaining their valid written informed consent. The study proposal was approved by the Institutional Research Committee [IRC] and Institutional Human Ethics Committee [IHEC].

The study found that, only less than 50% of all answers related to the knowledge domain on '*application of biostatistics principles in biomedical research*' were found to be correct. Majority [more than 62.5%] of study participants were unaware or not heard of any software tools related to biostatistics. This study also showed that, majority of the study participants [more than 67.25%] opined as 'strongly agree' for the question to a '*good research must have training in biostatistics*'. More than 92% of study participants opined to have *seminars/ workshops/CME* on biostatistics course for their improvement in biostatics subject.

It was also observed that, more than two-third opined to culminate the biostatistics course/subject in undergraduate/postgraduate medical curriculum. In this study, it was also found that, only less than one-sixth of the study population was confident of drawing the conclusion from the results of the study.

This study concluded that, there was a poor knowledge and poor practices but with positive attitude towards the application of biostatistics principles in biomedical research among medical final year undergraduate students in a southern teaching medical institution.

P25

KNOWLEDGE AND PRACTICES TOWARDS THE BASIC BIOSTATISTICS PRINCIPLES AMONG UNDERGRADUATE NURSING TRAINEES OF SOUTHERN TERTIARY CARE CENTRE AND HOSPITAL

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Biostatistics forms one of the core fundamental aspect of research programme. It has been understood that, good knowledge in biostatistics makes the one to carry sound research in their speciality, which in turn have positive impact in bringing the changes & providing the better health care to the mankind.

A cross-sectional study was carried over a period of fifteen months in a southern based tertiary care centre & hospital. Prevalidated structured questionnaire defining different domains of application of biostatistics principles in medical research was distributed to the nursing undergraduate trainees who formed the study population.

It was observed that, only less than 50% of all answers related to the knowledge on '*application of biostatistics principles in research*' were found to be correct. Majority [77.33%] of study participants were unaware or not heard of any software tools related to biostatistics. This study also showed that, most of the study participants opined as 'strongly agree' for the question to a '*good research must have training in biostatistics*'. More than 85% of study participants opined to have *seminars/workshops/CME* on biostatistics course for their improvement in biostatics subject.

This study concluded that, there was a poor knowledge with poor practices, towards the application of biostatistics principles in research among undergraduate nursing trainees in a southern based teaching tertiary care centre & hospital. However the undergraduate nursing trainees showed positive attitude towards the application of biostatistics principles in research.

P26

ADVERSE DRUG REACTION MONITORING IN A SOUTHERN TERTIARY CARE CENTRE AND HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

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Adverse drug reaction monitoring is an integral part of Pharmacovigilance Programme of India [PvPI]. PvPI helps the physicians to use the drugs judiciously as well as brings the changes in drug labeling, whenever necessary through the regulatory bodies.

This study was carried at a southern tertiary care centre and hospital over a period of two months. It was a prospective observational based in nature during the months of July and August 2013. The study proposal was cleared by the Institutional Human Ethics Committee [IHEC]. The collected ADRs from tertiary care centre and hospital were analysed using various ADR causality assessment scales [WHO, Naranjo Algorithm, Schumock & Thornton and Modified Hartwig and Siegel scales].

A total of 93 ADRs were collected during the months of July and August 2013. It was found that antimicrobial drugs [35.48%] were responsible for maximum causation of ADRs, followed by drugs related to endocrine system [31.18%], CNS [20.43%], autacoids [10.75%], CVS [1.08%] and GIT [1.08%].

ADR causality assessment by WHO scale revealed, maximum number of ADRs were possible [76.34%] followed by probable/likely [13.98%], unlikely [7.53%] and conditional/unclassified [2.15%]. It was seen in Naranjo algorithm scale that ADRs were possible in 67.74%, probable in [22.58%] and definite in 9.68% of cases. Modified Hartwig and Siegel scale found 61.29% of ADRs were mild in nature followed by 38.71% as moderate in nature and none as severe in nature. The Schumock & Thornton preventability scale identified 52.69% of all ADRs were definitely preventable, 16.13% as probably preventable and rest as not preventable.

This study showed that drugs acting on microorganisms were responsible for maximum number of ADRs and drugs related to CVS and GIT contributed for least number of ADRs. Majority of the ADRs were possible in WHO and Naranjo ADR causality assessment scales. It was also noticed that majority of ADRs were mild in nature on Modified Hartwig and Siegel scale; and definitely preventable on Schumock & Thornton ADR assessment scale.

P27

RELEVANCE OF HERBOVIGILANCE

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Herbovigilance is similar to pharmacovigilance but for herbs. Frequently used in chronic conditions such

as diabetes, arthritis, asthma, cancer and end-stage renal disease, herbal remedies are given special importance under the Ministry of Health & Family welfare with the creation of the department of AYUSH as well as establishment of the National Medicinal Plants Board in 2000. Despite the common misconception that they are completely safe, herbal medications can result in adverse reactions such as: Indicated for asthma, datura stramonium causes hallucinations and is fatal in overdose; chronic licorice ingestion causes potassium depletion; ginkgo biloba causing bleeding and many others reportedly causing hepatotoxicity, renal failure treatment failure and allergic reactions. Several preparations of herbal products also include 0.1 to 0.3 mg betamethasone that results in adverse effects associated with corticosteroids. Contamination, misidentification and adulteration of herbal products are also commonplace. Sometimes, even due to plant-to-plant variation and several other factors such as harvesting time, place of origin and process of production may affect the adverse effect profile of the herb. Lack of adequate clinical trials, poor regulatory measures, inadequate quality control systems, poorly controlled distribution methods (such as internet based orders) and little to no information about contraindications or drug-drug interactions for marketed medicinal herbs further puts emphasis on the importance of herbovigilance.

Keywords: Herbovigilance, AYUSH, Adverse Drug Reactions, Medicinal plants, herbal medicines.

P28

A REVIEW ON THE CONVENTIONAL DRUGS, ALTERNATIVE THERAPIES AND THE MANAGEMENT STRATEGIES OF ULCERATIVE COLITIS

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Ulcerative colitis (UC) is a chronic bowel disorder characterized by inflammation of the colonic mucosa. The most common symptoms of UC are diarrhea, blood in the stool, and, occasionally, abdominal pain.

Conventional drug therapy for UC involves use of aminosalicylates, corticosteroids, azathioprine/6-mercaptopurine, cyclosporine and anti-tumor necrosis factor therapy. Alternative therapies include probiotics, nicotine and fish oil. Controlled trials have shown that transdermal nicotine added as a therapy has a beneficial effect in active UC. Since side-effects with transdermal nicotine occur in up to two thirds of patients, particularly in lifelong nonsmokers, scientists have developed an oral nicotine preparation in which nicotine was combined with a polyacrylic carbomer which give sustained release of nicotine in the distal ileum and colon.

Medical therapy aims to induce and maintain a clinical remission, reduce the risk of colorectal cancer and improve quality of life. Aminosalicylates are currently the first choice therapy both for the induction and the maintenance of remission in the patients with mild-to-moderate UC. For moderate-to-severe cases or those who do not respond to aminosalicylates therapy, additional options including immunomodulators, biological agents, cyclosporine, tacrolimus and surgery are available.

Keywords: Probiotics, necrosis, conventional therapy, remission.

P29

RETROSPECTIVE ANALYSIS OF ADVERSE DRUG REACTIONS

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Adverse drug reactions (ADRs) are a major cause of morbidity and mortality in Hospitals and pose great economic burden on the health care system. This study was conducted with the aim of creating awareness and developing the culture for proper communication and reporting of ADRs among health care professionals.

This study is a retrospective analysis of total 60 reported ADRs from AMC at a tertiary care hospital during a period from March 2015 to April 2016. These ADRs were analyzed for the pattern and type of reactions, body systems involved, causative drugs, severity of reaction, their outcome, management and causality assessment

by WHO UMC Causality assessment scale.

Patients in the age groups of 41-50 years were most commonly involved with slight male preponderance. Skin reactions like rashes and itching were the most commonly observed ADR. The most common causative drugs for ADR were antimicrobial agents; IV route was the most common route responsible. Majority of ADRs belonged to type B, were non serious and moderate in severity, most of the patients recovered. On causality assessment scale, majority of the ADRs were found to be probable with the causative drugs.

Most of the ADRs were treatable by early and appropriate management. The major limitation was under-reporting of ADRs which can be overcome by creating awareness and enhancing the culture of ADR monitoring and reporting among health care professionals for safe use of drugs.

P30

A SINGLE POINT ASSESSMENT OF PREVALENCE AND PATTERNS OF SPORTS INJURIES AMONG YOUNG INDIAN ADULTS

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Sports brings fame to a nation and at the same time participation in sports also entails a risk of injury which accounts for substantial morbidity and cost to both individuals and the society. This study aim to assess the prevalence and patterns of sports injuries among young Indian adults.

This cross sectional study utilized a self-administered questionnaire, conducted at NIPER SAS Nagar, Punjab, India. 196 participants were enrolled based on their active participation in different kind of sports; only 146 participants met the inclusion criteria. The data obtained from 146 participants from sister institutions across the country is presented. The data was computed using Microsoft excel® and free version of SPSS. The studied sample had 46.5% of prevalence of sports injuries. Males were mostly affected by injuries. 40.1% of prevalence was reported among those participants who were devoid of coaching facilities. The practice of preventive measures was also low. Participants played lawn tennis followed by kabaddi and volleyball suffered more injuries. Injuries are not covered by any insurance policy; and, out of pocket expenditure was high.

Lack of technical expertise in sports injury management is a matter of concern as large number of participants reported lack of coaching facilities. The results of this study also demand that attention be paid towards preventive measures and periodic health screening to promote youngsters to continue to enjoy sports in a safer way. Finally, it may pave way for sensitization in young students at the college/school level.

P31

EFFICACY AND SAFETY OF DIENOGEST VERSUS MEDROXYPROGESTERONE ACETATE (MPA) IN ENDOMETRIOSIS: A COMPARATIVE STUDY

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Endometriosis is a common chronic gynaecological disorder in women of reproductive age. It is a common cause of chronic pelvic pain, dysmenorrhea, dyspareunia and dyschezia. It is a potential risk factor for infertility & dysfunctional uterine bleeding. Dienogest (newer progestin) has shown to provide good results in taking care of endometriosis symptoms with less side effect profile. This study aimed to assess and compare the efficacy & safety of dienogest versus medroxyprogesterone acetate in endometriosis.

A pilot study of 12 weeks was conducted on 30 patients. Patients diagnosed with endometriosis were randomised to receive Dienogest, 2 mg OD (Group A, n=15) & Medroxyprogesterone acetate, 10 mg BD (Group B, n=15). Efficacy was assessed using VAS scale and Biberoglu and Behrman scale. The safety was evaluated by observing adverse drug reactions (ADRs). Both the groups led to statistically significant reduction in VAS Scale for chronic pelvic pain, dysmenorrhea and improvement in Biberoglu and Behrman scale over a period of 12 weeks. Better

reduction of VAS Scale for chronic pelvic pain (92.69% vs 83.67%)and dysmenorrhea (96.47% vs 91.18%) was seen in group A than group B. Better improvement in Biberoglu and Behrman scale was also observed in group A than group B (87.92% vs 87.34%). However, this difference was not statistically significant. Uterine bleeding and weight gain were the commonest ADRs. Vaginal dryness and bloating were statistically significant more in MPA. Dienogest as well as MPA showed good results for improvement of endometriosis but slightly better response was observed with dienogest.

Keywords: Endometriosis, Dysmenorrhea, Dyspareunia, Visual analogue scale score, Biberoglu and Behrman scale

P32

PHARMACOVIGILANCE PRACTICES IN NATIONAL MALARIA CONTROL PROGRAMME OF INDIA

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Many health care programmes involve the direct administration of medicine to the large population and communities for the prophylaxis, treatment and irradiation of disease, will generate the possibility of ADRs, that's why pharmacovigilance practice is essential for safety assessment. India switched to artemisinine based therapy in form of artesunate+ sulfadoxine and pyremethamine. These drugs were highly effective and increase the risk of ADRs and drug resistance. Hence recent change in prescribing practice necessitates pharmacovigilance of antimalarial drugs specially artemisinine based therapy.

Cross sectional survey was conducted health care professionals (HCPs) involved in National Malarial Control Programme Of India. A-5 point Likert scale based questionnaire was developed as study tool.

A total of 154 HCPs participated in the study (age: 42.+- 10.1 years with33.8% females. About 61% felt that only medically qualified HCPs are responsible for ADR reporting. Likeliness to report in future was mentioned by 45% HCPs the knowledge score was relatively lower for life science graduates (P=0.09). knowledge correlated positively with attitude (r2 =0.114, P< 0.0001). Based on the caveats identified, a specific and targeted in service education with hands on training on ADR monitoring and reporting needs to be designed to boost real time pharmacovigilance in India.

P33

MEDICATION ERROR

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A medication error is 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.

Main causes for medication errors are- incomplete information about patient, health professionals not being up to date about drugs , inappropriate drugs labels and error in prescribing , administration ,dispensing and others. Undesirable outcomes include adverse drug reactions, drug-drug interactions, lack of efficacy, suboptimal patient adherence and poor quality of life and patient experience, It could be fatal also.

This poster presents the common and other dimensions of medication errors and it's preventive and controlling measures.

P34

PHARMACOVIGILANCE IN PHARMACY PRACTICE

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Pharmacovigilance is the practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions. Pharmacovigilance (PV) plays a key role in the health care system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human. Moreover, Pharmacovigilance has traditionally involved in mining spontaneous reports submitted to national surveillance systems. Pharmacovigilance also known as drug safety surveillance is the science of enhancing patient care and patient safety regarding the use of medicines by collecting, monitoring, assessing and evaluating informations from healthcare providers and patients.

Keywords: Pharmacovigilance, its role to health care system

P35

MEDICATION ERRORS, ITS CAUSES AND PREVENTION

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A medication error is 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. The most common causes of medication errors are: Poor communication between you and your doctors, Drug names that sound alike, Medications that look alike and Medical abbreviations. These errors are of 2 types : Mistakes(error in planning action) and Skill-based errors(errors in executing correctly planned actions). Following the rights of medication administration can prevent medication errors. This review article comprises of the causes, types and prevention of medication errors.

Keywords: Medication errors, medical abbreviations, rights of medication

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GENERALIZED BULLOUS FIXED DRUG ERUPTION - A CASE REPORT

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Fixed drug eruption (FDE) is the most common cutaneous adverse drug reaction. Fixed Drug Eruption(FDE) is a distinctive type of cutaneous drug reaction that is described by development of well-defined circular, hyperpigmentation plaque, erythematous patches, morbilliform exanthem as a result of systemic exposure to a drug; these reactions normally resolve with hyperpigmentation and may recur at the same site with re exposure to the drug. Severe FDE share clinical features with Stevens-Johnson syndrome / toxic epidermal necrolysis. FDE commonly occurs on the genitals, lips, trunk and hands. Diagnosis is usually based on clinical examination finding. Histopathologic examinations will help to clinch the diagnosis. The usual eliciting drugs are analgesics, antibacterials, anticonvulsants and sedatives .Cefotaxime, a broad-spectrum third-generation cephalosporin, appeared to be a safe and effective therapy in greater than 90% of infections including cellulitis, abscesses and necrotizing ulcers of the skin and subcutaneous tissues but here we report through poster presentation a rare case of 36 years old female patient developed generalized bullous FDE after intravenous administration of Cefotaxime.

Keywords: ADR Reporting, Pharmacovigilance, Cefotaxime, Drug induced disorders.

P37

PHARMACOGENOMICS AND PHARMACOVIGILANCE

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Pharmacogenomics is major emerging trend in medical sciences, which influence the success of drug development and therapeutics. In current times, though pharmacogenetic studies are being done extensively for research, its application for drug development needs to get started on a large scale. The major determinants of success of a new drug compound, viz safety and efficacy, have become more predictable, with the advent of pharmacogenetic studies. There is a need felt for pharmacogenomic studies, where the effects of multiple genes are assessed with the study of entire of genome. The genetic factors that can affect the drug response include variations in the genes coding for drug metabolizing enzymes, receptors and transporters. A classic example of genetic polymorphism affecting drug metabolism would be that of the enzyme CYP2C9, which is coded by the polymorphic gene CYP2CP. Its variant alleles namely *2 and*3 are poor metabolizers, with only 12% and 5% respectively of enzyme activity, as compared to normal allele .Advances in pharmacogenetic testing will expand the number of clinically important pharmacogenetic variants. Communication and interpretation of these test results are critical steps in implementation of pharmacogenetics into the clinic. Computational tools that integrate directly into the electronic medical record (EMR). This report, we review the importance of pharmacovigillance in detecting post marketing adverse drug events and potential for developing pharmacovigilance programs by integrating pharmacogenomics with pharmacovigilance.

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HAEMOVIGILANCE PROGRAM OF INDIA: CURRENT SCENARIO AND COMPARISON TO GLOBAL STANDARDS

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Haemovigilance is an organized scheme of monitoring, identifying, reporting, investigating and analysing adverse events and reactions pertinent to transfusion and manufacturing of blood products. This system is also an elemental part of quality control in a blood system, bringing about corrective and preventive measures, and for the perpetual advancement of the quality and safety of blood products and the transfusion process. Nowadays, haemovigilance setups have been enforced throughout the globe in most developed countries, to monitor the adverse reactions and episodes associated with blood donations and transfusions. Indian Pharmacopoeia Commission has started a Haemovigilance program of India (HvPI) in 2012 under its Pharmacovigilance Program of India in collaboration with National Institute of Biologicals, Noida, Uttar Pradesh, under Ministry of Health & Family Welfare, Government of India with a primary objective to track adverse reactions/events and incidences associated with blood transfusion and blood product administration and to identify trends, recommend best practices and interventions needed to improve patient care and safety. This presentation is an update on the current scenario of haemovigilance in India and tries to measure the progress made by HvPI towards achieving global standards as set by IHN & WHO. The sources used are scholarly articles, websites of Indian Pharmacopoceia commission and international organizations. The results show that significant progress has been made since the program was started in 2012 but things could have moved faster towards international standardization with more focused effort and resource allocation.

P39

MEDICATION ERROR

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Medication errors defined as any error in the prescribing, dispensing, or Administration of drug, irrespective of whether such errors leads to adverse consequences or not, are the single most preventable cause of patient harm. In the study of FDA that evaluated reports of fatal medication errors from 1993-1998, amounting for 41% of fatal medication errors. According to the report, between 44000 and 98000 deaths may result each

year from medical errors in hospital alone. According to WHO, medical errors can also increase resistance to antibiotics. Resistance to antimicrobials can take place when there are modifications in bateria intended as treatment ineffective. A systemic review of literature relating to MEs in prescribing, transcribing, dispensing, administration and documentation in adults and children. The aim of this systemic review was to review studies of the incidence and types of MEs in and identify the main contributing factors involved. All health care professionals have a responsibilty in identifying contributing factors to medication errors and to use that information to further reduce their occurrence. The abstract briefly describe about medication error with antibiotic resistance.

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HERBOIGILANCE

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Herbovigilance primarily comprises of vigilance towards herbal drug which includes their merits and demerits (adverse drug reaction) , the data is collected and framing it for public benefits. Herbal products are preferred by half of population because they are natural, safe and therapeutic index(toxicity) . In this article I briefly explain ADR's related to herbal drug , program conducted in india related to herbovigilance, drug interaction related to plants(herbs).

Keyword: Herb-Drug Interaction, Herbavigilance, Improprer Labeling, Contamination, Inaprropriate Dosing, Unknown Composition.

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HEMOVIGILANCE

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Hemovigilance is a term related to monitoring of blood. A set of surveillance procedure covering whole transfusion chain from donor to recipient and intermediates intended to collect and access information on ADR's and undesirable effects. The system of hemovigilance varies due to differences in spectrum of reporting, all versus serious outcomes. The data generated allow us to carry out desirable changes in transfusion system and will enhance patient safety. This article briefly describes about the history of hemovigilance, why it was needed, and hemovigilance programs with objectives, blood donation programs conducted, communication and networking, graphical representation of acquired data.

Keywords: Blood transfusion reaction, ADR, Pharmacovigilance, Hemovigilance.

P42

STUDY ON SOME ASPECTS OF MEDICAL DEVICES SECTOR IN INDIA

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Medical devices (MD) have played an important role in healthcare sector and India has not witnessed the similar growth as compared to developed countries. Cardiovascular (CVD) is the number one cause of death globally. National Pharmaceutical Pricing Authority (NPPA) has imposed price controls on stents to curb the unethical oligopolistic tendencies and competitive pricing.

The data was captured for the five years of top five MD companies. Total net sales of CVD devices to the South Asian countries and import/export of high/low end medical devices (HEMD/LEMD) in India were compared. Various online resources that are available as open access were used.

There was remarkable increase in the net sales from 2013 (20,120USD mn $) to 2017 (31,056USD mn $). Import of HEMD has grown from 2013(2,620USD mn $) to 2017 (2,900USD mn $). Export of LEMD has grown from 2013 (820USD mn $) to 2015 (1,100USD mn $) however, in 2016 & 2017 it was decreased (980USD mn $ & 1000USD mn $ respectively). BOT (Balance of Trade) of India in 2012-13 (-1800USD mn $), 2013-14 (-1,600USD mn $), 2014-15 (-1,630USD mn $), 2015-16 (-1,890USD mn $) & in 2016-17 (-1900USD mn $).

BOT of India is negative as import is more than export which indicates trade deficit, negative balance and decrease in the relative strength of country's economy. Domestic production of HEMD in India should be supported at higher rate to reduce the dependency on the import and making this sector highly significant with potential for exports.

Keywords: MD, Import, Export, HEMD/LEMD, BOT, Economy.

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CROSSTALK BETWEEN REACTIVE OXYGEN SPECIES AND PRO-INFLAMMATORY MARKERS IN DEVELOPING VARIOUS CHRONIC DISEASES

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The inflammation process in the human body plays a central role in the pathogenesis of many chronic diseases. In addition, reactive oxygen species (ROS) exert potentially a decisive role in human body, particularly in physiological and pathological process. The chronic inflammation state could generate several types of diseases such as cancer, atherosclerosis, diabetes mellitus and arthritis, especially if it is concomitant with high levels of pro-inflammatory markers and ROS. The respiratory burst of inflammatory cells during inflammation increases the production and accumulation of ROS. However, ROS regulate various types of kinases and transcription factors such nuclear factor-kappa B which is related to the activation of pro-inflammatory genes. The exact crosstalk between pro-inflammatory markers and ROS in terms of pathogenesis and development of serious diseases is still ambitious. Many studies have been attempting to determine the mechanistic mutual relationship between ROS and pro-inflammatory markers. Therefore hereby, I present the hypothetical relationship between ROS and pro-inflammatory markers in which they have been proposed to initiate cancer, atherosclerosis, diabetes mellitus and arthritis.

Keywords: Atherosclerosis , Arthritis , Cancer , Diabetes , Reactive oxygen species (ROS) , Pro-inflammatory markers

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EVALUATION OF SAFETY PROFILE OF YELLOW FEVER VACCINE IN HEALTHY TRAVELERS

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Every year, many Indian travellers are traveling to endemic countries like Africa, America etc. and get vaccinated before immigration by the Yellow Fever vaccine (YFV). Like any other drug/Vaccine, Yellow Fever vaccine also shows the adverse events following immunization. All healthy Indian Volunteers visiting the clinic for Yellow Fever Vaccination were followed up telephonically with prior obtained informed consent. On Day 7 & Day 14 visitors were contacted for occurrence of any adverse event followed by immunization. A total of 219 travelers was recruited. 200 were successfully followed-up for AEFI with the response rate of 91.3%. The average age of travelers was found to be 32 ١,٠٦±.

Overall, 46 travelers had experienced AEFI. Majorly fever, diarrhea, headache and fever along with myalgia were found to be the most common side-effects among travelers. Maximum number of AE was found in the age group 15-65 yrs (24.4%). No SAE was reported by any age groups (1 day-15yrs, 15-65 yrs, >65yrs).

On the basis of presenting study it shows that yellow fever vaccine produces mild to moderate adverse events, but with time it subsides as well, no medication is required to treat AE. Thereby, YFV is found to be safe and well tolerated in healthy Indian travelers.

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ADVERSE DRUG REACTIONS INVOLVING CUTANEOUS EVENTS DURING OR AFTER ANTI-CANCER THERAPY WITH EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) TYROSINE KINASE INHIBITORS (TKIS)

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EGFR is a transmembrane protein receptor tyrosine kinase for members of Epidermal Growth Factor family. These bind to the receptor and lead to cell growth and differentiation. Human Epidermal Growth Receptor 1 (HER1) is the most common type of EGFR found in humans. In many cancers the overexpression or mutation of EGFR is observed. Therefore, at present the use of EGFR TKI has been the approach to cancer therapy in such cases. Despite the positive outcomes, such targeted therapies are seen to have various cutaneous adverse reactions which are usually mild including pruritus, xerosis, papulopustular rash, hand-foot skin reaction and alopecia. Although the side effects induced by inhibitors of EGFR are milder as compared to those observed with classic cytotoxic chemotherapy they may still lead to reduction in dose and even discontinuation of the treatment if not managed timely. As a result, this can reduce the effectiveness of anti-cancer therapy and also significantly affect patient's well-being, treatment compliance and quality of life.

A structured literature search was conducted on PubMed with the goal of attaining and gathering information on cutaneous adverse effects of EGFR TKI and reporting mechanisms. The information was then used to form this review.

This review provides an understanding of the various cutaneous adverse reactions on using different kinds of TKI such as gefitinib and erlotinib therapy, cetuximab and panitumumab therapy and others.

The management and timely diagnosis of these cutaneous adverse reactions therefore becomes necessary for better outcome of the therapy, patient compliance and reduction in chances of skin comorbidities.

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AN OVERVIEW OF HEMOVIGILANCE

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Hemovigilance is a relatively new branch but an important part of quality system branch for blood transfusion. It is a set of organised surveillance procedures covering the whole transfusion chain which are intended to collect and assess information on the serious adverse effects or unexpected effects in the donors resulting from the therapeutic use of labile blood components i.e. red blood cell concentrates, platelets and plasma and to prevent the occurrence or recurrence of such incidents. In this review we discuss the history and present state of this relatively new branch of transfusion medicine as well as some developments that we foresee in the near future. The ultimate aim of hemovigilance is to improve the safety of blood transfusion.

Search through various articles published on PubMed, ScienceDirect and WHO website.

Hemovigilance is an essential component of quality management in a blood system and is needed for the continual enhancement of quality and safety of blood products and transfusion process by monitoring and safeguarding the adverse effects associated with the use of blood products.

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DRUG UTILIZATION STUDY OF ORAL HYPOGLYCEMIC AGENTS IN A UNIVERSITY TEACHING HOSPITAL

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The present study is aimed to determine the drug utilization patterns in type 2 diabetic patients on oral hypoglycemic agents in HAHC Hospital, a teaching hospital of Jamia Hamdard, New Delhi.

Patients with established type 2 diabetes (n = 218) visiting the OPD and IPD were interviewed using a structured questionnaire.

A majority of the type 2 diabetic patients in this setting were treated with multiple antidiabetic drug therapy. The most commonly prescribed antidiabetic drug class was biguanides (metformin) followed by sulphonylureas (glimepiride), thiazolidinediones (pioglitazone), insulin and alpha-glucosidase inhibitors (miglitol). As monotherapy insulin was the most common choice followed by metformin. The most prevalent multiple therapy was a three-drug combination of glimepiride + metformin + pioglitazone. More than half of the type 2 diabetic patients showed poor adherence (compliance) to the prescribed therapy.

This study strongly highlights the need for patient education or counselling on use of antidiabetic and concomitant drugs, monitoring of blood glucose and glycosylated haemoglobin (HbA1c) levels, diet control, and correction of diabetic complications. Metabolic control was poor and HbA1c monitoring was underutilized. Clinical monitoring of patients' adherence to prescribed treatments is recommended and measures should be taken to improve the same.

P48

ADVERSE DRUG REACTION MONITORING AND REPORTING AT ADVERSE DRUG REACTION MONITORING

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Adverse drug reactions (ADRs)) contribute significantly in health care cost through increased patient morbidity and mortality. Thus, there is an urgent need to create awareness among health care professionals towards ADR monitoring and reporting. Main Aim to ADRs Monitoring is to the promoting rational use of drugs, safe use of medicine, improving patient care, improving public health.

This was a prospective and observational study conducted in Sarojini Naidu medical college Agra from 1st January, ٢٠١٧ to ٣١st December, 2017. These ADRs were analysed for the pattern and type of reaction, body system involved, and causative drug, severity of reaction, their outcomes, management and causality assessment by WHO UMC causality assessment scale. Total ADRs reported were 150 during one year. Among them, 89.33 % were found to be non serious and 10.67 % were serious. 33 % were related to skin, 27 % were related to GIT, and 10 % were related CNS and others. Most common ADRs were implicated only due to antimicrobial agents, a maximum number of ADRs were observed in 25–50 years of age group. In causality assessment, the probable cases had a higher incidence, followed by possible.

The present evaluation has revealed opportunities for interventions especially for the avoidable ADRs which will help in promoting safer drug use, information to the healthcare professionals. Improve the quality of patient care and educate to increase awareness.

Keywords: Adverse drug reactions, Causality assessment, ICSRs, Antimicrobial agents

P49

CLASSIFIED WARNING SIGNS ON POTENTIALLY INAPPROPRIATE MEDICATIONS: NEED OF THE HOUR

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Label on the formulation is an index of the safety, efficacy and indications of its components. In addition, label bearing a warning sign/slogan on the formulation is of great help to patients and physicians. Now a days, Potentially Inappropriate medications (PIMs) are projecting as a major cause of ADR in older people. Although American Geriatric Society (AGS) has published Beer guidelines which contain list of multiple drugs to be avoided in elderly patient yet there are reports of PIM related ADRs just because of lack of awareness of physicians or inadequacy of knowledge to innocent patients towards PIMs. Indications/warning signs on label about schedule of drugs and usage play a major role in avoiding accidental use of drugs. Hence it was resolved to analyse the status of label for any warning sign in all the formulations classified as PIMs as per Beer criteria.

The medicines enlisted in Beer guidelines were procured and critically reviewed for the labelling parameters, indication any cautious statements.

It has been observed that although medicines are enlisted in drug alert list as well as in Beer criteria still no such labelling (not for the use of elderly patients) has been mentioned on the medicines available in the market. Hence it is recommended that regulatory authorities should revise the labelling parameters and a separate schedule should be allotted for drugs to be used in elderly patients with a cautious label "Not for geriatric population".

P50

WASTE MANAGEMENT IN PHARMACY AND ITS ECONOMIC IMPLICATIONS

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Hospital waste management occupies a critical place in the management of health care sector.Wastes are the unwanted materials which can no longer be used in the manufacturing processes that can eventually turn into hazardous or non hazardous material, to humans/environment. Pharmaceutical wastes are in different forms mainly as strips, expired products, manufacturing wastes etc. Waste management covers collecting, sorting, processing, recycling and reusing material. Disposal of waste from the health care should be as hygienically and economically as possible by method to minimizing the risk of public health. Insufficient awareness of the medical wastes at different levels which is found to be unsafe as both clinical and nonclinical waste is thrown together. Unwanted medicines including expiry date, unused, contaminated drug product should be disposed.

Guidelines are given by FDA and Environmental Protection Agency (EPA). Waste treatment and disposal methods include autoclaving, incineration, landfill, sewerage, microwave, chemical disinfection, and others (like plasma arc torch, pyrolysis and electro oxidation, quartz infrared treatment and radiation).

The industry should be encouraged to investigate expiration dates to establish a maximum shelf life for a drug product to minimize wastage. These approaches provide an effective solution to an issue that has the potential to affect much of life on earth to make environment eco friendly.

P51

RISK ADJUSTMENT IN COMPETITIVE HEALTH PLAN MARKETS

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In recent years many countries have chosen to use prospective payment arrangements for health plans such as health insurers, sickness funds together with health plan competition, as a means of creating incentives to be cost conscious, while preserving quality, innovation and responsiveness to consumer preferences. Risk adjustment is an important mechanism for attenuating problems that threaten the effectiveness of this strategy for resource allocation in health care. Without adequate risk adjustment, competing health plans have incentives to avoid individuals with predictable losses and to select predictably profitable members. This selection and the resulting risk segmentation can have adverse effects in terms of access to care, quality and efficiency of care. We use risk adjustment with the use of information to calculate the expected health expenditures of individual consumers over a fixed interval of time (e.g., a month or year) and set subsidies to the consumers or health plans to improve efficiency and equity. Although risk adjusters may be used by insurers for their premiums. By competitive, we mean markets in which individual consumers have a periodic choice of health plan and health plans may take actions, such as designing, pricing and marketing their products, to attract or repel enrollees. Health plans may also manage or provide health care, and this can influence how risk-adjusted payments should be made; however we focus primarily on plan-level rather than provider-level incentives.

P52

EFFICACY OF ULIPRISTAL ACETATE VERSUS LETROZOLE IN REDUCTION OF SIZE OF SYMPTOMATIC UTERINE LEIOMYOMAS

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Uterine fibroids (leiomyomas), are the most common benign gynaecological tumors, and lead to symptoms like menorrhagia, pressure symptoms, pelvic pain and infertility. Ulipristal acetate, is a recently approved selective progesterone receptor modulator (SPRM) which has been shown to exert antiproliferative, antifibrotic, and proapoptotic effects on leiomyoma cells. Letrozole is an aromatase inhibitor and involves inhibition of aromatase enzymes thus preventing the conversion of androgens to oestrogen. To evaluate the effect of ulipristal acetate as compared with letrozole on uterine myoma size and pressure symptoms in reproductive age group women.

This Prospective interventional study was conducted on 46 premenopausal women aged between 20 and 50 years with myomas ≥2cm in size and menstrual or pressure symptoms who were randomized to receive treatment for up to 12 weeks with oral ulipristal acetate(group 1) at a dose of 5 mg per day or to receive oral letrozole(group 2) at a dose of 2.5mg daily. The effect of the drugs on pressure symptoms was studied using Visual analog score (VAS) and on myoma size using ultrasonography which were recorded at baseline and at 12weeks.

VAS Score was reduced from 59.13 ± 15.6 to 18.13 ± 12.9 in group1 and from 62.17 ± 13.8 to 28.56 ± 17.51 in group 2 at baseline and at 12 weeks respectively. The mean myoma size was reduced from 3.9 ± 1.7 cm to 2.8 ± 1.4 cm in patients receiving ulipristal acetate and from 4.4 ± 1.9 cm to 3.8 ± 1.8 cm in letrozole group at the end of 12 weeks. The reduction in the VAS Score and mean myoma size between the two groups was statistically significant (p-value<0.05) at 12 weeks. Ulipristal acetate showed more reduction of myoma size and improvement in pressure symptoms as compared to letrozole in fibroids.

Keywords: Uterine leiomyomas, Ulipristal acetate, SPRM, PBAC score

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ASSESSMENT OF CARDIOVASCULAR RISK USING CARDIOVASCULAR RISK SCORE CALCULATORS IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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Cardiovascular Disease (CVD) is one of the leading causes mortality in the patients with Chronic Obstructive Pulmonary Disease (COPD). Various CV risk calculators have been evaluated in subjects with CV risk. For the prevention of CV diseases, it is essential to find out 10-year CV risk that can help in identifying high CVD risk individuals, albeit without underestimating or overestimating the risk. The study aimed to compare and comment on the various cardiovascular risk score calculators for cardiovascular risk assessment in Indian subjects with COPD.

COPD patients and controls were matched for age in a 1:1 matching ratio were included in a case control study. The study included only those patients who were above 40 years of age, willing to give a written informed consent and having no primary diagnosis of another respiratory disease and chronic inflammatory conditions. Cardiovascular risk prediction models of Joint British Society calculator-3 (JBS3), QRISK2, Reynolds risk score (RRS) and Framingham Risk Score (FRS) were utilized to assess the 10year cardiovascular risk for the COPD group.

A total of 40 COPD patients and 40 controls were included in the analysis. The study subjects had a median age (Interquartile range) of 59.50 (11.00) years in COPD group and 56.00 (17.50) years in control group (P=0.5238). FRS calculator has identified maximum number of subjects (45%) to be in high CVD risk category. The study concluded that FRS calculator was most useful for identifying high CV risk subjects in COPD subjects.

P54

DESIGN AND DEVELOPMENT OF LIPID NANOPARTICLES FOR EFFECTIVE TREATMENT TO RHEUMATOID ARTHRITIS

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Designing a robust functionalized nanolipid carrier system which would deliver antirheumatic drug only to the target area. This would be an effective approach to deliver lipid carrier for effective targeting to RA to overcome unwanted toxicities associated with existing arthritis therapies.

The research is aimed at developing lipid-based nanoparticles having DMARD. LNPs were prepared by thin-film hydration method using lipoid S100 and ligand. LNPs were characterized for DSC, mean droplet size and XRD. Optimized LNPs were subjected to *in-vitro* characterization and RAW 264.7 was selected to study the events such as MTT assay.

The particle size and PDI of the optimized formulations was 128.9±0.2nm, 155.6±1.2 nm and 131.3±0.5nm respectively. Zeta potential was 12.6± 0.2nm, -10.2±0.8nm and -29.4± 0.6nm. The spherical vesicles were dispersed and presented a well-defined outer lipid bilayer. TEM images showed the surface coating on liposomes. Through DSC, it could be seen that TEF presented a single sharp peak that corresponded to the melting point of the drug in the crystalline form. Optimized LNPs showed a sustained release pattern after 24 hours. Using this well-established cellular model of inflammation, we have evaluated that a liposomal drug encapsulation strategy is more effective than the free drug.

Results demonstrate that this approach will provide effective treatment for RA and will serve as a potential prophylactic against the advancement of cartilage degeneration.

P55

LIPID BASED NANOPARTICLES AS A POTENTIAL NANOCARRIER FOR IMPROVED ORAL DELIVERY OF EXEMESTANE: FORMULATION DESIGN, PHYSIOCHEMICAL CHARACTERIZATION, IN VITRO AND EX VIVO INVESTIGATIONS

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Exemestane (EXE) is an orally active irreversible aromatase inactivator used for the treatment of advanced postmenopausal breast cancer. But its bioavailability is about 5% due to low solubility in water and the extensive first pass effect. This study aims to design and fabricate an optimized Nanostructured Lipid Carrier (NLC) of EXE, which permits efficient absorption following oral administration.

EXE loaded NLC was prepared by ultrasonication. Central composite design (CCD) was used to determine the role of key independent variables affecting the dependent variables particle size, PDI and % EE. Moreover, *ex vivo* and *in vivo* efficacy of the formulation was measured by gut permeation study and MTT assay respectively.

The optimized formulation demonstrated almost spherical morphology under TEM analysis with particle size of 155.6±3.66 nm, PDI 0.133±0.97 and zeta potential -29.0±0.65 mV. *In vitro* release studies founded sustained release over 24 h in Phosphate Buffer Saline pH 7.4. DSC study had demonstrated reduced the crystallinity and stability enhancing the effect of NLC. *Ex vivo* studies and Confocal Laser Scanning Microscopy (CLSM) showed the formulation has better permeation when contrasted with drug suspension. MTT assay revealed that the formulation cause sufficiently more cytotoxicity as compared to drug suspension due to greater bioavailability and greater penetration.

Finally, NLCs made of Precirol ATO5 and flaxseed oil improved the oral bioavailability and permeability of the drug through the intestinal milieu.

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PHARMACOVIGILANCE IN GENOMIC ERA

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Pharmacovigilance means keeping a watch on drugs during the post marketing period regarding any adverse drug reactions in susceptible individuals. Pharmacogenomics is the study of genetic basis for variation in drug response. Interindividual variability in drug response has been attributed to difference in genetic composition among individuals and tis gave origin to the concept of personalized medicine.

Use of internet and social networking to study and analyse the benefits of integrating pharmacogenomics to pharmacovigilance and concept of personalized medicine.

Use of genetic information along with the molecular basis of the disease give rise to the concept of personalized medicine that is highly efficacious, safe and free of side effects. By understanding the genetic composition and all the genetic predisposing factors responsible for adverse drug reactions (ADRs) in an individual can provide the best treatment option for an individual. There are various pharmacogenetic tests such as those that concentrate on the enzymes required for metabolism of drugs, identifying specific loci on gene having strong predisposition to adverse drug reaction due to a particular drug etc. Applying these pharmacogenetic tests before the introduction of any drug can prevent the occurrence of ADRs.

Pharmacogenomics is an up-growing branch that deals with how genetic make- up can affect pharmacokinetics and pharmacodynamics responses of drug therapy among individuals. Contribution of pharmacogenomics to pharmacovigilance helps to identify all those susceptible individuals that are at increased risk of development of ADRs.

Keywords: Pharmacogenomics, Pharmacovigilance, Adverse drug reactions, Personalised medicine

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SIMULTANEOUS ESTIMATION OF TWO ANTICANCER DRUGS BY SIMPLE SPECTROPHOTOMETRIC METHOD

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The present work aimed to develop and validate spectrophotometric methods for simultaneous estimation of Tamoxifen citrate and Broccoli extracted drug in a pure and tablet dosage form. Method is based on solving a simultaneous equation. Absorbances of Tamoxifen citrate and Broccoli extracted drug were measured at their respective absorbance maximas (λmax) of 275 and 260 nm. Method are validated according to ICH guidelines.

A linearity range for Tamoxifen citrate and Broccoli extracted drug is 2-20μg/ml at respective selected wavelengths. The coefficient of correlation for Tamoxifen citrate at 275 nm and for Broccoli extracted drug at 260 nm is 0.9981 and 0.9997, respectively. A percentage estimation of Tamoxifen citrate and Broccoli extracted drug from the tablet dosage form is 99.99 and 99.94 respectively, with a standard deviation less than 2. The proposed methods are simple, rapid, and validated and can be used successfully for routine simultaneous estimation of Tamoxifen citrate and Broccoli extracted drug in a pure and tablet dosage form.

Keywords: absorbance ratio method, simultaneous equation method, spectrometric estimation, Tamoxifen citrate, Broccoli extracted drug

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A COMPARATIVE STUDY ON EFFICACY OF LATANOPROST AND TIMOLOL IN PRIMARY OPEN ANGLE GLAUCOMA

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Glaucoma is a chronic, progressive optic neuropathy caused by a group of ocular condition which leads to damage of the optic nerve with loss of visual function. It is 2nd leading cause of blindness. In this study we compared the Efficacy of Latanoprost eye drop Versus Timolol eye drop in patients of glaucoma.

It was a comparative, prospective, randomized, open label interventional study of 6 month duration, conducted in the department of Pharmacology in collaboration with department of Ophthalmology, Rohilkhand Medical College and Hospital, Bareilly.

A total of 40 cases of age >40 years satisfied the inclusion criteria and comprised the sample size. They were then randomized and divided into two groups. Group L (n=20) received Latanoprost eye drop once a day and Group T (n=20) received Timolol eye twice a day. The mean IOP at baseline of both the groups was comparable (p value=0.623).Although both the regimen individually produced significant reduction in mean IOP ($p<0.05$) but there were no statistically significant difference ($p >0.05$) when the mean value of the IOP of both the regimen were compared at each of the 3 follow ups. We also observed a higher reduction in percentage of mean IOP from baseline to the final follow up in Latanoprost group. Latanoprost group has a higher efficacy in reducing the mean IOP. Moreover once daily dosing of Latanoprost leads to higher compliance rate and also it has a safer systemic side effects profile.

Keywords: Glaucoma, Latanoprost, Timolol Maleate, Intraocular Pressure.

P59

DETERMINATION OF FORMALIN IN THE FISH SAMPLES FROM AIZAWL CITY, MIZORAM, INDIA

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In Mizo tradition, though fish is not a major source of food but as more and more lifestyle related diseases are increasing, fish has now become an important part of healthy diet available in Aizawl market. By nature, fish

contain fat free amino acids and water which is susceptible to spoilage by microorganism and biochemical reactions. To keep the freshness of fish, fish vendors and fishermen carelessly use formaldehyde as preservative agent which will increase the shelf life. Formaldehyde is known to cause cancer. Formalin practice has been going on unabated in fish markets of the country due to some unscrupulous trader's ill intentions and also negligence of the public consumers to check the trends.

The present study was conducted for quantitative analysis of formaldehyde presence in common fish species by HPLC method. A survey on cancer patients and fish consumers was conducted to find out their eating habits of fish and they were surveyed in a face to face contact using pre-tested questionnaire.

In order to afford suitable measures to moderate the situation, present study was conducted to investigate the status of formalin laced fish marketing and also to collect data regarding the eating habits of fish and to spread awareness of its impact on human health. The analysis of the study indicates that formalin was present but in permissible limit.

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ADVERSE EFFECT IN BLOOD TRANSFUSION: A NEED FOR CRITICAL HAEMOVIGILANCE

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The study tends to elucidates Haemovigilance which deals with the adverse reactions reported during blood transfusion. The present also focusses on the available haemovigilance system used as practice as minimum standard globally.

A critical review method was conducted using large databases like Pubmed, JSTOR, MedlinePlus, Hubmed and CiteSeer^x were searched. The search terms "Haemovigilance", "Blood Transfusion" and "Blood Transfusion reaction" were used. A total 7 paper were included as per the inclusion and the exclusion criteria. The result signified the major adverse reactions occurring were due to immunological haemolysis due to ABO incompatibility and alloantibodies, non-immunological haemolysis, transfusion transmitted bacterial infections and hypersensitivity/ anaphylaxis. While some other reactions cannot be categorized in specific category were mild allergic reactions, mild fever/chills, hypotension, dyspnea/mild breathlessness, pain at infusion site, chest pain/discomfort, tingling and numbness, anxiety and hypertension.

In India, Haemovigilance program was launched at national level on December 10, 2012, but across the globe it came into existence nearly a decade ago. Haemovigilance still required to meet the deficiency at grassroots level. Furthermore an insight of research in haemovigilance need to be focus to strengthen the haemovigilance system all over country.

Keywords: Haemovigilance, Blood Transfusion, Adverse Reactions.

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ROLE OF PHARMACOVIGILANCE IN PHARMACY PRACTICES IN INDIA: A REVIEW

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Pharmacovigilance (PV) or the pharmacological science of drugs safety is a dynamic process that involves various steps like detection, assessment, screening of pharmaceutical products in order to understand the interaction a drug may have in the human body. As this field of clinical science plays a significant role in the healthcare services, in this paper, I intend to trace the history and development of pharmacovigilance and the related pharmacy practices in the Indian Scenario.

The paper will try to achieve it objectives by doing a review of literature with help of secondary sources like journal and newspaper articles, government reports, blogs etc.

A robust PV is salient to the medical system. Since the field of Pharmacovigilance is fastly growing, there is a

dire need to take a step back and look at our past in order to locate the lacunas that might be existing in our regulatory frameworks and policies. This is only possible when the existing literature on the Indian pharmacy practices are critically reviewed.

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170 YEARS OF PHARMACOVIGILANCE AND ITS FUTURE ASPECTS

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Pharmacovigilance or drug safety, is a pharmacological science related to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. The etymology of the word, "pharmacovigilance" is: *pharmakon* (Greek: drug) and *vigilare* (Latin: "to keep watch"). Medication errors, such as overdose, misuse, abuse and drug exposure during pregnancy and breastfeeding, are also of interest.

We researched through several articles on websites like "the lancet" and implemented the knowledge into this abstract. We have focused on history, various ongoing researches and future aspects of Pharmacovigilance. Pharmacovigilance's origin dates back to 1848 in England where a teenage girl died of ventricular fibrillation due to usage of chloroform as anesthesia. Since then various articles, discoveries and even, committees were established which would act as spontaneous reporting system.

In 1902, 'Biologics control act' was passed, followed by 'food and drug act'. The famous thalidomide withdrawal was done in 1961, followed by formation of yellow card scheme by UK in 1964. WHO's involvement in ADR's started in 1967. In 2012 GvP's were released to expand and clarify the issues. New clinical regulation were signed in 2014 to replace old ones. The newest introduction in this field are BCMA to prevent medication error, herbovigilance, oncology researches and eco Pharmacovigilance.

Pharmacovigilance continues to play a crucial role in meeting the challenges posed by the ever increasing range of medicines, which carry an inevitable/unpredictable potential harm. Therefore, it is essential that we know the posing dangers and possible remedies or precautions.

Keywords: Pharmacovigilance (PV or PhV), Barcoded Medication Administration (BCMA), Adverse Drug Reactions (ADRs), GvP (Good pharmacovigilance practices), WHO (World Health Organisation)

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BLOOD TRANSFUSION – REACTIONS AND PREVENTION

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To overview the adverse reactions associated with blood transfusion and different methods employed to prevent them.

Blood transfusion is the introduction of whole blood or blood components directly into the circulation for therapeutic purposes. Whole blood donation is generally considered to be a safe procedure, but occasionally adverse reactions of varying severity may occur during or at the end of collection. Transfusion reactions are broadly classified into – early reactions and late untoward effects. Suitable precautions can be taken to prevent a particular adverse reaction in a susceptible person. Recently, it was found that saline-washed blood transfusions significantly reduced the incidence of transfusion reactions as compared to packed blood transfusion.

Our review is based on information from the reports of Transfusion Risks (academic.oup.com), OnlineLibrary, The New England Journal of Medicine (nejm.org) and Google Scholar with the keywords 'blood transfusion', 'transfusion reactions'.

Six million units of blood are administered annually in United States. Two percent of all blood transfusions are accompanied by unfavorable reactions. Major complications from blood transfusion are hemolytic, allergic, febrile and bacterial reactions; circulation overload; embolism; transmission of infectious agents (hepatitis),

Currently the use of saline-washed blood transfusions have reduced the incidence of adverse reactions. This is likely the result of the removal of leukocytes and plasma achieved by the washing process.

Keywords: Blood Transfusion, Prevention, Saline-Washed, Adverse Effects

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PLATELETS CONCENTRATE – CONTAMINATION AND PREVENTION

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To overview the contamination of platelet concentrate used for transfusion and various methodologies to prevent contamination during storage Platelet concentrate (PC) transfusions are a life-saving adjunct to control and prevent bleeding in cancer, haematological, surgical and trauma patients. PC availability is limited by the development of platelet storage lesions (PSLs) and risk of bacterial contamination. PSLs are a series of biochemical, structural and functional changes that occur from blood collection to transfusion. In brief, exposure to artificial surfaces and high centrifugation forces during PC preparation initiate PSLs by causing platelet activation, fragmentation and biochemical release. Recent method for prevention of contamination include cryopreservation and cold storage. They offer the potential for prolonged storage, reduced bacterial proliferation and improved haemostasis in trauma population. Nowadays ultraviolet based pathogen inactivation system is used. Currently, three PI systems to produce pathogen-reduced PCs are commercially available, utilizing UV in the presence or absence of a photosensitizer. The INTERCEPT system uses amotosalen as photosensitzer in combination with UVA light (320–400 nm). The MIRASOL system uses vitamin B2 (riboflavin) as the photosensitizer and UVA/ UVB light (270–360 nm). The THERAFLEX-UV Platelets system uses UVC light in combination with strong agitation which facilitates light penetration We have completed literature search from PubMed, ScienceDirect and Google Scholar with the keywords 'platelet concentrate', 'platelet storage lesions' and 'prevention of contamination'. PSLs develop during PC preparation and storage. Mechanical and biochemical forces during PC preparation induce platelet activation which persist throughout storage duration. Current developments to reduce room temperature PSLs have focused on reducing platelet glycolysis and activation, via bag material, storage media changes, cryopreservation and cold storage.

Keywords: Platelets, PSL transfusion, cryopreservation , ultraviolet

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MEDICATION ERRORS

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Medication errors are the failure of treatment procedure that can harm to the patient. Errors are preventable event that may cause inappropriate uses while the medication is in the control of health care professionals, patients or consumer. Just as drug can save our lives, error can harm our lives. Most common error involves medication, related to administration of improper doses, omission errors, and prescription error and also due to patient unawareness. Errors arises due to many reasons like incomplete patient and drug information, miscommunication in drug order, lack of appropriate labeling of drugs, environmental factors etc. but the most important cause of medication error is lack of pharmacological knowledge, wrong doses and also use of abbreviations instead of full names. Medication errors have important implication for patient safety and their identification is necessary to improve clinical practice. Detection of errors done by computerized monitoring, chart review, administrative databases and also using direct observation which includes direct reporting and patient monitoring. Pharmacies, nurses and medical practitioner should take of administration of medication to prevent errors. Pharamacovigillance also provides a system to identify these errors. Tools such as audit and FMCEA are used in error prevention. Errors in general can be prevented by proper handling and storage, double checking, reconciled procedures, cross checking of zeroes and decimals. Reduction in medication errors brings a better healthcare system for human beings and others.

Keywords: Medication error, omission error, implication, omission error, pharmacovigillance, pharmacological

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TRANSFUSION REACTIONS- TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

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To overview Transfusion-related acute lung injury (TRALI) caused by transfusion reaction along with various methodologies to prevent it. Hemovigilance plays an essential role in ensuring patient safety with regard to blood transfusions. Transfusion has become extremely safe but can still be associated with adverse reactions. Transfusion-related acute lung injury (TRALI) is a syndrome characterized by acute respiratory distress within 6 hours following blood transfusions and is presently the leading cause of transfusion-related mortality. Tachypnea, tachycardia, and elevated airway pressure are frequently observed. Hypoxemia and lung infiltrates are detected on chest X-rays in almost all patients with TRALI, and half of patients show a pinkish, frothy sputum [25]. Fever, hypotension, and cyanosis occur in less than one-third of patients with TRALI. There are two mechanisms which lead to the development of the syndrome: immune-mediated and non-immune mediated TRALI. Immune-mediated TRALI is caused by anti-HLA (human leukocyte antigen) antibodies class I, II and/or less frequent antibodies directed against specific antigens of granulocytes i.e HNA (human neutrophil antigen), which can be present in the serum of the recipient or donor, and react with the donor's or recipient's leukocytes, respectively. A two-hit hypothesis has been suggested[6] wherein the first-hit leads to localization of neutrophils to the pulmonary microvasculature. The second hit occurs when the aforementioned antibodies are transfused and attach to and activate neutrophils, leading to release of cytokines and vasoactive substances that induce non-cardiac pulmonary edema. Several studies have reported incidence ranges of ١ in ٧,٩٠٠ units of fresh frozen plasma (FFP) to ١ in ٤٣٢ units of whole blood. Supportive care is the mainstay of therapy in TRALI. Oxygen supplementation is employed in all reported cases of TRALI and aggressive respiratory support is needed in 72 percent of patients. Intravenous administration of fluids, as well as vasopressors, are essential for blood pressure support. Use of diuretics, which are indicated in the management of transfusion associated circulatory overload (TACO), should be avoided in TRALI. Corticosteroids can also be beneficial. We have completed literature search from PubMed, Google Scholar and Wikipedia .

We can prevent this by investigating the donors for HLA and HNA antibodies and defer them from future donations. We can also defer multiparous female donors as they have conceived more than one child and might have developed the antibodies through exposure to fetal blood thus they carry a higher risk of inducing immune-mediated TRALI and therefore predominantly collection is from male donors, use solvent detergent treatment plasma screening for donors with anti-HLA antibodies thus mitigating TRALI risk from platelets and mitigate TRALI risk from RBCs are some of the ways by which we can reduce the risk of TRALI.

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SYSTEMIC REVIEW OF PHARMACOECONOMIC MODELS OF SCHIZOPHRENIA

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To identify economic models of pharmacotherapy for schizophrenia and to present the structures of these models and to compare cost-effectiveness of atypical antipsychotics in treatment of schizophrenia. Schizophrenia is a severe and chronic mental illness, it imposes a great burden on both economics and quality of life. It's estimated societal cost ranges from 37% to 214% of GDP per capita. Many treatments are available for schizophrenia, with very different benefit/risk profiles. Economic evaluation produces data incorporating the risks and benefits of the treatments. This approach to the evaluation of ahttps://doi.org/10.1185/03007995.2010.537594nomic evaluations outweigh clinical trial based analyses. However, model-based structure may generate inconsistent conclusions on cost-effectiveness for the same comparison, even when same modelling technique is used.

Considered all model-based economic evaluations published after 2000 searched using pubmed Medline and Embase via Ovid. A pattern of pharmacoeconomic models for schizophrenia was identified, current structures focus on general Schizophrenia future modelling should concentrate on rare cases of schizophrenia. More subtle structures and pattern- level models should be used in future.

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PHARMACOVIGILANCE RISK ASSESSMENT AND DATA ANALYSIS TOOLS FOR ADVERSE EVENT REPORTING OF SODIUM-GLUCOSE CO-TRANSPORTER-2 (SGLT2) INHIBITORS: A SYSTEMATIC REVIEW

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Selectivity aids identification of unique targets in modern pharmacology. The Sodium-Glucose co-Transporter-2 (SGLT2) located in kidneys, prompted companies to develop SGLT2 inhibitors that blocks the re-absorption of glucose in the kidney, increase glucose excretion, thus preventing the occurrence of hyperglycemia, along with body weight and blood pressure reduction. The current review focuses on adverse event reporting of SGLT2 inhibitors. The studies on type 2 diabetes mellitus patients published from 2008 to 2018 on Google Scholar and PubMed, were identified adopting Boolean search methodology in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, incorporating keywords like, 'pharmacovigilance', AND, 'SGLT2 inhibitors'. The thirty articles included in review reported that SGLT2 Inhibitors found to increase the risk for genital and urogenital tract infections, diabetic foot syndrome, toe amputation (dapagliflozin); diabetic ketoacidosis, kidney damage, lower limb amputation (canagliflozin and empagliflozin); pruritis etc.. The risk assessment tools offer limited information, no therapeutic drug monitoring studies (individual case safety reports reported in global and national databases), exposed to bias, redundancy (disproportionality analyses or meta-analysis), overlook demographic heterogeneities and reporting behaviors (voluntary/spontaneous reporting), unpublished and missing data issues (clinical trials-long term and pilot studies).

The quality of pharmacovigilance risk assessment techniques must be assessed to assure their responsible use and publication, facilitating clinicians, reviewers and editors to avoid overlapping research and finally establish their transferability in clinical practice.

Keywords: Sodium-Glucose co-Transporter-2 inhibitors, pharmacovigilance, diabetes mellitus, hyperglycemia.

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ROLE OF PHARMACOGENOMICS' IN DRUG DISCOVERY AND DEVELOPMENT

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Pharmacogenomics and pharmacogenetic are two inter-related term as there is no standard definition of the Pharmacogenomics. Pharmacogenetic is used to differentiate between the compounds but Pharmacogenomics is a term used to differentiate between the patient that are widely used for the drug development and therapy. Pharmacogenomics is the broad term in which we study about all the component of genes to find out various determinant of drug response. The various treatment therapy like cancer chemotherapy and oral-anticoagulant are now carried out with the help of pharmacogenetic status of patient, to minimize the toxicity and failure of the drug therapy. At present the traditional method of selection of drug and dosage form is replaced by the pharmacogenetic method. When this principal is implemented on drug discovery and development, then it reduces the drug dose, Increase rate of absorption and drug targeting etcetera. Current success of pharmacogenomics can be found in different dosage form like codeine, Warfarin, Carbamazepine .It is used in various stage of drug development which are mentioned in table.

Stage	Application of Pharmacogenomic
Drug target identification	Identification and characterization of the gene coding for the drug targeting and to assess the variability,
Phase I clinical trial	Patient selection- inclusion/exclusion criteria

Phase II clinical trial	Dose range selection Dose modification
Phase III clinical trial	Interpretation of trial results based on pharmacogenetics test results
Phase IV clinical trial	Analysis of report adverse event with pharmacogenomics data during development by FDA.
Patient therapeutics	Personalization of drug therapy. Pharmacogenetic data in drug labelling. Identification of responders and non-responders. Identification of high risk group of adverse event.

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AN INSIGHT ON CHILDHOOD INTERSTITIAL LUNG DISEASE – CLASSIFICATION, PATHOPHYSIOLOGY, TREATMENT

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Childhood ILD is a broad term for a group of rare lung disease that can affect infants, children, and teens. The prevalence rate of chILD has been calculated and found to be at 0.13-16.2 cases per 100,000 children per year in India and median mortality in the developed nation was found to be 13 percent. The disease leads to lung growth abnormalities, neuroendocrine cell hyperplasia of infancy. Pulmonary interstitial glycogenosis, developmental disorders such as alveolar capillary dysplasia. The pathophysiology of the disease is not significant generally the exchange of gases in alveoli and perialveolar get derange, restrict lung physiology and functioning. Risk factors for the disease include the family history of interstitial lung disease or childhood ILD, having inherited surfactant disorder in family history, having immune system disorder, having the autoimmune disease like collagen vascular disease. The certain type of childhood ILD is most common in infants and young children, while others can occur in children of any age. Screening and prevention of disease at this time is quite challenging, PFT, X-ray, CT scan are methods for diagnosis. Corticosteroids, hydroxychloroquine, mucolytics are few medications prescribed in chILD.

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PHARMACOVIGILANCE IN PHARMACY PRACTICE

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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 possible drug related problems. As a care provider and in the context of pharmaceutical care, the pharmacist has a responsibility and an active role in monitoring the safe use of medicines. Pharmacovigilance basically targets safety of medicines. Pharmacist plays a crucial role in health systems in maintaining the rational and safe use of medicines since they are drug experts who are specifically trained in this field. Effective use of pharmacist's workforce will improve the outcome of the pharmacotherapy as well as decrease global health costs.

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PHARMACOECONOMICS ANALYSIS : THE NEED OF HOUR

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Healthcare in India is still in a lingering position where despite the massive production and innovation in pharmaceuticals majority of the population fails to derive essential healthcare due to costly and out of pocket expenditure. The cause for this scarce supply and lack of resources is due to inappropriate selection of the

medication, lack of policies and guidelines which adhere to the real world evidence and requirements of the population and fit in their expenditure without unnecessary stress on the patient who is the payer. This study is an overview of the present status and to throw light on the significant need of pharmacoeconomic studies in India. This review article involved the use of internet and databases like Pubmed, Google scholar to find articles depicting the present status and recent proposals made in healthcare in the pharmacoeconomic context. Government policies controlling drug prices and guidelines making health policies like drafts of National pharmaceutical pricing policy (NPPP) private-public collaborated scheme like FICCI HEAL 2015 were looked into to derive updates. Keywords like Pharmacoeconomics, Healthcare, Indian status were searched.

India is a country of developing mixed economy by nominal GDP ranking 6th in the world. Our country's pharmaceutical production gives access for the most affordable anti-HIV treatment and has given hope to innumerable with AIDS, the credit of producing worlds least costly vaccines in the world and exporting it about 150 countries and producing low cost generics in comparison to sky high branded medicines of developed countries. Despite of this reputation of being referred to as the pharmacy of the developing world, about 80% of India's population is not covered under any health insurance policy or any government aided health scheme. The countries GDP expenditure on health care is as minimal as cumulative 4.2% , with only 1% by the public sector which is the lowest globally. Most of the expenditure about 80% of this by the patient is private or out of pocket. The pharmacoeconomic status lags much behind the doable situation. Emphasis on pharmacoeconomic studies to derive data which fill in gaps for building the foundation of such schemes, strengthening the healthcare insurance and selection of the most appropriate drugs by the healthcare providers can help transform the situation and aid medicines to reach the compelling demand in the needful population.

Keywords: Pharmacoeconomics, India, Healthcare, Need , Healthcare insurance

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Medication errors

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Introduction: - Medication errors are common during transitions of care. Dispensing errors are common in hospital pharmacies. Investigating dispensing errors is important for identifying the factors involved and developing strategies to reduce their occurrence.

Methods: - A systematic search was conducted to detect published reports of randomized trials using the National Library of Medicine's PubMed database, the Cochrane Database of Systematic Reviews, and Google Scholar inclusive to August 17, 2018. Search terms included pharmacist, medication, errors, readmission, transition, and discharge. A priori main outcomes included medication errors and health-care resources utilization (hospital readmission and/or emergency room visits). Quantitative analysis was performed using a random effect method.

Results: - Thirteen randomized trials examining 3503 patients were included in the final analysis. The aggregate effect of the 10 studies evaluating the effect of pharmacists intervention on the incidence of medication errors during transitions of care favored pharmacist over control with an odds ratio (95% confidence interval [CI]) of 0.44 (0.31–0.63). The overall effect of 4 studies evaluating the effect of a pharmacist intervention on the incidence of emergency room visits compared with control favored the pharmacist intervention, odds ratio (95% CI) of 0.42 (0.22–0.78), number needed to treat (95% CI) of 6.2 (3.4–31.4).

Conclusions: - Pharmacist transition of care intervention is an effective strategy to reduce medication errors after hospital discharge. In addition, a pharmacist intervention also reduces subsequent emergency room visits. Hospitals should consider implementing this intervention to improve patient safety and quality during transitions of care.

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CRISPR mediated FAT1 and p53 Knockout in Glioblastoma cells

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Objective: Generation of stable FAT1 and p53 Knockout in Glioblastoma cell line U87MG using Lenti-CRISPR V2 vector.

Introduction: Glioma is a brain tumor arising from the cancerous glial cells of brain. Studies have suggested FAT1 to have dual role both as tumor suppressor and as oncogene in cell/context dependent manner. Another gene p53, a known tumor suppressor gene, is altered in about 87% cases of Glioblastoma tumors. Here in our study, we have used CRISPR/Cas9 technique to generate a stable knockout of FAT1 and P53 genes in U87MG cell line to study the functional link between FAT1 and p53 gene in human glioma cell line, U87MG.

Results: The 3 best scored sgRNA oligos designed using online software (Optimized Crispr Design: www.crispr.mit.edu) were commercially synthesized. The oligo segments were annealed at 950C for 5 minutes followed by 20 minutes at room temperature. The annealed oligos were then subjected to phosphorylation using PNK enzyme.The vector Lenti-CRISPR V2 was linearized using BsmB1 restriction enzyme and then dephosphorylated using Alkaline Phosphatase. The sgRNA oligos and linearized plasmids were ligated using T4 DNA ligase enzyme. Transformation of the cloned vectors was done in Stbl3 competent cells. Colonies were picked, inoculated into LB media, processed for plamid isolation and PCR confirmation. After confirmation, the positive colonies were selected and used for virus preparation in HEK cells for transduction in U87MG cell line for gene expression analyses by realtime PCR and Western blotting.

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Current Perspectives of Herbal Medicines in Care of Heart Diseases

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Every third person of population is suffering from various kinds of heart disease such as congestive heart failure, coronary heart disease, ischemia and stroke. It is severe health problem of mankind and lead to death because of significant alteration in biochemical and endogenous enzymes creatine phosphokinase, high density lipoprotein, alanine transaminase, low density lipoprotein, serum glutamate oxaloacetate transaminase, alkaline phosphatise, very low density lipoprotein, triglycerides, cholesterol, malonaldialdehyde, glutathione reductase, Glutathione peroxidase, Superoxide dismutase, catalase and glutathione. The availability of various synthetic allopathic medicines in the market may not be abundant for therapy of heart diseases and causes side effects or adverse drug reactions (ADRs) initiated by them. Therefore Scientist focuses their research of interest towards herbal therapy of medicinal herbs to overcome these markers responsible for heart disease with fewer side effects and minimal cost in comparison to allopathic medicines and also have cardio-tonic and cardio-protective effect. This review focused on current perspectives of herbal medicines in care of heart diseases and certainly facilitates in enlisting the medicinal herbs incurring cardioprotective action.

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Current Aspects of Pharmacovigilance in Healthcare Professional

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In the present era people are employing advance and more efficacious drugs with various medical circumstances which are being fabricated with growing scientific approaches. Efficacy and safety of patients are the two dominant affairs about any medicine. Pharmacovigilance backing safe and apt employ of drugs. The purposes of pharmacovigilance to devoted the judgment of effectiveness, mischief, welfare and hazards of drugs and also boost literacy, clinical guidance, rational and safe benefits of drugs. Adverse drug reactions (ADRs) have become a primarily problem in growing countries so the different method of pharmacovigilance include cohort event monitoring, individual case safety reports, longitudinal electronic patient records, periodic safety update reports, clinical review of case reports, casual reporting, expedited report and record linkage that overcome untoward effects and ADRs. Casual reporting of ADRs is a crucial element of pharmacovigilance. Awareness of pharmacovigilance could form the basis for interference ancipated at bettering reporting standard and reducing the ADRs. The present review emphasized on current aspects of pharmacovigilance in healthcare professional. This review definitely play significant role for healthcare professional of various field in overcome ADRs and ultimately reduce the mortality rate.

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Pharmacovigilance and Adverse Drug Reaction in Herbal Medicine

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The use of Ayurvedic medicines is popular in India and in recent times has become accepted in other countries. Pharmacovigilance is the science and practice related to the detection, assessment, understanding, and prevention of adverse effects of drugs or any other possible drug related problems. The objective of the present article is to review the recent trends and challenges posed in the practice of pharmacovigilance of herbal drugs, especially in the Indian context and to shed light on the importance of pharmacovigilance practice in establishing and maintenance of rational use of these drugs. There is increasing awareness of the need to develop pharmacovigilance for herbal medicines. Applying standard pharmacovigilance techniques (WHO guidelines) presents additional challenges, related to the ways in which herbal medicines are regulated, used, named, and perceived. Proper reporting of suspected adverse drug reactions to herbal medicines is currently the main method of detection. However, there is under-reporting for herbal medicines, since users do not seek professional advice about their use of such products, or report adverse effects. Herbal medicine practitioners are not recognized as reporters to spontaneous reporting schemes. Several other conventional pharmacovigilance tools, such as prescription-event monitoring and the use of computerized health record databases, are currently of little use for evaluating the safety of herbal medicines although modified methods have been developed. This process of pharmacovigilance of herbals in India has come a long way since its initiation. The promotion of the systematic and rational use of drugs requires the reporting of adverse events possibly caused by herbal and traditional medicines also.

Key words: Adverse drug reactions, pharmacovigilance, herbal medicines

SUPPORTING ORGANISATIONS

Delhi Pharmaceutical Sciences & Research University (DPSRU)

Council of Scientific and Industrial Research

ISPOR INDIA CHAPTER

International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
India Chapter

Society of Pharmacovigilance (India)

Ministry of Health & Family Welfare
Government of India

Indian Pharmacopoeia Commission

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