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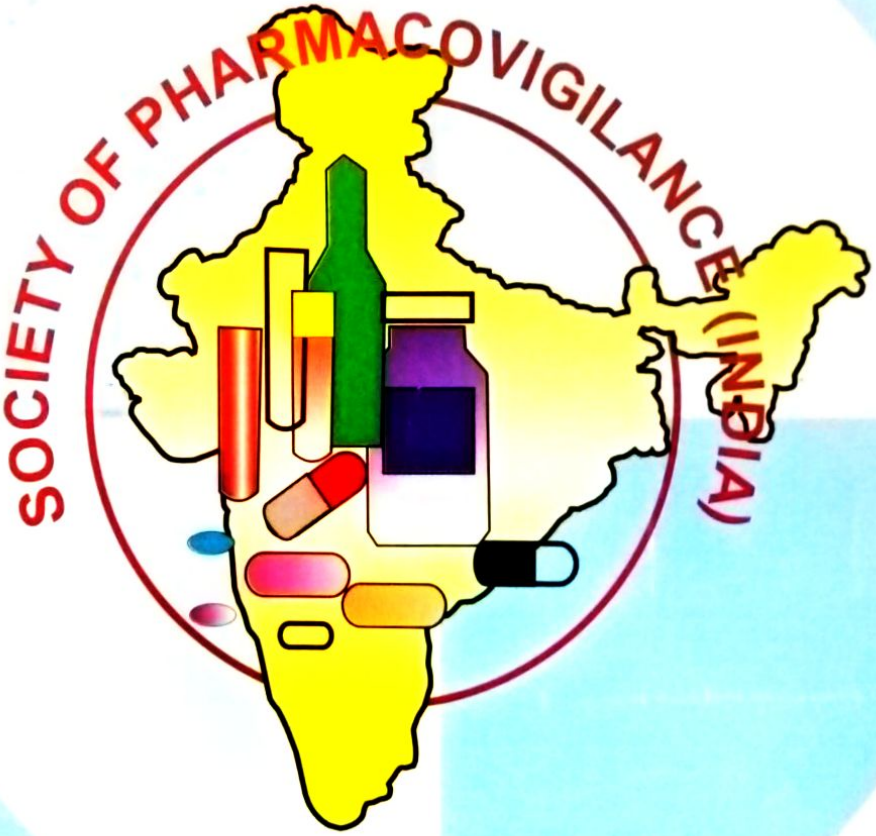

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PRE-CONFERENCE WORKSHOP ON SAFETY EVALUATION OF DRUGS

Safety Monitoring During Clinical Trial

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During drug development phase (clinical trials) monitoring of patient safety is a critical component as prior to the marketing authorization of a drug, rigorous safety monitoring is required. Safety monitoring in clinical trials can be defined as a planned, ongoing process of reviewing data collected in a clinical trial with the primary purpose of protecting the safety of trial participants, the credibility of the trial, and the validity of trial results [1].

Clinical trial applicants (Sponsors) need to work proactively and collaboratively with all stakeholders (investigator, clinical research staff at the investigator site, IRB/EC, health authorities) to ensure a systematic and efficient approach to safety monitoring so as to adequately characterize the safety profile of the product in order to obtain regulatory approval and marketing authorization.

Safety monitoring may be conducted in a variety of ways, including the pharmaceutical company sponsoring the study, the investigators who are trained to collect and report adverse event data and to provide follow-up information on request, Ethics Committees (ECs), known as Institutional Review Boards (IRBs) and, for some studies, Data Monitoring Committees (DMCs) [2].

ECs/IRBs are responsible for approving an interventional clinical study based on an evaluation of, among other things, whether the study's design and conduct minimize the risks to subjects and whether the anticipated benefits reasonably outweigh the potential risks. An EC/IRB evaluation typically entails review of the study protocol and associated procedures, relevant background information, informed consent documentation, and proposed plans for informing participants about the benefits and risks of the study. An EC/IRB may request information about the approach to study monitoring, including the statistical basis for early termination, if relevant, and what steps the sponsor is taking to minimize the risks to patients while assuring data quality.

Patient safety is monitored during all clinical studies, but not all studies require monitoring by a formal external committee like DMCs (also known as Data and Safety Monitoring Boards [DSMBs]). DMcs or DSMBs are generally established for large, randomized multisite studies that evaluate treatments intended to prolong life or reduce risk of a major adverse health outcome such as a cardiovascular event or recurrence of cancer. DMCs are generally recommended for any controlled study of any size that will compare rates of mortality or major morbidity and in other circumstances where safety concerns may be unusually high.

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Types of ADR and Methods of ADR Monitoring

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The provision of rapid, early alerts to Adverse Drug Reactions is the primary goal of any pharmacovigilance programme, for which a basic understanding is essential. Adverse Drug Reaction can be classified accordingly to severity viz mild, moderate and severe. This categorization may be for layman but the prevalent pharmacological classification is more scientific: Type A (Augmented) Reaction, Type B (Bizarre) Reaction, Type C (Continuous) Reaction, Type D (Delayed) Reaction, and Type E (End of use) Reaction.

Nearly 75% reactions (Type A) can be explained on the basis of the knowledge of Pharmacological actions. These are dose dependent and can be reproduced in animal experimentation. The other type (B) which constitute about 25% are antigen-antibody reactions or hyper sensitivity reactions. These are unrelated to dose and are unrelated to pharmacological actions of the drug. Other reactions including type C, D and E are usually drug specific.

Several methods have been employed for monitoring ADRs. Most convenient and prevalent is spontaneous monitoring. The others include Targeted reporting (specific drug), Cohort Event Monitoring (monitoring new chemical entity) Electronic Health Record Mining (supplementary source of date). Intensified ADR reporting (Additional efforts to monitor a specific drug). Besides these commonly used, several other methods are used for specific purposes. The statistical considerations need to be addressed while planning any epidemiological study.

Challenges of Pharmacovigilance Programme

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Origin of pharmacovigilance in India goes back to 1986, when a formal adverse drug reaction (ADR) monitoring system consisted of 12 regional centers, each covering a population of 50 million. India is a hub for clinical trials flooded with more than 6,000 licensed drug manufacturers and 60,000 branded formulations. Pharmacovigilance is an important part of clinical research and practice, yet there is an immense need to understand the importance of pharmacovigilance.

The Pharmacovigilance Programme of India was launched with an objective to safe guard the health of people of India. While major advancements in this discipline have taken place in West, implementation and compliance still remain as challenge in India. So, it is important to address various challenges of pharmacovigilance. In India, the events are not properly reported due to lack of time, low motivation, ignorance. Lack of continuing medical education on pharmacovigilance and dearth of drug information particularly at the level of primary health centres and private practitioners lead to underreporting of ADR. The practice of self-medication, use of traditional medicines pose other challenges as adverse events in such cases often go unreported. In addition, there are lacunae like lack of communication among healthcare professionals, shortage of trained personnel and inadequate training on pharmacovigilance at undergraduate level.

These challenges can be addressed and the mission to safeguard the health is achievable by incorporating changes like making pharmacovigilance reporting mandatory at all levels, introducing pharmacovigilance inspections. Intensive training should be given in all aspects of pharmacovigilance to various stake holders including the patients, efficient system of communication, creating a clinical trial database for SAEs and ADRs for signal detection and access to relevant data for various stakeholders. Thus it can help in proper implementation and compliance of the programme.

Guidelines for Publication of Adverse Drug Reaction Reports

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Doctors, nurses and pharmacists are primarily concerned with provision of health care to the needy. Drugs remain the most useful tool in health care delivery – they do heal and help but can hurt and harm, too. Adverse drug reactions (ADRs) are almost inevitable.

The ability to recognise, redress and report ADRs is an indispensable component of health care. ADR cases typically originate with health care providers (HCPs) who, while caring for patients, suspect a potentially causal relation between a medication, prescribed or self-used, and an adverse event (AE). Besides reporting an AE case as requested or required by the relevant health authorities, the HCPs may also elect to submit the observation to a biomedical journal for publication.

Why Publish of AE Case Reports?: Publication of ADR case reports in professional journals would help potential researchers in generating hypotheses on possible product-event association that can be formally tested in observational or interventional studies. Such publications also enable decision-makers – clinical, regulatory or insurance, to better understand a product's potential for benefits and risks. Published ADR case reports may provide important clue to the ongoing postmarketing surveillance of a given medicinal product as they lend credence to important signals raised in these AE reports. Published case reports can have a significant clinical impact, especially for rare events that might not be detected in clinical trials. They serve to increase awareness of the possible association between the exposure and the AE and thus stimulate further reports. A case series, on the other hand - might provide a stronger signal than a single case; represents systematic confounding by biases; only builds the foundation for explanatory hypotheses, but cannot provide information on the quantitative population risk; represents an unknown numerator due to underreporting, and the unknown denominator (total no. of exposed patients) and cannot provide balanced information on the risk factors for such an event.

Quality of Published ADR Case Reports: The completeness of published AE case reports vary considerably, with lack of relevant info about the patient, the event, all potentially relevant exposures, the clinical decision making processes, and most importantly, the possible alternative aetiologies. This makes it difficult, if not impossible to arrive at a definitive diagnosis for the event. Deficiencies in vital information such as differential diagnoses, provisional assessment of causality, pharmacological or biological plausibility - can limit the value of published reports.

Publication of ADR Reports – Guidance: Journals vary widely in AE report publication policy. The ISPE and ISoP jointly made recommendations for AE report publication – they're relevant to authors for writing AE reports for publication; editors of journals while allowing publication and universities, institutions to incorporate them into the professional (medical, nursing, pharmacy) course curricula.

The ISPE-ISoP Joint Recommendations on reporting ADR cases include the following:

- Event details – onset and duration, severity, causal relation with drug exposure, treatment given and response, outcome
- Patient details – medical history, physical exam and lab test findings, co-morbidities
- Drug (exposure) details – suspect drug, indication of (suspect) drug use, drug-event interface highlighting temporality, dechallenge-rechallenge impact, concomitant meds
- Title consistent with the content

Drug Safety in the 21st Century - Let Us Not Repeat Past Mistakes.

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Over the last 100 years, drug development and use has evolved from a backyard science to a multimillion dollar industry. There have been great advanced in all therapeutic areas of medicine; but this has not been without significant errors resulting in death and morbidity.

In several instances, the lessons of the past have gone unheeded and we continue to repeat some of the mistakes of our forebears. This has been most visible in drug safety where drug related morbidity and mortality (mostly in children) have shaped the current face of drug development and use globally.

The key US regulatory Acts (Biologics Control Act, 1902, The Federal Food, Drug and Cosmetic (FDC) Act, 1938 and the Kefauver-Harris amendments) have dictated drug development internationally. All of these legislative changed followed either deaths or severe morbidity in children.

Over the last 30 years we have seen a range of international withdrawals and restrictions in marketed medicines due to severe, and often predictable, adverse drug effects. These include:

- Mibefridil and multiple CYP 450 drug interactions
- Cisparide and Long QT syndrome
- Rofecoxib and Cardiac Death
- Troglitazone and Liver Failure
- Sildenafil and non-arteritic anterior ischemic optic neuropathy

However, probably the most famous drug disaster, thalidomide, has made a recent resurgence as we develop strict safety guidelines in its use. Even now, commonly used medicines such as over-the-counter pain relievers and cough medicines continue to cause morbidity and mortality both due to under-recognition of their adverse reactions or failure to use them safely.

The hope for the future is the development of individualised medicine and the ongoing scientific discoveries in the field of pharmacogenomics.

INTERNATIONAL SYMPOSIUM ON SAFE MEDICINE AND SAFE PATIENT

How pharmacovigilance databases can contribute to medicine safety and safe medical practice to improve patient safety.

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The chief purpose of pharmacovigilance in conjunction with medicine regulation is to ensure that the medicines approved for clinical conditions have acceptable potential benefit to risk ratios. Sponsor companies are required to provide complete information for prescribers about the efficacy and safety of their medicines and to make changes to this information in a timely manner as post-marketing findings emerge. Usually this information concerns a newly recognised adverse reaction or interaction. On occasions, however, adverse drug reaction reports provide evidence of prescribing patterns and patient susceptibility that can influence the nature and intensity of adverse reactions and this can also be communicated. Examples are adverse drug reaction reports that emphasise the need to monitor patients in order to prevent or promptly diagnose specific adverse reactions, to avoid prescription of medicines known to be interacting, to pay careful attention to risks and potential benefits when considering age and co-morbidities, and to consider whether the indications for the reported medicine were appropriate. Overt medication error may also be evident and pharmacovigilance centres can be useful repositories of such reports so that analyses can be made for root causes. By comparing reports in the New Zealand and Indian pharmacovigilance databases it is clear that patterns of drug use and adverse reactions are often similar but there is also variation indicating the need to accrue local data in order to provide relevant advice.

Why Pharmacovigilance of Pain Killers

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On an average 1 in 5 adults take one or the other analgesic for ailments ranging from mild headache, fever and pain. However, the data about their safety is unclear. Reports in literature are abound with cardio vascular, and gastrointestinal, nephropathy and other ADRs with non-selective nonsteroidal anti-inflammatory drugs and selective cyclo oxygenase -2 inhibitors. However there is little information about the third major analgesic group opioids. The US food and Drug administration recently required manufactures of major opioids to put in place a Risk Evaluation and Mitigation strategy because of their uncertain risk to benefit ratio.

Sever nonmalignant pain affects a large proportion of adults. Optimal treatment is not clear, and opioids are being prescribed to many, but little is known about their safety. Opioids when used without taking proper precautions such as starling with very small doses, monitoring patient for the development of intestinal paralysis (spastic), Respiratory depression, pinpoint pupil, cardio vascular manifestations, manifestations due histamine release. On the first suspicion of ADR, Naloxone should be administered. In US and European Countries opioids alone and also together with Naloxone are available.

In an Apex Hospital at Delhi, a 74 years old lady died of codeine (high dose) included intestinal paralyses, respiratory depression and cardio vascular manifestations as Naloxone was not administered.

Tackling Readmissions: Where Are We Heading?

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Patient safety is increasingly becoming one of the most pressing healthcare delivery challenges. Globally around 10% of the patients are impacted due to healthcare errors every year. The issue gets compounded in the developing world where 50% of medical diagnostic equipments are unusable or partly usable leading to delay and errors in care delivery. India alone records over 5 million injuries every year due to lack of proper patient safety systems. Globally unsafe injections cause 1.3 million deaths every year primarily due to transmission of blood-borne pathogens. As per studies, patients with one patient safety incident during the initial hospitalization have double the risk of readmission leading to increased risk and discomfort for the patient.

One of the key ways to improve patient safety is by reducing avoidable readmissions. Care delivery inefficiencies and inadequate measures to curb them can lead to higher readmission rates. Such readmissions are preventable and are caused by poor quality of care during the initial admission; lack of proper communication with patients, their caregivers and their clinicians; inaccurate pre-discharge assessment; and lack of coordination of care after discharge. As high as 34% of the patients discharged from acute-care hospitals in the US were re-hospitalized within 90 days according to a recent study. Lack of appropriate pharmacovigilance and human errors result in loss of 3 million healthy life years in India annually.

Bridging the gaps in patient safety to curb readmission rates will result in better resource utilization, greater quality of care and higher patient satisfaction. This requires a collaborative approach from all stakeholders to streamline process and induce safety measures throughout patient engagement cycle such as use of technology to reduce risks, empowering patients with knowledge, post-discharge care management etc.

Apollo Hospitals Group, India's largest integrated healthcare provider is committed to patient safety through a robust infection control program, continuous clinical monitoring, quality initiatives and a sophisticated information management system. The group has 8 JCI and 10 NABH accredited hospitals along with the first JCI accredited stroke program in the world.

Overview of Adverse Drug Reaction reporting system in Nepal - an experience from Regional Pharmacovigilance Center of Western Nepal

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Introduction: Pharmacovigilance in Nepal is in the preliminary stage. There are 7 regional centers whereas Department of Drug Administration (DDA) acts as national center. Pharmacovigilance Center in Manipal Teaching Hospital is one among 7 regional centers where the present study was conducted. The objective of the study was to study the incidence and pattern of ADRs in medical ward and to assess the causality, severity and preventability of reported ADRs

Methods: The suspected Adverse Drug Reactions (ADRs) were collected by pharmacists in the ADRs reporting form during the ward round. The details of suspected drug, drug reaction and all related data were

documented. Naranjo Algorithm, modified Hartwig and Siegel and modified Shumock and Thornton scale were used for assessment of causality, severity and preventability respectively. All the suspected ADRs were reported to National Pharmacovigilance Center and then to Uppsala Monitoring Center through the electronic online data base called Vigiflow.

Results: Among 1,105 patients studied, 51 patients experienced ADR (4.61%). Incident of ADRs are more with antibiotics (47.06%) and Ceftriaxone was at top of list (15.69 %). Dermatological system (25.49%) and gastrointestinal system (19.61%) were affected more. About 33.33% of suspected drugs were discontinued. About 41.18% of ADRs required medical treatment where antihistaminic (24.32%) and antipruritic (21.62%) were most commonly used to treat ADRs. In total, 64.71 % of ADRs were probable, 62.75% were mild in nature and 60.78% were probably preventable.

Conclusions: Study suggests ADRs are still of great problem in hospitalized patients and more than 60% of them are preventable. Reporting of ADRs can provide better way to prevent the future occurrence healthcare provider plays an important role.

Monitoring drug safety in pregnancy and lactation

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In western countries, approximately 80% of the women use either prescribed or over the counter drug at any point in time during pregnancy. At the time of marketing, knowledge on the safety of the use of drugs during pregnancy is still limited, as pregnant women are rarely included in pre-marketing research. Also after marketing, collecting information on drug use during pregnancy is bothersome, but it is obvious that this knowledge is needed for a rational use of drugs.

Many conditions require treatment with drugs during pregnancy, since the underlying condition may pose a risk for mother and child. An example is the use of anti-epileptic drugs (AEDs) which is associated with an increased risk of birth defects. Since epilepsy itself is also associated with potential risks for mother and child, an optimal AED treatment is needed.

The current lack of knowledge on the teratogenic risks of medical drug use hampers healthcare professionals in making evidence-based decisions on whether or not the beneficial effects of treatment outweigh the possible risks for the developing fetus and the pregnant woman. Information on drug use often relies on case reports and case series and a limited number of dedicated case-control studies.
Over the past years, there is a growing number of additional approaches on monitoring the safety of drugs during pregnancy. Next to the use of voluntary reporting systems, linkage of various databases like perinatal registries and databases on reimbursement of drugs are being used that may enable a systematic collection of information and fill this gap of knowledge.

At the Teratology Information Service of the Netherlands Pharmacovigilance Centre Lareb, trained pharmacists and physicians advise there practicing colleagues and midwife on the treatment of drugs during pregnancy and lactation. Information is collected from literature and from monitoring previous cases on which questions were posed to the center. To enable collecting dedicated information on drug use during pregnancy and lactation in a systematic way, the pREGnant project was initiated in 2013 in order to develop and implement a national register for medical drug use during pregnancy in the Netherlands. This register will be used for signal detection and conducting epidemiological studies. Exposure to medical drugs and other potential risk factors are monitored prospectively. Data are collected by means of web-based questionnaires that are completed by pregnant women. At different moments during pregnancy and after

birth of the child, information is gathered on medical drug use, the health of the pregnant woman, pregnancy complications and outcomes, and the health of the child. Initially, inclusion of pregnant women mainly takes place at midwiferies, although other approaches will be taken and evaluated as well. The register focuses on all drug use during pregnancy, but is designed in such a way that targeted studies can be carried out to specific groups of drugs or the circumstances under which they are used. This offers the opportunity for embedding cohort studies and thereby diminishing the burden for healthcare professionals involved. An example is the collection of data on the use of antiepileptic drugs that are also forwarded to the international EURAP (International Registry of Antiepileptic Drugs and Pregnancy) study, an international AEDs and pregnancy registry that does not interfere with the treatment prescribed by the patient's physician. Women taking antiepileptic drugs at conception are eligible for inclusion whether the indication for treatment is epilepsy or other disorders. When AEDs are being used, dedicated questions are posed on the underlying condition and the use of these drugs. This is example is one of many initiatives that are currently being developed to optimize the collection of information on the use of drugs during pregnancy and lactation.

Drug Safety in Children – A Special Case

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Until recently, children have been treated by society in general, and the pharmaceutical industry specifically, as small adults. This has resulted in a series of therapeutic disasters mostly affecting children. While adults have benefited from these mishaps with advances in both the safety and efficacious use of medicines, children have remained therapeutic orphans. Until recently studies in children have been limited or totally absent. Therapies used in children are often untested and doses are extrapolated from those in adults. This has resulted in both over-dosing and under-dosing.

A series of legislative changed in the USA dating from the 1990 were intended to improve the situation and encourage or even force pharmaceutical companies to include children in their development programs. However, these incentives have had limited effect with relatively few real therapeutic advances in children being attributed to them despite a large monetary investment.

The more recent European legislative changes including the paediatric investigational plan as part of all new drug development programs are showing more promise. The EU appears to be less likely to offer waivers to sponsors than seemed to occur in the USA and there has been a recent rapid rise in the number of paediatric studies involving new chemical entities.

Alongside this has been advances in evidence based prescribing for children such as the ***British National Formulary for Children*** (BNFc) which evolved out for the UK Medicines for Children. At an international level, the instigation of the ***Essential Medicines List for Children*** by the World Health Organisation has focused the world on making medicines Child Size. The first WHO international ***Model Formulary for Children*** was published in 2010 and is a further incentive for countries to develop local formularies to support the appropriate treatment of child in their regions.

The challenge for the future is the improved evidence for the use of medicines in children and the development of improved and more palatable formulations to cover the full age range from premature neonates to adulthood.

K.C. SINGHAL ORATION

Another perspective in pharmacovigilance

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Pharmacovigilance, the science dedicated to the safety of drugs as used in the clinical practice, is based on experiences from both healthcare professionals and patients with drugs used in daily circumstances. In this way knowledge on the harmful effects of drugs can be generated, both at the individual and the population level. Eventually, this knowledge will be applied in clinical practice again. Various stakeholders are involved in pharmacovigilance, each having their own role in a process that is eventually designed to increase the safety of use of medicines.

Since the early 60's the safety of drugs after marketing is studied in a systematic way in order to signal hitherto unknown associations of drugs and adverse drug reactions (ADRs). In the early days, gathering this information mainly relied on spontaneous reporting, but over the years additional approaches like observational research became more important. Safety information generated by these approaches is primarily used to make decision on the balance of risk and benefits of drugs once they are marketed. For this reason, this safety information needed to get insight in potential risks of drugs should reflect the point of view of the regulatory authorities, responsible for making these decisions. Large, sometimes complicated and costly studies are needed to get reliable data on the incidence of ADRs especially when pharmacological related drugs are being compared. The physicians treating patients using these drugs, will not only be interested in the incidence of ADRs, but also have a need for information about potential risk factors and clinical signs and symptoms of the ADRs involved. Unfortunately, since a tailor made approach is needed, this information is not always provided by the aforementioned studies.
From a patient's perspective, the incidence and therefore risk of getting ADRs is important as well, but moreover, information on the time course of ADRs, information on the impact on quality of life and even experiences of other patients are welcomed. Experiences with ADR reporting by patients in the Netherlands showed that especially latter type of information is reported, reflecting different perspective on drug safety as compared to health authorities and healthcare professionals. The call for detailed & reliable information on incidences of ADRs gave rise to growing sizes of databases. This is not necessarily an advantage, since the time-consuming individual case by case analysis of every incoming report that will provide information on time course, risk factors & individual experiences, is very often not feasible anymore. Although the nature of signal detection has changed over the years from qualitative to a quantitative approach, the importance of reliable clinical information of ADRs did not change.

Apart from approval and use of drugs in practice, other aspects, like the circumstances under which drugs are being used, will become important as well. Knowledge about off-label use, medication errors and counterfeiting will call for a different focus which not only spontaneous reports but also and dedicated prospective cohort studies may provide. Is it time for another perspective in pharmacovigilance? In the majority of studies, the perspective the regulator and health care professional is still leading, and to a lesser extent the perspective of patients. The aforementioned needs of various stakeholders and altered scope of pharmacovigilance are likely to be pivotal for changing, more balanced landscape in pharmacovigilance the next years.

NATIONAL SYMPOSIA: PHARMACOVIGILANCE OF AYURVEDA, SIDDHA AND UNANI DRUGS (ASU DRUGS)

Adverse Effect with Ayurveda Drugs- Facts and Fallacies

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Introduction: Traditional systems of medicines are being used since centuries for healthcare by people in countries of South-East Asia Region as well as in other parts of the world. In recent times, public interest has shifted towards traditional medicines for various concerns. They continues to be a valuable source of remedies to the people around the world to secure their health. World Health Organization (WHO) also encourages, recommends and promotes traditional medicines in national health programmes because such drugs are easily available, comparatively safe, people have faith in such remedies, and their industrial production is environment friendly and are attracting attention of developing countries as an alternative or adjuvant to synthetic drugs.

Though herbals are used frequently; on later period, herbo-mineral and metallic preparations occupied a significant place in Ayurvedic therapeutics. Since then, they are being routinely prescribed in different parts of India for centuries. The preparations are attributed to be safe and efficacious even in minute doses. Being used for over a long period, these medicines are acknowledged as safe, which is the ultimate proof for their non - toxic beneficial effects. However, the use of metallic preparations has raised safety concerns and debate in scientific community in the past couple of decades. Such concerns have tried to malign the reputation of Ayurveda at global levels. This also made clear to establish Pharmacovigilance system for Ayurveda Drugs.

Classical Contrive: A drug can be panacea or poison. A drug fulfilling the criterion of a standard drug will always become panacea provided, if it is used properly. On the other hand, a poorly prepared or manufactured drug however used skillfully, will always prove to be a poison. Classics of Ayurveda do mention the hazards of drugs, which are not properly manufactured. Such mentions clearly show that they were fully aware of the hazards of drugs of poor quality. Based on this knowledge, seers have prescribed specific processing techniques (like Shodhana and Marana etc.), which will remove the hazardous properties from these drugs. They have also prescribed testing methods (like Bhasma Pariksha), which will tell the manufacturer whether the drug has attained a form, which does not have hazardous properties when used judiciously by a physician.

Adverse Drug Reactions and Ayurveda: There is a popular misconception that Ayurveda drugs are devoid of adverse reactions. Charaka describes adverse reactions to medicines when they are prepared or used inappropriately. Attention is given to factors like the plant to be used (prakriti), its properties (guna), actions (karma; prabhava), habitat (desha), season in which it grows (ritu), harvesting conditions (grahitam), method of storage (nihitam) and pharmaceutical processing (upaskritam), which must be considered while selecting the starting material that goes to form the medicine. Great care has been imposed while using all preparations in therapeutics. Charaka also describes factors to be considered when selecting medicines in order to minimize adverse reactions like the constitution of the patient (prakriti), age (vaya), disease (vikruti), tolerance (satmya), psychological state (satwa), digestive capacity (ahara-shakti), capacity for exercise (vyayama shakti), quality of tissues (Sara) and strength (bala). Ayurveda drugs are to be administered orally in specified quantities with great caution along with requisite anupana (vehicles). Anupana is anticipated to play a key role in safety aspects. In absence of anupana, adverse reactions are likely. A gap of one or two or three days is to be observed while administering metallic preparations.

Ayurveda considers a number of factors while administering a drug. Right drug at the Right dose by the Right route at the Right time for the Right person will always provide beneficial effects. Increased morbidity, risk of unwanted effects etc. have been repeatedly been attributed with irrational drug use. WHO also considers irrational use of medicines (overuse, underuse or misuse) as a major problem worldwide that results

in widespread health hazards. This aspect has been considered by the pioneers of Ayurveda in detail in addition to the other possible ways by which toxicity, untoward effects can occur and provided all the guidelines to avoid the occurrence of such incidences. Even, if in any eventuality, some untoward effects are noticed due to noncompliance of code of conduct of the treatment, the treatment procedures for such conditions have also been prescribed.

Few recent studies on Ayurveda Metallic Preparations: Studies on mercurial preparations like Makaradhwaja are reported to improve the quality of life, attributed with anti-stress activity, safe at higher dose levels. Rasa sindhura, another mercurial preparation is proven to increase life-span, and fecundity of Drosophila. Garbhachintamani Rasa has shown to improve hepatic functions, Mahamrutyunjaya Rasa is proven to be cardiotonic. Arogyavardhini Vati, another herbo-mineral preparation is found to be safer at higher therapeutic dose levels. Bhasmas of Abhraka (mica), Mandura (iron), and herbo-mineral formulations like Swasa Kuthara rasa (mercury, sulphur) and Smriti Sagara rasa (mixture of metals) were reported to be free from genotoxicity. Another metallic preparation, Swarna Makshika Bhasma (Chalcopyrite predominant of Copper) is also reported to be free from genotoxic potential.

Pharmacovigilance of Ayurveda, Siddha and Unani Medicines: Considering such reports and to develop ADR related data on Ayurveda drugs, Institute for Post Graduate Teaching & Research in Ayurveda, Gujarat Ayurved University, Jamnagar has taken the lead and conducted one workshop during 3rd and 4th December 2007 in the premises of Gujarat Ayurved University under the sponsorship of WHO Country Office, India. Looking in to the active initiation, Director of AYUSH, Ministry of Health & Family Welfare, New Delhi announced establishment of a Pharmacovigilance Cell at the institute level, which will prepare the protocol and ADR Reporting Format for implementation of Pharmacovigilance system for ASU Drugs. Subsequent to this, Department of AYUSH has declared Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar as National Pharmacovigilance Resource Centre for ASU Drugs (NPRC - ASU).

Conclusion: Comprehensive information available in the classics clearly reflects that the pioneers of Ayurveda were well aware of the toxicity or untoward effects that can occur with the improper usage of metals or minerals. They have documented specific processing techniques, therapeutic dosage and concurrent diet advice to avoid any ill effects. Even so, if some complications are noticed due to faulty processing, improper administration or non-compliance of code of conduct, treatment procedures for such complications have also been prescribed. This implies that, the seers were well versed with the pharmacokinetics and pharmacodynamics.

All this information leaves no doubt that the pioneers of Ayurveda were well aware of both the remarkable therapeutic benefits and potential toxicity of metals and minerals. They took precautions to avoid any adverse reactions resulting from their use in therapeutics. To conclude, it can be said that rational use of Ayurveda drugs was well established before the period of Charaka Samhita (more than 5000 BC) which is evident from the clear descriptions available in the classic. The need of the hour is to generate awareness, practice rational drug use and develop a database for adverse drug reactions with Ayurveda drugs.

Pharmacovigilance in Unani Medicine

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Lot of emphasis has been given in Unani Literature with respect to the possible adverse/harmful effects of various drugs and also the measures by which these adverse drug reactions can be avoided like concept of *Muzir and Musleh* and various *Tadabeere Advia* (Detoxifying processes) before administration of such drugs.

Hence the Unani Therapies are comparatively safe. Still chances of Adverse Drugs reactions are there due to overdosing, impurity, adulteration, improper quality of drugs, drug to drug interactions, etc. Therefore, pharmacovigilance is equally important in Unani System of Medicine and we can use the huge network of Unani clinics, dispensaries and hospitals spread all over the country for reporting the adverse drug reactions, if occurs anywhere , and then establishing the causal relationship and finally in finding the ultimate measures by which such reactions can be avoided. This will help in finding the safe and effective remedies for general public and will also result in confidence building for the use of these drugs not only in our Country but also in accepting our traditional therapies at a global level.

Pharmacovigilance of Ayurveda: Where are we heading?

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Pharmacovigilance of Herbal Medicines: Barking up the right tree

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The renewal of interest in herbal medicines attracts attention towards their efficacy and safety. It is popularly held that the former lacks evidence whereas later creates doubts in the mind of people. In India, herbal medicines are not confined to the realms of medicine, but part and parcel of cultural ethos too. For instance, Ayurveda and Unani Tib have become a soft power of Indian heritage locally as well as globally. Unani enjoys its popularity in Urdu knowing society. Many studies in India and abroad have reported achiles.

Why and How Unani System of Medicine Insisted Upon Pharmacovigilance for Each and Every Drugs in The Light of Medical Ethics

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Since the time of immemorial, Unani System of Medicine through its contribution based on basic principles and methodologies provides beneficial effect with less harm on human body. Pharmacovigilance is inherently practiced and followed along with addition of experience of new indications in Unani formularies. Among all the system of medicines, Unani Medicine has still a very rich and effective method of drug preparation to combat side effects or harmful effect of drugs on human organs. And that is why it is popular as a 'safe medicine', having no or minimum side effects or harm to human in the light of medical ethics. This paper deals and elaborates in details all the methods including in vivo and vitro techniques being used in Unani system of medicine for vanishing their unwanted actions.

NATIONAL SYMPOSIUM: PHARMACOVIGILANCE OF SPECIAL CLINICAL AREAS

Symposium on "Running AMCs and what next after reporting? Are we seriously contributing to Global ADRs?"

Pharmacovigilance Programme of India: Current Status and Future Callenges

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Indian Pharmacopoeia Commission (IPC) functions as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) to monitor the safety of medicines. NCC is striving hard to create awareness in ADRs reporting as a result culture of reporting is increasing. NCC is well connected with all 150 ADRs monitoring centers in ADRs monitoring and other activities on PvPI. IPC is collaborating with similarly placed national and internationals organizations to promote patients safety. Currently India is the 7th largest contributors to global drug safety database equally the completeness score for Indian data is 0.94 out of 1. NCC is also playing an important role in ensuring the safety of medicines used in National Health Programs (NHPs). PvPI is collaborating with Revised Tuberculosis Control Program and National AIDS control program to monitor the safety of medicines in their respective programs. NCC also initiated direct patients reporting to PvPI by introducing consumer reporting form. To empower the public in reporting ADRs, NCC introduced helpline (toll free) facility with Short Message Service to build the confidence of ADRs reporter. PvPI has been established and reporting has been started. In future, evidence based regulatory action can be taken.

Experience of AMC, CMC, Ludhiana

Dinesh K. Badyal
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The ADR monitoring centre at CMC, Ludhiana started functioning from 2012. The centre has contributed approximately 500 ADRs till now. The centre started with its own infrastructure and residents started collecting the reports. TA was appointed soon and we expanded collection of ADRs. The earlier number of reports was less (10-20), so we started awareness sessions in various departments. This lead to increase in the reports. In the process we interacted with physicians to find out reasons for not reporting as this is the major issue for any AMC. The main hurdles were lack of time, apprehension about legal hassles and non-familiarity with the process of reporting. Even physicians were not aware about the importance of reporting in the country. Hence, we started providing feedback to the reporting physicians in the form of authentic literature etc. We also started publishing in-house newsletter "Pharmascan" for the physicians and which has been appreciated by all and we are continuing it. However, at this point we need more funding for the centre as our work has increased and we wish to expand the ADRs collection to more areas. Even now customer ARD reports from the region are being sent to us for verification. We hope that the support system from the national coordinating centre will improve further to help us cope with the increased reporting. We would like to see a common platform provided to all AMCs where authentic literature is available free for distribution and also access to statistics of ADR reporting from India and Worldwide.

ADR Monitoring Center- Pramukhswami Medical College, & Shree Krishna Hospital, Karamsad, Anand, Gujarat.

Bharat Gajjar

Associate Professor and Head, Department of Pharmacology, Pramukhswami Medical College & Shree Krishna Hospital, Karamsad, Anand, Gujarat.

Co-coordinator, ADR Monitoring Centre, PvPI, Ministry of Health and Family Welfare, Govt. of India.

Our institute, Pramukhswami Medical College & Shree Krishna Hospital, Karamsad, Anand, Gujarat has been designated as 'Adverse Drug Reactions Monitoring Centre' of 'Pharmacovigilance Programme of India (PvPI)' since February2014. We had also worked as a peripheral centre of 'National Pharmacovigilance Programme of India (NPPI)'. Clinicians are the main stakeholders in this programme. It is a big challenge to make them aware regarding the importance of ADR reporting and make them to report ADRs. The role of 'National Coordinating Centre' is also crucial in the success of the programme. Our experiences in running the centre and constraints faced by us will be discussed in the presentation. Our future strategy to generate awareness amongst the Health Care Professionals regarding importance of ADR reporting will also be discussed.

ADR Monitoring Center- J. N. Medical College and Hospital, A.M.U., Aligarh (U.P)

Mohammad Nasiruddin

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ADR Monitoring Centre (AMC) at J.N. Medical College, A.M.U., Aligarh was established in 2011. The Coordinator of AMC, technical associate and residents attended various training courses held at PGIMER, Chandigarh and IPC, Ghaziabad related to pharmacovigilance which helped a lot in functioning of the AMC. In the early days of establishment, I had a meeting of the Chairmen of various clinical departments along with the Dean faculty of medicine and Principal & CMS to get feedback for making the programme more effective. Sensitization & awareness programmes were organized for faculty members and residents of various departments of J.N.M.C.H. On the advice of faculty members of various departments, ADR collection boxes were installed at various places within the hospital along with one minute reporting form containing contact number and e-mail address of the Co-ordinator for spontaneous reporting of ADRs.

The AMC has organized two programmes for bringing awareness and increasing ADR reporting among medical professionals. Firstly a seminar on "Advance Pharmacovigilance" was held at JNMCH, AMU, Aligarh on 11th October, 2012 sponsored by Abbott Knowledge Academy under the aegis of IPS, which was attended by faculty members and residents nominated by chairmen of various departments of JNMC, AMU. This seminar helped in increasing the ADR reporting which is the target of this AMC. CME on "Pharmacovigilance", under Pharmacovigilance Program of India (PvPI) was held at JNMCH, AMU, Aligarh on 7th December, 2013. This was attended by faculty members, residents, private practitioners, government medical officers and para-medical staffs.

We are reporting around 10-12 ADRs every month. These reporting are mostly on personal basis. The clinicians who prescribe and follow-up treatment outcomes are best suited to detect adverse reactions in their patients based on information gathered from the patients and their own clinical observations. However, due to the lack of interest and clinical acumen, and time constraint, many untoward adverse incidents pass unnoticed. I P C has started toll free number for the doctors, para-medical staffs and patients to report ADRs directly. It is moral and ethical duty of medical professionals to report ADRs noticed by them to save the society for further damage.

Pharmacovigilance of Cardiac Drugs

Atul Singhal
Senior Cardiac Consultant, Aligarh

Treatment of cardiovascular illnesses requires a delicate balance in terms of exact diagnosis and precise management. When this balance is disturbed by appearance of any unexpected or expected adverse drug reaction (ADR), during the times of pharmacological intervention, it warrants unnecessary difficulties for cardiologists. The problem then becomes more difficult to resolve than preexisting condition of the patient. ADRs pose intellectual challenge for doctors to cope up the abnormal response. In the present paper, author will discuss ADRs of some commonly used medicine in cardiac practice in absence of their normal therapeutic response.

Pharmacovigilance of Anticoagulant Drugs

Mohd Azam Haseen
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Anticoagulants are one of the most commonly used drugs in patients of cardiovascular disorders. The drugs included in this category are vitamin K antagonists, Heparin, Heparinoids, oral thrombin inhibitors, factor Xa inhibitors and others. They reduce blood clotting which can help prevent deep vein thrombosis, pulmonary embolism, myocardial infarction and ischemic stroke. They are used also used with curative intent in patients with deep venous thrombosis (DVT) and embolic arterial blockage. They are also needed in patients with prosthetic heart valves, stents or atrial fibrillation for long periods of time and sometimes for entire life.

Though these drugs are of great utility they can also lead to life threatening complication as they have a narrow therapeutic range and there activity levels in blood need to be constantly measured to obtain optimum benefits. Patients aged 60 years or more are more susceptible to bleeding complications. These drugs have wide range of interactions with food we eat, like dark leafy vegetables decrease the efficacy of Vitamin K antagonists. Their intake should be avoided whilst taking anticoagulants or, if coagulability is being monitored, their intake should be kept approximately constant so that anticoagulant dosage can be maintained at a level high enough to counteract this effect without fluctuations in coagulability. The new oral anticoagulants (NOACs) including dabigatran, rivaroxaban, and apixaban have been shown to be as good as or better than the coumarins (vitamin K antagonists) with less serious side effects.
Both the clinician and the patient should be aware of their side effects and constant monitoring of patient taking these drugs is necessary to prevent life threatening complications.

Changing Trend of ADRs with Chemotherapeutic Agents in Last Two Decades

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Parul Agarwal, MD
Consultant Anaesthesiologist and Critical Care Expert

Chemotherapy now holds an important place in it of majority of cancers. Advancement in the treatment of cancers in last two decades has been predominantly powered by the plethora of new chemotherapy agents introduce during this period. The agents have been based on some peculiar anatomical, physiological or pathological property of the cancer cells. However this has led to a variety new adverse drug reaction also.

Premarketing clinical trials are designed primarily to identify benefits and common side effects of new drugs and the size of these studies usually does not exceed 3000 patients which limit the chances of detecting likely ADRs before approval. A recent study has reported 25 seniors ADRs associated with 22 oncology drugs after approval nearly 50% of them are drugs approved before 1995. Patients insert was revised for 4 ADRs. There revisions often differed from similar ADR that occurred in drugs of same class.

Advent of targeted agents has improved the efficacy of drugs and reduced the side effects but has also led to new variety of ADRs as well identifying targets such as EGFR gone mutation in NSCLC, Her-2 new receptor in breast carcinoma, BCR/abl mutation in CML leads to more effective targeting of the disease and as a result higher efficiency. But at the same time a different set of ADRs are also expected some of which may appear long time after approval.

Fundamental role of various professional such as oncologists and hematologists, specialists hospital pharmacists and nursing staff as well as the patient can highlight adverse events associated with chemotherapy both in phase immediately after the administration of drugs especially innovative, and in the late toxicity and ADRs from interactions between drugs used for co-morbidities.

Pharmacovigilance of Paediatrics drugs.

Dr. Anurag Tomar
Consultant Paediatrics, Jaipur

Pharmacovigilance programmes monitor and help ensuring the safe use of medicines which is critical to the success of public health programmes. The WHO defines 'pharmacovigilance' as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems". Even though pharmacovigilance is still in its infancy; it is not popular in India and limited with specific age group, and almost negligible in paediatrics. The safety of drugs used in patients of an adult age group cannot be extrapolated to pediatric age group. The pharmacokinetics and pharmacodynamics of many commonly used drugs vary significantly between these two age groups of patients. Further, adverse drug reactions (ADRs) in children can have a relatively more severe effect when compared to adults. Thus, the ADRs can lead to significant morbidity among children. It has been observed that ADRs in children not only result in hospital admissions or prolonged hospitalization but also may lead to permanent disability or even death. The information regarding the frequency, severity and types of drugs most frequently involved in adverse reactions in the pediatric age group is of particular interest, since pre-marketing clinical trials are done mostly in adults. Also, many medicines used in children, however, are not specifically marketed for use in this age group, i.e. they are used off-label or are unlicensed. In a meta-analysis by Lazarou et al, fatal ADRs among both adults and children ranked as the fourth to sixth leading cause of death in the United States. Another study demonstrated that ADRs were associated with an average of 243 reported deaths among young children, from newborn to 2 years of age, each year. On the basis of a meta-analysis of 17 prospective studies conducted in the United States and Europe, the incidence of ADRs among hospitalized children was 9.5%, with severe reactions accounting for 12% of the total. While limited studies from India have reported ADRs in children. The safety profile of a drug thus marketed with its testing done on adults can vary significantly when used in children. This aspect of drug therapy is often difficult to predict for newer drugs. Therefore there is urgent need for an active drug surveillance system to capture risk information in children.

Symposium on "Pharmacovigilance of CNS Active Drugs"

Is it time to ban codeine?

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Consulatant Anaesthesiologist and Critical Care Expert
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During the last 20 years these has been a dramatic increase in our knowledge of the site and mechanism of action of the opioids. Although there is always a gap in our knowledge of opioid pharmacology and the rational and appropriate use of these drugs well controlled clinical trials conducted in U.K. and USA has waged war against the use of Opioids especially codeine in treatment of chronic pain. Various pharmacokinetic factors influence drug dosing, route of administration, titration of dose and advance effects. Various adverse drug reaction of opioids especially codeine pose a threat to patients well-being, e.g. central nervous system depression, hallucination confusion, constipation urinary retention, nausea, vomiting, multifocal myoclonus, respiratory depression, allergy and lastly opioid dependence.

Now with the advent of newer analgesic agents the use of opioids gradually gone down. Even cancer patient with pain vary greatly in their response to analgesics pharmacokinetic and pharmacodynamic factor along with psychological factor influence of an analgesic in an individual patient. The various aspects of the mechanism of action, pharmaco-genomics, variability in the response and metabolism of codeine as well as ADRs pertaining to it will be discussed.

Pharmacovigilance of CNS active drugs

Dr. Sandeep Kaushal
Professor and Head, Dept. of Pharmacology, Dayanand Medical College, Ludhiana

CNS active drugs form a major group of drugs used by all the practitioners. These are also among the top drugs responsible for causing adverse drug reactions (ADRs). As these drugs are highly effective and have a high chance of physical and psychological dependence, which is an area of interest for us. Some members of this group are covered by Narcotic drugs and Psychotropics Substances Act. The focus of my talk will be on antiepileptics (AEDs) which is an important member. These AEDs are now being used for a number of other indications like mood disorders (Valproic acid), Neuralgia (Carbamazepine), migraine (Topiramate), weight loss (Topiramate), and neuropathic pain (gabapentin). The older, time tested AEDs like Phenytoin, Carbamazepine are notorious for cutaneous ADRs (including Steven Johnson Syndrome and Toxic Epidermal Necrolysis). The incidence of these serious cutaneous reactions is less with newer AEDs. A new scale to evaluate the severity of ADRs based on frequency and duration of these events is available. Most of these ADRs are of augmented type. A new dimension of pharmacogenomics has been added in the use of Carbamazepine especially in South East Asian descendants. This has been verified by a number of studies in Indian population. The spectrum of these shall be discussed in the presentation.

Pharmacovigilance of Psychiatric Drugs

Dr. P.P. Singh

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Introduction: Pharmacovigilance has been defined by the World Health Organization (WHO) as the science and activities related to the detection, assessment, understanding, and prevention of adverse drug effects [1]. The birth of pharmacovigilance has a close relationship to psychiatry; the controversy surrounding the use of thalidomide in pregnancy is widely known [2].Polypharmacy is widely practiced in psychiatry; hence the theoretical chances of the occurrence of ADR are thereby also enhanced.

Aim: The presentation will delineate pharmacovigilance issues pertinent to psychiatry.

Method: An adverse drug reaction (ADR) can be defined as any adverse patient outcome that occurs at therapeutic doses of a drug, and which can be causally linked to use of the given drug[3]. This presentation will enumerate mild, moderate and severe ADR associated with the use of psychotropics, along with examples from our practice. Some examples of the Types of ADR will also be presented.

Conclusion: Pharmacovigilance is the duty of every person in charge of patient care. As psychotropic drugs directly affect the brain and behaviour such activities become paramount and essential part of the patient care.

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Determination of LD_{50} of *Ocimum sanctum*

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Introduction: *Ocimum sanctum* is a well reputed medicinal herb being used in the treatment of various ailments in this Indo Pak Subcontinents since ancient time. We tried to find out how far it is safe for human consumption. The lethal dose50 (LD_{50}) is an important indices in this regard to find out the therapeutic index. It is very important on way to establish it in modern science.

Result: On this way the Lethal Dose (LD50) has been determined to be 676.08 mg/kg. This is supposed to be safe drug. Chronic effect on various organs and as well as effect on reproductive system specially the effect yet to be evaluated.

KEYNOTE LECTURE:

From Pharmacovigilance to Drug Risk Management

Prof Hervé Le Louët

Head of Pharmacovigilance Department (APHP)
Member of the PRAC (European Commission)
President of ISOP
Vice President of CIOMS

NATIONAL SYMPOSIA: ENSURING MEDICINE SAFETY- AN OBLIGATION OF PHARMACEUTICAL INDUSTRY

Risk Management Plan- A New Paradigm in Pharmacovigilance

Vineet Shastri
Director Pharmacovigilance, Global Data and Safety Monitoring, Life Cycle Safety, Quintiles Technologies India Ltd.

This presentation briefly describes the basic philosophy of drug safety management, an life cycle long endeavour and entails the principles of risk management. We would talk about who all are the stake holders for risk management, expectations from regulators, objectives of RMP, how it is structured, what are routine and additional pharmacovigilance activities, what covers risk minimization measures and how effectiveness is evaluated. Rest of the talk will be discussed in presentation.

Ensuring Medicine Safety – How Does the Industry Do It?

Deepa Arora
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Safety related activities carried out by industry can be broadly categorized into premarketing and post marketing activities. During clinical development, all reasonable efforts are made to characterize safety of the investigational drug. These are but not limited to conducting specific studies, inclusion of parameters for safety evaluation in clinical studies and planning large long term studies.

Safety related activities in the post marketing period can be divided into four:

1. **Identification & confirmation of signals**: signals here refer to new adverse reactions or a higher incidence of known adverse reactions. Signals are identified by careful analysis of safety data collected through clinical studies and post marketing spontaneous reports. Literature searching and analysis is an important part of signal detection. Signals are generated through both qualitative as well as quantitative analysis, but qualitative analysis is the key to confirmation of the signals.
2. **Regulatory compliance:** compliance related activities are specific to each country as regulatory requirements are different. Broadly these include processing and medical review of ICSRs, including expedited reporting, submission of periodic reports, literature searching, updating the label and various other activities. Pharmacovigilance inspections are conducted in various countries to assess the compliance.
3. **Safety related communication**: this is one of the key activities. Only identification and confirmation of new adverse reactions are not sufficient. Any new information that is generated for a drug should be communicated to all stake holders. This area still needs to be further developed in India. In developed countries, industry is responsible for communicating information about safety to all stake holders, i.e. regulatory authorities, prescribers, pharmacists as well as patients. In India, direct communication by industry to patients is limited. Lack of education may be one of the reasons. Communication of industry directly to patients is very sensitive and it should be carefully monitored by regulatory authorities as is done in developed world.
4. **Risk minimization**: safety communication is one of the most important methods of risk minimization. Some other tools used to minimize risks include restricted access, training of physicians, training of pharmacists, and regular assessment of patients for various safety parameters.

Individual Case Safety Reports: Standards for Reporting In Investigational & Post Authorisation Phase.

Manoj Sharma

Global Pharmacovigilance Division, Panacea Biotec Limited, New Delhi

Pre marketing studies (Phase I, II, and III trials) necessarily take place in controlled situations with selected groups of people. Though a new drug appears to be safe in these studies, unseen adverse effects can occur when a drug is released for use in general population in 'real world clinical practice'.

Pharmaceutical industry has the obligation for continuous monitoring of the products once a marketing authorization is granted.

Individual case safety reports (ICSR) are received both in clinical development and post authorization phase. The reports are analysed for the validity and are processed in the database (e.g., excel, Argus™, Aris G, Vigibase etc). For an ICSR to be valid the following four criteria shall be present: a) Identifiable Patient; b) Suspected Drug; c) Suspected ADR; d) Reporter details. In India the ICSR arising from clinical trials during drug development phase are reported in Appendix XI (Schedule Y format). For ICSRs received during marketing experience of the drug (post authorization phase) there are different regulatory formats adopted by the different countries. These reporting formats include: Suspected ADR reporting form (India); Medwatch / FORM 3500A (USA); Yellow Card (UK); SGML (EMEA) etc. CIOMS I is the internationally acceptable reporting format.

As per international guidelines on expedited reporting (ICH E2A and ICH E2D) all serious adverse events (other than death and life threatening ADRs) are reported within 15 calendar days where as the cases of death and life threatening ADRs shall be reported within 7 calendar days.

The collated ICSRs in database are further used for the analyses in a periodic manner to generate periodic safety update reports. These are analyzed for the safety signals and benefit risk profile of the drug.

Adverse Events Following Immunization – Industry's Obligation

Jamal Baig,

Country Head, Drug Safety and Risk Management, Merck Sharp Dohme, (Gurgaon)

Vaccines are large and complex proteins administered mostly for prophylaxis, so the risk to the recipient should be minimal, additionally, vaccines have tendency for delayed hypersensitivity/anaphylaxis etc. and need special safety monitoring and Pharmacovigilance activities. In India, registration applicant has to conduct the clinical trial as per the schedule Y of the Drug and Cosmetic act 1940 and strictly comply with the adverse event reporting requirements there under. Post approval the PSUR is submitted for years and SUSARs reported expeditiously to CDSCO. Each batch of imported vaccines is tested in the government laboratories before being released for marketing. In Nov 2013, the Prof Ranjit Roy Chaudhary report was submitted to the Govt. of India, the recommendations if implemented could change the vaccine pharmacovigilance landscape. Globally, major drug regulatory agencies like US-FDA, MHRA (UK), EMA (Europe), TGA (Australia) have different requirements for Clinical Trials, Registration and Post approval surveillance. Mostly the Market Authorization Holder (MAH) has to submit the Risk Management Studies (RMP) and Post Marketing Surveillance (PMS) Vaccines Adverse event following immunization (AEFI) is critical for success of any immunization program. AEFI surveillance system in India for the vaccines delivered through 'universal immunization program (UIP) of government sector is now a decade old, but the reporting remained suboptimal. AEFI is defined as a medical incident that takes place after an immunization, causes, concerns, and is believed to be caused by immunization. Global (US) we have the Vaccine Adverse Reporting System (VARES) a vaccine safety surveillance program co-sponsored by the Centre for Disease Control and Prevention (CDS) and the US-FDA. VAERS is a post-marketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of vaccine licensed for use in the US.

NATIONAL SYMPOSIUM ON MISCELLANEOUS THEMES INCLUDING ENVIRONMENTAL AND BIOLOGICS PHARMACOVIGILANCE.

Template for Designing Model for Screening of the Effect of The PPCPs n Terrestrial Environment

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Pharmaceutical and Personal Care Products (PPCPs) and their metabolites have a wide range of effects on environment. They induce damage to biological life forms everywhere including air, water and land. The known effects are just the tip of the iceberg, with majority of the effects of PPCPs and their metabolite (produced during interaction with physical and biological environment) are still unknown. At present there are no models to assess the effect of PPCPs in the terrestrial environment. Designing a model for ecopharmacology studies is always a challenge as it has to take into account the diverse food chains and their interaction with biological and physical environment. Therefore, we devised a template for designing the model for a particular food chain of a given environment. The template consists of 3 generation model of a laboratory animal with its interaction with the local niche. The drug is introduced into the system through water supply and the urine as well as excreta of the animal is then used to grow small herbs. These herbs serve as food for the second species of animals (which also includes the pregnant animals -3rd generation). The samples of soil, urine, excreta, herbs etc. are analyzed by using HPLC for drug and different metabolite levels. The levels are then compared with the pre-drug readings. The system is carefully evaluated for differences in levels of drug and appearance of new metabolite with reference to clinical, biochemical or histo-pathological anomalies in the test animals. This template model can be modified according to different food chain in a particular geographical region and gives us a tool to conduct more comprehensive ecopharmacology studies.

Pharmacometabonomics: Role in Personalized Medicine and Pharmacovigilance

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In order to improve the quality, safety and efficacy of medical treatments, pharmacotherapeutic regimens need to be tailored in accordance with the pharmacokinetic and pharmacodynamics characteristics and personalized needs of individual patients. A primary goal of personalized medicine is to provide the best medical treatment for each individual patient by determining which drug will have the best efficacy and the least toxicity and/or adverse effects. Furthermore, understanding inter-individual variations of response to drug treatment, especially in patients with potential adverse reactions, might lead to biomarkers that can be used to predict the low incidence of idiosyncratic toxicity. So far medical treatments have been based on epidemiological studies of large patient populations, without taking into account an individual's genotypic as well as phenotypic variability. As a consequence, drug therapy often fails to be curative and may on the contrary produce substantial adverse effects. As such, there is need to evolve to a more individualized approach.

There is increasing recognition of the limitations of the pharmacogenomic approach, which does not take account of important epigenetic, endogenous and environmental influences, such as nutritional status, the gut microbiota, age, latent disease and the co- or pre-administration of other drugs. These and some other factors like gender, physical activity, hormone, and stress levels modify the metabotypes of both individuals and populations and hence the prevalence and risk of disease. Therefore analyzing metabolites (small molecules <1 kDa) in body fluids such as urine and plasma using various spectroscopic methods provides information on the metabotype (metabolic phenotype) of individuals or populations, yielding a top-down "systems level" readout of the biochemistry, physiological status, and environmental exposure of individuals and populations that can be exploited in personalized medicine and minimization of risk due to ADRs. Metabolism-driven approaches enshrined under Pharmacometabonomics can therefore prove highly tractable as they combine

the gathering of systemic information based on minimally invasive analysis with high throughput capabilities.

sADR Reporting made easy- "ADR Reporting" app for INDIA.

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Every drug & its formulation may cause a known effect, Adverse drug reaction or an unknown one, Suspected Adverse drug event. Worldwide, Pharmacovigilance programes are being run, for their detection, causality assessment, risk evaluation & their mitigation strategies (REMS) planning, as WHO International drug monitoring programme, since 1968. For a conservative estimate of 10 billion-year exposure of drugs or its formulation, to mankind, these programmes have been able to detect only around 10 million Individual case safety reports (ICSRs), till October 2014. This comes down to 0.001% of case detection rate. We, are also having a nationwide, Pharmacovigilance programme of India (PvPI) since 1996 & we are categorized along with numerous other countries as, LMIC (Low & Lower middle income countries) group in WHO database. This group, which represents more than 33% of world population has contributed around 1.8% of data in terms of worldwide contribution in VIGIBASE. An important reason, behind is low level of awareness & paper-based data collection, most of which is lost in files & courier. I have conceptualized & was able to get an android mobile based application, "ADR Reporting" app built upon, to overcome this impediment. Suspected Adverse Drug Event or Reaction reporting, now being paperless, can be submitted to appropriate database instantaneously. Nationwide promotion & utilization of this app, will improve the Quality as well as the volume of ICSRs, tremendously. We will be able to design & implement better REMS, stimulate more research & increase our share in Global database, in a significant manner.

Animal Simulator ... Animal experiments simplified

Dr. Varun Gupta
Head of Content Education Solutions | South Asia
Elsevier Health Solutions Elsevier

Animal Simulator (www.animalsimulator.com) is an educational software package which simulates animal experiments to help students remember, understand principles of physiology and pharmacology. It is Computer Assisted Learning package which simulate animal experiments in Physiology and Pharmacology. These programs can be used to demonstrate physiological and pharmacological effects on different animal systems. The package is user friendly, highly interactive and full of animated sequences which make simulation appear realistic.

ABSTRACTS FOR PRIZE SESSION

(PN SAXENA AWARD)

PS 1.

Comparison of Adverse Drug Reactions of a Fixed Dose Combination of Sitagliptin and Metformin with the Individual Drugs – An Evidence Based Study

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Aims & Objectives: The aim of this study was to assess the safety of a fixed dose combination sitagliptin and metformin in comparison with respective individual drug in treatment of type 2 diabetes.
Methodology: PUBMED indexed publications from 2005 onwards were searched for assessing adverse drug reactions of the above drugs in type 2 DM patients with treatment duration of 12 weeks to 2 years. It was an extensive review of literature where data were primarily collected from full papers on RCTs and meta-analysis on type 2 DM treated with metformin (500-1000mg), sitagliptin (50-100mg) or their combination drugs metformin+sitagliptin (500/1000 +50/100mg).
Result & conclusion: The ADRs of FDC of metformin & sitagliptin were assessed in comparison with respective individual drugs. The adverse effects of only Metformin reported by studies were GIT related, like diarrhea, nausea, vomiting, abdominal pain & flatulence. Out of that diarrhea was found to be significant (27% - 33.3%).As compared to metformin, the incidence of diarrhea in different studies of FDC were found to be less (2.30% - 17.9%). 2 studies showed pancreatitis being the significant (2.2% - 8%) ADR caused by sitagliptin alone whereas none of the FDC studies highlighted such ADR.4 studies highlighted nasopharyngitis as one of the significant ADR (10%) caused by sitagliptin alone, whereas in FDC with Metformin incidence was found to be 4%.Hypoglycemia (1.7%) was reported with FDC metformin + sitagliptin, whereas none of the articles on sitagliptin or metformin alone mentioned of hypoglycemia. The causality of any ADR has not been established in any of the papers. There was no report of any other side effects like reduced vitamin B12, lactic acidosis due to metformin, sitagliptin or FDC. So from currently available evidences, FDC of metformin + sitagliptin is found to be well tolerated and safer than individual drugs. From pharmacovigilance point of view the authors find that these issues are not well addressed in such evidences though the sample size is small. As a result an important area in ADR reporting is missing, which calls for robust monitoring and reporting of ADR to capture the actual data.

PS 2.

Adverse effects of topical corticosteroids: A cross-sectional study

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Introduction: Corticosteroids are one of the most commonly misused drugs by all routes of administration and are associated with a wide spectrum of adverse effects. The present study was undertaken to assess the adverse effects of corticosteroids on skin and skin structure.
Methods: The present study was a cross-sectional study undertaken between April and October 2014 following approval from institutional ethics committee. Following details were collected and compiled from the study participants: Demographic details, drug related (name, dose, route, strength of the formulation in case of topical), adverse effects (nature, site and causality assessment with the suspected drug). Descriptive statistics was applied for analysis of all the categories.
Results: A total of 100 participants were recruited during the study period with a mean (SD) age of 27.84 (13.21) years with 55% males and 45% females. The most commonly administered corticosteroid was betamethasone (65%), followed by clobetasol (25%), triamcinolone (5%), hydrocortisone (4%) and beclomethasone (3%) and they were administered as creams in majority of the patients (94%). The most common indication for administration includes acne (46%), followed by Tinea (40%), Urticaria (2%) and Melasma (2%), others include Perioral dermatitis (1%) & Ochronosis(1%). With regard to the topical

application, 54% had used the cream at dose of 0.10% and 35% at 0.05%. Two-thirds (66%) of the patients were advised by private practitioners while the rest (34%) were given the drug over the counter from pharmacy stores. Adverse effects that were observed include acne (43%), tinea (41%), acneiform eruptions (13%), striae (5%), hirsutism (5%), atrophy (3%). WHO causality assessment of all the adverse drug reactions showed probable association. Face (59%) tops the list among anatomical sites followed by groin (34%), chest (8%), arm (8%), back (5%), and waist (5%).

Conclusion: Rampant irrational use of corticosteroids leads to many dermatological conditions that warrant potential medical treatment. Prescription and availability of corticosteroids should be restricted for public use and should be banned as an over the counter medicine. More sensitization is required for the medical fraternity with regard to the ill-effects of corticosteroid use.

PS 3.

Spectrum of Dermatological ADRs at a Tertiary Care Hospital

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Aim / Objective: To determine frequency of dermatological ADRs and to establish causality.

Methods: This concurrent, observational study was carried for duration of one and a half year i.e. from March 2013 to September 2014 and patients were enrolled from different departments. Data regarding patient demographics and ADRs were collected by patient interviews, collaborated by information in respective patient file. It was entered in CDSCO ADR reporting form. Causality was assessed by WHO causality assessment scale. No changes in treatment decision, schedule or duration were made as part of study.

Results: A total of 110 ADRs were reported in 100 patients (45 males, 55 females). The most common ADR noted was rash (28.18%) followed by itching (24.54%), anaphylactic reaction (14.54%), Steven Johnson syndrome (10.90%) and miscellaneous (21.81%). Drug most commonly prescribed was Phenytoin (10%) followed by Ciprofloxacin (6.66%). The most common diagnosis noted was Diabetes mellitus (12%) followed by Epilepsy (9%). Most of the ADRs were probable (85%).

Conclusion: Most common dermatological ADRs seen with prescribed drugs were rash and itching along with serious ADRs like anaphylactic reaction and Steven Johnson syndrome. So continuous

PS 4.

KAP Study on Safe Injection Practices in a Tertiary Government Hospital

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Background: Unsafe injection practices and waste disposal are well-recognized sources of serious blood-borne infections in health care-settings.

Objective: A Knowledge, Attitude and Practices study was designed to assess injection practices in this tertiary level teaching hospital.

Methods: Knowledge was assessed using a questionnaire and attitude and practices were observed subsequently on nurses and trainee resident doctors working in different departments of the hospital. A total of 90 participants were assessed, including 50 residents and 40 nurses and their responses were noted and analysed. Study design: Cross-sectional.

Results: Only 24 (27%) resident doctors and nurses knew how to correctly draw injectables from vials with aseptic precautions.29 (32%) believe that injectables may be drawn at bedside rather than at a predesignated station. As many as 30% believe that intravenous cannula should be placed at patients' bedside rather than an appropriate procedure room, and 31 (34%) think it is enough to clean the site with spirit and betadine. The knowledge level did not correlate with the level of training or years of experience. Observation revealed

significant deficiencies in safe injection practices in larger number of participants. **Conclusions:** There is serious lack of knowledge regarding safe injection practices among health care providers in this hospital. Moreover in many instances knowledge is not converted into appropriate practice, reflecting a lackadaisical attitude. The deficiency in knowledge and practices is largely unrelated to the level of training, years of practice or place of posting.

PS 5.

Vancomycin induced Stevens Johnson's Syndrome

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Introduction: Stevens –Johnsons Syndrome (SJS) is a rare autoimmune condition usually affecting the skin and mucus membranes. Multiple pharmacologic agents to viral infections have been implicated as etiological factors for its development. We report the case of a 3 year girl with right sided post pneumonic pyothorax developing SJS during the course of her treatment with vancomycin .She responded after stopping the offending drug and her eruptions healed gradually.

Although several classification schemes have been reported, the simplest classification is as follows **1.** Stevens-Johnson syndrome: A minor form of toxic epidermal necrolysis, with less than 10% body surface area (BSA) detachment; **2.** Overlapping Stevens-Johnson syndrome/toxic epidermal necrosis: Detachment of 10-30% of the BSA; **3.** Toxic epidermal necrolysis: Detachment of more than 30% of the BSA.Various pharmacological agents like Vancomycin, NSAIDS, sulphonamides, anti-epileptics and anti-psychotics have been implicated in causing SJS as are immunocompromised state and viral diseases like HIV and herpes.

Case Report: A 3 year old girl presented with fever and difficulty breathing from the last 3 weeks. She was diagnosed as a case of Right sided pyothorax and an Intercostal Chest Tube was placed (ICT). She was started on intravenous vancomycin and amikacin. Initially her symptoms improved but after 4 days of therapy she started developing perioral ulcers with fever of moderate to high grade. Her antibiotics were upgraded to meropenem along with vancomycin and her counts were repeated which showed a decreasing trend with neutropenia. Her oral ulcers and fever did not improve and she was diagnosed as a case of SJS .All intravenous medications were stopped and she was started on oral linezolid with triamcinolone ointment and mouth wash for the perioral ulcers. Her fever improved within 24 hours and her ulcers started healing within 3-4 days. Her ICT was removed after radiological evidence of lung expansion and she was discharged in satisfactory condition.

Conclusion: Stevens- Johnson syndrome although a rare autoimmune disease is a milder form of Toxic Epidermal Necrolysis, its urgent recognition and stopping the offending drug is necessary for its effective management. In patients receiving vancomycin who develop eruptions possibility of SJS or its variants should always be kept.

PS 6.

Monitoring of Adverse Drug Reaction with Special Reference to Detoxification of Unani Drugs

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Unani Medicine is based on Greek philosophy which believes in the humoural theory that presupposes the presence of four *Akhlat* (Humuors), having different *Mizaj* (Temperament). It is holistic approach to the healing of disease that believes in restoring balance to the physical, mental, emotional and spiritual aspects of man, using lifestyle modification, diet and medicine to have an effect on cure. The adverse reaction to the ingestion of certain drugs have been known since ancient times and wide spectrum of diseases involving

virtually every system in the body have been ascribed to certain drugs (also known as iatrogenic artifact). To protect from the undesirable effects, Unani physicians had suggested a proper reasoning in the method of preparation of drugs, including a rationale combination of various ingredients, method of administration, various preservatives, indications and contraindications in different situations and adverse drug effect profile such as adverse drug-drug or food-drug interaction. Moreover *Muslehat* (Correctives) to the drugs had also been used since a long time to minimize the unwanted effects of drugs and the processes of *Tadabeer* (Detoxification) were employed to reduce the adverse drug reaction in Unani Medicine. The details of these aspects would be discussed in the present paper.

PS 7.

Fixed Drug Eruption Due To Omeprazole: A Case Report and Review of Literature

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Background: A Fixed Drug Eruption (FDE) characteristically represents a skin lesion that recurs at the same site or sites each time the offending drug is administered. It is one of the most common patterns of cutaneous adverse drug reaction in Indian patients.

Objectives: To report a case of Fixed Drug Eruption due to Omeprazole.

Methods: The causality assessment was carried out using the Naranjo's ADR probability scale and WHO UMC Causality Assessment Scale.

Results: Causality of FDE due to omeprazole is probable according to WHO UMC causality assessment scale while probable/likely according to Naranjo's ADR probability scale.

Conclusion: Fixed drug eruptions commonly occur due to antibiotics, analgesics and anticonvulsants. Rarely, Omeprazole is implicated as a cause of FDE. There are only 3 cases reported till date. This case is reported for its rarity and to create awareness among the physicians regarding one of the rare ADR of a seemingly innocuous drug.

PS 8.

Patient Safety Enhancement through Pharmacovigilance

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Background: Patient safety can be enhanced by minimizing the incidence, decreasing the impact of adverse events and maximizing the recovery from them, under pharmacovigilance program.

Objective: To improve the safety of patients through effective pharmacovigilance program.

Methods: Second professional medical undergraduates were trained in ADR reporting from our tertiary care hospital. ADR data from Jan 2012 to Sept 2014 were evaluated. During this period, medicine safety information and updates were sent to clinicians, nurses and pharmacists in regular bulletins and email alerts, and then improvement in patient safety was assessed.

Results: Total 179 ADRs were reported by the trained medical students in three years. Maximum ADRs were in the age group of 21-40 years (36%) and 41-60 years (34%). Medicine department reported maximum number of ADRs (33.5%), followed by Dermatology (15%) and Surgery (8%). Oral (46%) and IV routes (35%) were commonest routes of administration causing ADRs. Most of the ADRs were reported with the antimicrobials (57%) followed by NSAIDs (13.4%). Most of the reported ADRs were dermal (57%), followed by gastrointestinal system (17%) and CNS (18%). Causality assessment by Naranjo's scale showed that most of the ADRs were of probable (56.98%) relationship, and most were 'Type A' (78%) ADRs.
Conclusion: Training and involvement of medical undergraduates strengthened the ADR reporting system and improved ADR reporting by the clinicians in our institute. Regular, periodic apprising of medicine safety information to clinicians certainly enhances patient safety through safe medicine prescription. The hands-on training in pharmacovigilance to medical students and staff will go a long way in patient safety.

PS 9.

A Study on Hypersensitivity Reactions of Injectable Iron in Antenatal and Postnatal Patients

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Aim and Objectives: To evaluate the safety and adverse hypersensitivity reaction profile of injectable iron sucrose in antenatal and post natal patients with moderate anaemia.
Material and Methods: 70 antenatal (2nd and 3rd trimester) or postnatal women with haemoglobin 7-9 gm% without any other comorbidities were selected randomly and were given intravenous iron sucrose as per the deficit calculated. They were followed for the hypersensitivity reactions. Adverse effects were categorized into 4 grades according to Ring and Messmer classification.
Results: 24.3% patients developed adverse reaction out of which 7% patients developed local reaction at intravenous cannula site. 14.3% of the patients developed Grade-I adverse reaction which subsided without any treatment. 2.8% patients developed Grade-II reaction all of them required urgent medical measures and close monitoring apart from discontinuation of the drug. Most of the Grade I & II reactions occurred just after initiation of infusion. None of the patients required ventilator support or intensive care. None of the patients developed Grade-III and IV reaction.
Conclusion: Injectable iron sucrose is a safer and well tolerated drug with less number of adverse hypersensitivity reaction most of which are of milder grades. Thus injectable iron can be the preferred alternative over oral iron in antenatal and post natal patients who are either noncompliant or cannot tolerate the gastrointestinal side effects of oral iron. It also decreases the need of blood transfusion. Furthermore, larger clinical trials are needed to draw a conclusion.

PS 10.

Lamotrigine Induced Fulminant Hepatic Failure

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Introduction: Lamotrigine is indicated for management of seizures either alone or in combination with other anticonvulsant agents. Adverse effects with it are usually mild. Less than 1% of subjects show deranged LFTs during long therapy. Lamotrigine induced hepatotoxicity is rapidly reversible within one to two weeks of stopping the drug. However, prolonged exposure may result in irreversible, rapidly progressive liver failure.

Case Report: This is a case of 22 yrs. old male with past history of seizure disorder and was on treatment with sodium valproate 500 mg BD for 3 years but because of recurrent seizure attacks he was shifted to tab. Lamotrigine. After 2 months of lamotrigine therapy, he was brought to hospital in unconscious state and was found to have diffuse maculopapular rashes. Biochemical investigations revealed deranged blood urea, serum sodium, liver function tests, serum bilirubin and prothrombin time. Based on clinical signs suggestive of hepatic encephalopathy grade-4, coagulopathy and hyperbilirubinemia, diagnosis of fulminant hepatic failure was made. Clinical status of the patient did not show any improvement and on fourth day of admission patient succumbed to his illness.

Discussion: Lamotrigine induced rash and hepatotoxicity is a hypersensitivity reaction to the drug protein complex. Incidence of hepatic failure with lamotrigine is very rare. According to WHO causality assessment scale, the association of fulminant hepatic failure with lamotrigine was possible in this case.

Conclusion: Fulminant hepatic failure with lamotrigine is unusual presentation. Cases of lamotrigine induced fulminant hepatic failure should be adequately reported for proper assessment of incidence.

ABSTRACTS FOR FREE ORAL PRESENTATIONS

O 1.

Risk & Benefit of Nanotechnology in Human & Health

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Introduction: The European Science Foundation (ESF) had defined nanomedicine as the science and technology of diagnosing, treating and preventing disease and traumatic injury, of relieving pain, and of preserving human health using molecular tools and molecular knowledge of the human body. ESF identified five main areas: (i) analytical tools, (ii) nanoimaging, (iii) nanomaterials and nanodevices, (iv) novel therapeutics and drug delivery systems and (v) clinical, regulatory and toxicological issues.

Risk Management: Calls for more toxicological information that will help to protect workers' risk assessment paradigm, consisting of Hazard Identification, Hazard Characterization, Expo- sure Assessment and Risk Characterization for Whome are working with Nano factories & Nano Products. Nano toxicology should started immediately in medical products and medical devices for assessing risk by Nano particles in humans as well as animal experiments and in Hazards characterization as Epidemiological studies for workers ,consumers, exposed population, in vivo studies for route of administration , acute, chronic in different species with in vitro studies in human/animal, different cell types Models lung, skin, systemic etc. Other studies may direct to biomaterials cellular growth, cell behaviors and influenced by nano chemical. It should be made mandatory to prevent exposure by appropriate precautionary measures/regulations and by practicing best industrial hygiene to avoid future horror Nanotechnology, nanomedicine and nanotoxicology have bright future with multiple applications in many areas. Nanotoxicity provides for the necessary safety assessment of nano-enabled products.

Methods: First find out exposure and uses for various route of exposure via dermal, parental, inhalation, ingestion, implantation, dermal. Recently Nano crystalline silver is as antibacterial may influence inflammatory response and cellular toxicity.

So biomaterials and implants have reactionary process differently than large molecules and tissue necrosis and healings should be assessed. In addition its inherent toxicity, dosage uptake pharmacokinetics and pharmaco dynamics so physicochemical composition in Nano particle may have different effect over different biological compounds like endotoxins.

Discussion: It was observed that Nano particles damage the epithelial tissues of lungs and effect over immunity on Ig E in animal model system of oral burning allergy and induced toxicity in endothelial cells by induction of pro inflammatory cytokine IL8. Carbon tube exposure cause oxidative stress and cellular toxicity for dermal tissues.

Conclusion: We here only discuss about only Nano drugs not all nanotech worlds as they also effect to human by inhalation. Observations with several chemicals show that nano chemicals are more toxic than large particles. So further ethics and assessments should be done before making it popular it can cause silent damage to death of human.

O 2.

Prescription Pattern in Dermatology Out Patient Department of A Tertiary Care Rural Teaching Hospital in Central Gujarat

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Background: Skin disease refers to disorders exclusively of the superficial layers of the skin. The commonest skin disorders seen in developing countries are infectious diseases, eczema, allergies and

scabies, but they have not been regarded as a significant problem that could benefit from public health measures. Most skin diseases are chronic and require lifetime treatment.
Aim: To study the prescription patterns in the Dermatology Out Patient Department of a Tertiary Care Rural Teaching Hospital in Central Gujarat.
Materials and Methods: It is a prospective and observational type of study carried out at Dermatology Out Patient Department, Dhiraj General Hospital, Vadodara (Gujarat) from where 250 prescriptions were collected and analyzed for drug use and cost analysis using statistical methods and WHO drug use indicators.
Results: A total of 250 prescriptions were analyzed from 200 patients. Average drugs prescribed were 2.39/ prescription. Topical drugs (62.7%) were most commonly prescribed than systemic drugs (37.3%). Topical drugs were mostly in combination (26.66%) followed by antifungals (20.51%) and steroids (17.44%) alone. Antihistaminics (33.62%) commonly prescribed systemically followed by antifungals (22.41%) and antibiotics (20.69%). In 43.47% instances high potency steroids were prescribed while mild potency (15.22%) were least prescribed. Average cost of drugs per prescription was found to be 196.74 INR. A great majority of drugs were prescribed in brand names
Conclusion: Topical drugs more commonly prescribed and higher preference for brand names was observed.

O 3.

Munchausen Syndrome in A New Perspective - A Case Report

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A 17 year old, adolescent male was treated at Jawaharlal Nehru Medical College, Aligarh, for reason of drug ingestion. It was discovered that he took 35 tablets of Alprazolam 0.25mg. Past history revealed that he had demonstrated such behaviour on several other occasions (4-5 times). This case merited attention simply for the reason that there is a variance between motive-induced self-harm and pure desire to commit suicide. This case qualifies to be called "Munchausen Syndrome" as the events unfolded in the paper.

O 4.

Sleep Disorders related to Antidepressant drug use

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Background: Prescription of Antidepressants has been increased from the last decade. Also, they are responsible for producing so many ADRs such as dry mouth, blurred vision, weight gain and drowsiness, sleep disorders. Sleep disorders can generally be divided into 3 large groups: (1) insomnia, (2) those with a primary complaint of daytime sleepiness, and (3) those associated with disruptive behaviors during sleep—the disorders of arousal. So, active surveillance is needed to assess these ADRs.
Aim and Objective: To analyze the sleep disturbances as an adverse drug reaction (ADRs) of various antidepressants prescribed to the patients attending the Psychiatry OPD at Teerthanker Mahaveer Medical College & Research Centre.
Materials and Methods: The data were collected from the Red ADR boxes in the department of Psychiatry OPD at TMMC & RC, Moradabad, U.P. The patients, who were prescribed antidepressant drugs for a duration of 10 months (Dec, 2013- July, 2014) were included in the study.
Results: Total number of patients enrolled on the basis of inclusion and exclusion criteria = 50
Total number of ADRs = 65
Total no of patients with sleep disturbances as ADRs = 28
Conclusion: The drug most frequently implicated to cause sleep disturbances was Mirtazapine.

Increased sleep was the commonest ADR found to occur. Unusual ADRs such as sleep talking was also seen. However, we assume that more robust reporting is needed as this shall enable us to detect the category of sleep disturbance, based on polysomnography.

O 5.

Recent Trends in Pharmacovigilance

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Objective: To share recent updates in Pharmacovigilance (PV) at international, national and our institutional level.

Material and methods: The international updates were taken from WHO's Uppsala Monitoring Center (UMC) and World Health Organization (WHO) websites and publications featuring India's contribution to WHO-UMC. The ADR data from WHO Global Individual Case Safety Reports (ICSR) Database System was used to understand the Signal analysis and detection.

The national updates were taken from Central Drug Standard Control Organization (CDSCO), Indian Pharmacopeia Commission (IPC) and National Coordinating Center Pharmacovigilance Program India (NCC-PvPI). Recent guidelines by Medical Council of India for recognition of medical colleges emphasizes the existence of pharmacovigilance unit.

The institutional updates were taken from our Adverse drug Monitoring Centre (AMC) started from Dec 2012, in Department of Pharmacology, VCSGGMSRI, Srikot, Pauri-Garhwal, Uttarakhand. Strengthening of ADR reporting in the AMC centre was done by Sensitizing Medical Undergraduate Students for ADR Reporting (SMUAR) and clinicians in improving patient safety. Periodic circulation of Newsletter Pharmacovigil Garhwal, Uppsala Updates, WHO newsletter and e-circulation of pharmacovigilance updates was done.

Conclusion: Pharmacovigilance unit of VCSGGSRI, Uttarakhand is functional in geographically remotely located medical college yet is updated with recent developments in PV and has submitted ADRs reports on the vigiflow software contributing to global safety database. Our PV inputs are positively focused to deliver better patient safety.

O 6.

A Prospective Study of Prescribing Pattern of Drugs in NICU, Basaveshwar Teaching and General Hospital, Gulbarga, Karnataka

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Objective: A modern NICU (Neonatal Intensive Care Unit) is a microcosm of its own. A greater number of infants at smaller gestational age and weight require high-dependancy care at a tertiary care hospital with a good NICU setup. This calls for critical review of the drugs prescribed in NICU. The objective of this study was to evaluate the prescription pattern in terms of rationality of prescription in the NICU of a tertiary care hospital. It is also intended to monitor the adverse drug reactions during the study.

Materials and methods: A prospective analysis was performed for in-patient cases of neonates (aged 1-28days) admitted to the NICU (from April2014 to June 2014) in Basaveshwar Teaching Hospital, Gulbarga, Karnataka. The total number of neonates studied was 100. The data was analyzed for the demographics, indications for admission, average duration of NICU stay, various drugs prescribed and outcome of therapy.

Results: In the present study 34% of the neonates were preterm whereas 34% were low birth weight and 16% were very low birth weight babies. Commonest cause of admission to NICU was hyperbilirubinemia followed by neonatal sepsis and RDS (respiratory distress syndrome). Intravenous fluids (94%) and antibiotics (94%) were the most common groups of drugs utilized. Netilmicin was the most common

antibiotic used. 44% of neonates received oxygen whereas 30% received phototherapy. Average number of drugs prescribed per patient was 5.3. In our study 74% of the neonates improved while 8% were referred to higher center, 2% were readmitted 9% discharged against medical advice and 7% expired. One neonate had IUGR (intrauterine growth retardation) as an adverse effect of maternal corticosteroid intake and one neonate had acute renal failure due to maternal aminoglycoside antibiotic intake.

Conclusion: Polypharmacy is a common entity in pediatric prescription. Evidence based antibiotic prescribing is helpful in prevention of resistance and decrease therapeutic failure. Safe use of oxygen and intravenous fluids remains as the need of the hour to enhance survival rate and decrease infant mortality rate. Further studies are required to assess the cause for mortality in neonates and pharmacoeconomics of the drugs used in NICU.

O 7.

Drug Utilisation Study of Antidiabetic Drugs in an Urban Population

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Background: Diabetes mellitus is a group of metabolic diseases in which high blood glucose levels results either because of inadequate insulin production, or because the body's cells do not respond properly to insulin, or both. Early and prompt management is necessary to prevent complications.

Aim: To study the prescribing and dispensing patterns of antidiabetic drugs prescribed by physicians and consumed by the patients near the Race Course area in the city of Vadodara.

Materials and Methods: A prospective, observational and non-interventional study was carried out by examining total dispensing of antidiabetic drugs during one month in an urban pharmacy outlet. Over-the-counter drugs and drugs used in treatment of diseases other than diabetes were excluded. The study was initiated after getting approval by the Institutional Ethics Committee of Sumandeep Vidyapeeth.

Results: It was observed that total cost of antidiabetic drugs sold was INR 46204. A total sale of oral hypoglycaemic agents (OHA) was more than insulin. A total volume of OHA sold in a urban population over a month was 4711 units, including individual drug(s) or Fixed drug combinations (FDC). Amongst oral hypoglycaemic agents, biguanides (38.87%) and sulfonylureas (27.17%) had largest sold volume.

Conclusion: Biguanides were most commonly prescribed antidiabetic agents. Polypharmacy is growing concern. It should be strictly watched for.

O 8.

Pre-donation perceptions of adverse events in population of Mewat, Haryana: A limiting factor in blood donation

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Introduction: Haemovigilance is needed to modify the transfusion practices for safe blood donation. One of the prerequisite is the need of rapid replenishment of the blood stocks usually within 35 to 42 days. However some areas are experiencing the shortage of voluntary blood donation due to varied pre-occupied misconceptions including adverse events. This study was conducted to study the prevalence of the apprehensions of adverse events in the population of Mewat, Haryana regarding blood donation.

Material and Methods: A total of 100 voluntary randomly selected participants were taken. A one-time cross sectional questionnaire in Hindi and English was used in the survey. It was given to each of the subject to mark the pre-framed 15 choices of misconceptions about blood donation and a blank space was also provided to write other comments if there are any.
Results: The weakness of strength that would never be regained was stated by 74% respondents. The order of other main responses were 19% for volumetric deficit of blood, 13% for lack of knowledge or awareness and 6% participants thought that pain due to prick was the main reason for not donating the blood.
Conclusion: There is strong perception of adverse events such as an irreversible weakness for entire life followed by volumetric deficit of blood due to blood donation in the population of Mewat, Haryana. Mitigation of perception of adverse events through pre-donation haemovigilance may prove imperative for framing transfusion related policies and increasing voluntary/replacement blood donation in the Mewat region of Haryana.

O 9.

A Comparative Study on the Efficacy of Isoflavones for Management of Menopausal Symptoms

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Objective: To investigate the effect of soy isoflavones on chief menopausal symptoms in perimenopausal and postmenopausal women.
Methods: Women between 40 to 65yrs were enrolled, of which 90 were perimenopausal and 90 were postmenopausal. Baseline symptoms were recorded using the Menopausal Rating Scale (MRS).100mg soy isoflavone per day was given to patients in each group. Follow up and reassessment of symptoms was done after 3 months using the MRS.
Results: Mean age of menopause observed was 43.92 yrs. Mean total response score of the perimenopausal group was 21.44 and that of the postmenopausal group was 20.01. Somatic, psychological and urogenital subgroup score was 6.2, 9.27 and 5.93respectively in the perimenopausal group. The same for the postmenopausal group was 5.63, 6.10 and 8.30.
After 3 months of therapy, the total score improved by 17% in the perimenopausal group and by 15% in the postmenopausal group. Perimenopausal women showed a reduction in psychological sub-scale scores by 32% ($p<0.001$). 22% reduction in somatic subscale scores observed was statistically not significant. Urogenital symptoms showed no improvement.
In the postmenopausal women best response was seen in the psychological domain (30%) ($p<0.01$) in comparison to the somatic domain (16%) ($p<0.05$). No improvement was seen in the urogenital domain.
Conclusion: Soy isoflavones were effective for treating the chief menopausal complain i.e. depression, sleep disturbance, fatigue and hot flushes in the perimenopausal group. However, it was not effective for managing the urogenital and rheumatoid complains in the postmenopausal group.

O 10.

An Overview of Safety and Efficacy of Unani drugs and Formulations in Common Disorders

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Indian traditional medicine based on various systems including Ayuerveda, Unani, Sidha and Homeopath (AYUSH). Unani system of medicine is one of the ancient systems of medicine present in India sinc centuries. Started by Hippocrates in Greece (460BC), it has enormous record in the context of diseases, the

causes, clinical features, diagnostic method and management. Unani physicians have described many liver diseases giving patho-physiological changes, symptoms and their treatment in scientific manner.
In Unani Medicine, single drugs or their combination in raw are preferred over compound formulations. The naturally occurring drugs used in this system are symbolic of life and are generally free from side-effects. Such drugs as are toxic in crude form are processed and purified in many ways before use. The Greek and Arab physicians encouraged poly-pharmacy and devised a large number of poly-pharmaceutical recipes which are still in vogue. In Unani Medicine, although general preference is for single drugs, compound formulations are also employed in the treatment of various complex and chronic disorders. Since emphasis is laid on a particular temperament of the individual, the medicines administered are such as go well with the temperament of the patient, thus accelerating the process of recovery and also eliminating the risk of drug reaction.
The evaluation of these drugs is based on phytochemical and pharmacological properties. In Unani system of medicine various plants parts such as stem bark, root bark, aerial root, vegetative buds, leaves, fruits and latex are used in dysentery, diarrhoea, diabetes, Vitiligo, sinusitis, filariasis, eczema, malaria, jaundice, infective hepatitis, nervous system disorders, bronchial asthma, arthritis and several other acute and chronic diseases are some of the conditions where Unani therapies have earned recognition after scientific validation. Medicinal plants are popular in indigenous system of medicine for its hepatoprotective, antitumour, antidiabetic, and analgesic, anti-inflammatory and antimicrobial properties. The present review is therefore, an effort to explain some important effect and properties of some Unani medicinal plant in common disorders. Detail will be discussed in full length paper.

O 11.

Ignorance of Physicians Regarding Pharmacovigilance in 21st Century

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Introduction: Spontaneous adverse drug reaction is an important part of overcoming mortality due to ADRs. There is still a lack of understanding amongst health professionals on this topic like how it functions, what are the benefits of sharing ADR knowledge, and importance.
Materials and methods: The present study was a cross-sectional questionnaire based survey (validated questionnaire containing 22 items) followed by training sessions to observe KAP and impact of training and recording of adverse effects in physicians who were practicing in Subharti Medical college(SMC), Lala Lajpat Rai Medical College (LLRM), Private Hospital (PH) and Private Practitioners(PP). IEC approval was obtained for the study. Chi-square test was applied for analysis of categories.
Results: A total of 500 participants (Consultants-152, JRs-304, Interns-44; S-210, P H-105, LLRM-123, PP-62) were enrolled in the study. Only 3(0.6%) out of 500 doctors were aware of CDSCO ADR reporting forms (LLRM-2, SMC-1, PP-0, PH-0). Only 14(2.8%) of 500 doctors were informed by medical representative about the ADR of a new product (LLRM-14, Subharti-0, PH-0, PP-0). Only 39(7.8%) out of 500 doctors were apprehensive about the litigation or financial loss if they report ADRs (LLRM-39, SMC-0, PH-0, PP-0). Majority of physicians of all institutions opined that training programs were inadequate. Majority of physicians opined that under reporting was due to lack of time and training. A total of 496/500 (99.03%) said that continuous medical education was required to increase the ADR reporting. There were no spontaneous ADR reporting before the training sessions, but after the training sessions around 100 ADR reports were received by our department.
Conclusion: From this study, we conclude that majority of physicians lack knowledge of pharmacovigilance and they have indifferent attitude towards spontaneous ADR reporting.

O 12.

Bacteriological Profile and Pattern of Antibiotic Sensitivity and Resistance in Pus Culture Isolates at a Tertiary Care Teaching Hospital in Bhopal

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Objective: To study the bacteriological profile and the pattern of antibiotic sensitivity and resistance in pus culture isolates in a tertiary care teaching hospital.

Materials and Methods: Pus specimens submitted to the microbiology laboratory for routine cultures and sensitivity were analyzed prospectively for the duration of 2 months. Antimicrobial susceptibility testing was performed by Kirby-Bauer Disk Diffusion method.

Results: Among the total 440 samples analyzed, 319 samples (72.5%) were found to be positive for growth. Out of 319 growths, 286 shows single isolate and 33 shows mixed (double) isolates. Out of these positive samples, 273 samples (85.58%) were positive for Gram negative bacteria while 48 samples (15.05%) were positive for Gram positive bacteria and 2 samples (0.63%) were positive for growth other than bacteria i.e. fungal growth. Klebsiella was the most common Gram–negative bacteria isolated & other common Gram-negative bacteria isolated were Pseudomonas and E.coli species while Staphylococcus aureus & CONS were the commonest Gram–positive bacteria. Gram negative bacteria shows >35% sensitivity to Meropenem, Imipenem-cilastin, Cefoperazone and >20% sensitivity to Pipracillin-Tazobactum and Gatifloxacin. They were most resistant to Cefpodoxime, Cefprozil. Gram positive bacteria were >70% sensitive to Lincomycin and Ampicillin-Sulbactum while most resistant to Clarithromycin, Sparfloxacin, Gatifloxacillin.

Conclusion: Microorganisms are rapidly acquiring antimicrobial resistance owing to indiscriminate use of antibiotics. This underlines the need of periodic review of bacteriological culture and sensitivity pattern for any healthcare set up. This type of prospective studies provides an inexpensive tool to determine the sensitivity and resistance patterns of various antibiotics among bacterial population and thus help in formulating an antibiotic policy for safe and effective use of antibiotics at loco-regional and national level.

O 13.

Evaluation of Knowledge and Perception towards Adverse Drug Reactions (ADRs) among Patients visiting Tertiary Care Teaching Hospital.

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Aim & Objectives: Evaluation of Knowledge and Perception towards ADR among patients visiting hospital and emphasize need of awareness regarding ADR.

Methodology: An observational questionnaire based study was conducted at tertiary care teaching hospital. Randomly selected 150 patients were enrolled. Demographic details of respondents were noted and knowledge and perceptions was evaluated by filling up an anonymous questionnaire. Data were analyzed by using descriptive statistics.

Result: Demographic analysis revealed that 59% were males, 41% were females, 56% patients belonged to rural areas and 55% respondents were not graduated. Regarding knowledge about ADR, 78.6% were aware that medicines can cause ADRs. 93.3% were consuming modern medicines as compared to alternative medicines. 33% had suffered from side effects in past and also witnessed the same in others. None of the

respondents were aware of ADR reporting center so did not report ADRs. Regarding perceptions towards ADR 86.7% agreed that reporting ADRs is necessary, 100% respondents opined they should contact physician on occurrence of an ADR. 85.3% had notion that only treating doctors are qualified to report ADRs and not patients or any other paramedical staff. 39% respondents believed that ADR reporting should be practiced to prevent recurrence, while 96% believed that latter is beneficial for people. 56% believed reporting may strengthen the patient safety while 70% wanted dissemination of information on ADRs.
Conclusion: Educational interventions are needed to improve awareness among patients regarding importance of ADR reporting.

O 14.

Skin necrosis secondary to Heparin therapy: A rare occurrence

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Background: Skin necrosis secondary to intravenous or subcutaneous Heparin injection is a rare complication. Skin necrosis has also been reported with use of low molecular weight heparin as well as oral anticoagulants like warfarin. It occurs mainly in setting of Heparin induced thrombocytopenia (HIT) involving formation of immune complex comprising of antibody, heparin, platelet factor 4 (PF4) and platelet which block the capillaries supplying the skin.
Materials and methods: We present the case of an active young male without any apparent predisposing factor developing left lower limb Deep Vein Thrombosis involving common iliac, femoral and popliteal veins. He was started on intravenous heparin and warfarin in standard doses. On 4th day he developed painless blister and blackish discoloration of skin over dorsum of foot and 2nd toe. Injection heparin was immediately stopped and his platelet counts were sent which had fallen down to 75,000/mm^3 from initial 1, 98,000/mm^3. The lesion evolved over next day and skin became frankly gangrenous so we did debridement and sent the sample for histopathology which revealed nonspecific inflammation. The wound healed gradually and the patient did not develop any new lesions, his platelet count also normalized by 6th day. The case was also reported to ADR monitoring centre, Jawaharlal Nehru Medical College.
Conclusion: Though both heparin and warfarin can cause skin necrosis, we temporally correlate that skin necrosis in our patient was caused by heparin as patient simultaneously had heparin induced thrombocytopenia. Management involves stopping the offending drug and using heparinoids or direct thrombin inhibitors.

O 15.

Adverse Drug Reactions in Hospitalized Children

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Aim: To assess the pattern of adverse drug reactions in paediatric general ward.
Methods: In a cohort of 120 hospitalised children active surveillance of adverse drug reaction was done. Adverse drug reactions were analysed as per the CDSCO guidelines.
Results: 23 adverse drug reactions were observed in 23 patients. Adverse drug reactions observed were cushingoid facies, hypertension, posterior subcapsular cataract and oedema with steroids; maculopapular, erythrematous rash, hepatitis and thrombocytopenia with antiepileptic drugs. Among the antibiotics, vomiting was observed with chloramphenicol, fever and diaorrhoea with vancomycin was observed. Causality assessment of the 23 ADRs was done according to the CDSCO guidelines, 8 were probable and 15 were possible. Outcome of the 23 adverse drug reactions was recovered for 12, continuinig for 5, unknown for 3 and recovering for 3.

Conclusion: Antiepileptics, steroids and antibiotics were most common drugs implicated for adverse drug reactions in children.

O 16.

SAE explored by Pharmacovigilance approaches at a Tertiary care Hospital

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Background: Classification system for the analysis of ADRs which is based on dose relation, timing, and patient susceptibility. Data about serious ADRs is deficient so this study was planned as a preliminary initiative to contribute to PvPI.
Aim/Objective: To study the incidence of serious ADRs and to establish causality of these ADRs
Methods: This concurrent observational study was carried out on patients admitted for a duration of fifteen months i.e. from July, 2013 to September, 2014. Data regarding patient demographics and ADRs were collected by serial patient interviews, collaborated by information in respective patient file. Incidence rate of each ADR was calculated & causality was assessed by WHO causality assessment scale.
Results: A total of 101 serious ADRs were reported (46 males, 55 females). Mean age of patients was 46.90 years. ADR incidence was found to be 1 per patient. Average number of drugs prescribed was 1.64 per patient. Most common drug leading to Serious Adverse Drug Reaction was Phenytoin (13%) followed by Paclitaxel (6%). Most common ADR noted was Steven Johnson Syndrome (33%), rash leading to hospitalization (32%) and followed by fever (12 %), anaphylactic reactions (6%), DRESS (7%) and toxic epidermal necrolysis (10%). Patients suffering from serious ADRs had presented with diagnosis of seizures (20.75%) followed by ALL (7.73%). Most of the ADRs reported were Probable (90%).
Conclusions: Most common serious ADRs reported were Steven Johnson Syndrome and Rash. Caution is needed when prescribing these drugs to the patients & educating health care professionals and patients about drug effects and increasing their level of awareness regarding ADRs.

O 17.

Prevention of Adverse Effects of Anti-Cancer Drug using Herbal Extract – An Experimental Study of *Nigella Sativa*

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Aim/ Objectives: To study prevention of adverse effects of anti-cancer drug using herbal extract – An experimental study of *Nigella sativa*.
Material and Methods: Three groups [control (distilled water), cisplatin & Test - *Nigella sativa* pre-treatment + cisplatin] of 6 Wistar rats in each group were given cisplatin (2 mg/kg) twice weekly for 4.5 weeks. Ethanolic extract of *Nigella sativa* (500 mg/kg/day) was given in test group from week 0-5. Pain assessment was done at week 0, 3, 5 by hotplate and tail flick apparatus. At 5 weeks after giving anesthesia sciatic nerve, kidney and liver of rats of both groups harvested for histopathological examination.
Results: During induction of neuropathy at week 0 control group and *Nigella sativa* pre-treatment group were similar on hotplate & tail flick apparatus. At 3 and 5 weeks there was significant difference between control group & *Nigella sativa* pre-treatment group. All rats in cisplatin induced neuropathic pain group showed fall in reaction time greater than *Nigella sativa* pre-treatment group on hotplate & tail flick apparatus on week 3 & week 5. On histopathological examination of sciatic nerve we found that histology of *Nigella*

sativa pre-treatment group showed resolution of cisplatin induced neuropathy and decreased degenerative features as compared to cisplatin control group.
Conclusion: We conclude that *Nigella sativa* has a preventive effect on cisplatin induced neuropathy. Further studies are required to advocate clinical use of *Nigella sativa* in prevention of neuropathy.

O 18.

Antidepressant Activity of Cilostazol: An Experimental Study

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Objective: Besides antiplatelet activity, cilostazol has been reported to possess potent antidepressant activity. Therefore it was thought useful to compare antidepressant activity of cilostazol with that of clinically used fluoxetine.
Methods: In this study, the antidepressant activity of cilostazol was compared with that of fluoxetine in mice by forced swim test with activity wheel.
Results: Cilostazol (20 mg/kg) administered intraperitoneally significantly increased the number of rotations of wheel when subjected to forced swim test with activity wheel as compared to fluoxetine (20mg/kg)
Conclusion: The present study suggests that cilostazol possess potential antidepressant activity which could be of clinical importance for the patients suffering from depressive disorders.

O 19.

Adverse Drug Reaction Monitoring of Acamprosate for Treatment of Subjective Tinnitus in a Tertiary Care Teaching Hospital

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Objective: To assess the safety of acamprosate in treatment of subjective tinnitus.
Methods: It was a prospective study enrolling 30 patients of subjective tinnitus visiting the outpatient department of otolaryngology of Christian Medical College and Hospital, Ludhiana. These patients were prescribed acamprosate 333 mg thrice a day for period of 6 weeks. The adverse drug reactions were monitored at follow-up visits through adverse drug reaction checklist and spontaneous reporting at 2, 4 and 6 weeks. Results were analyzed using suitable statistical methods.
Results: Diarrhoea was the commonest adverse drug reaction (10%). The other common adverse drug reactions observed were nausea (6.7%), abdominal pain (6.7%) and pruritus (3.3%).
Conclusion: Acamprosate was found to be safe in the present dose in the treatment of subjective tinnitus.

O 20.

Self-Medication Practice and Perceptions among Undergraduate Medical Students: A Cross Sectional Study

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Background: Self-medication practice is widespread in many countries and the irrational use of drugs is a cause of concern. It can be defined as the use of drugs without consulting the physician to treat self-diagnosed disorders or symptoms, or the intermittent or continued use of a prescribed drug for chronic or recurrent disease or symptoms. It assumes a special significance among medical students as they are exposed to knowledge about diseases and drugs.

Aim: To assess practice and perception of self-medication among undergraduate medical students and to monitor Adverse Drug Reactions

Materials and methods: A cross-sectional questionnaire-based study was conducted among the undergraduate medical students of Mahadevappa Rampure Medical College, Gulbarga. Out of 448 students who participated in the study, 8 incomplete questionnaires were excluded from the study and only 440 were analyzed.

Results: It was found that 388 (88.18%) students practiced self-medication. The principal morbidity for seeking self-medication was cold and cough as reported by 304 (78.35%) students. Antibiotics were most commonly self-medicated as reported by 248 (63.91%) students. Majority of students 332 (85.56%) self-medicated because of mild nature of illness. 268 (60.9%) students felt that lack of knowledge about dose & frequency of administration as major disadvantage of self-medication. Most common adverse outcome was side effects of drugs, as experienced by 24 (6.19%) students.

Conclusion: Our study shows that self-medication is widely practiced among undergraduate medical students. In this situation, we should educate the students about advantages and disadvantages about self-medication.

O 21.

Phenytoin induced Stevens-Johnson syndrome in a 35 year male patient: A Case Report

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Adverse drug reactions (ADRs) are one of the leading causes of death among hospitalized patients and occur in 0.3 to 7 per cent of all hospital admissions. These may vary from mild rashes to severe reactions such as Stevens-Johnson syndrome (SJS). Antiepileptic drugs-induced SJS is a life-threatening severe cutaneous adverse reaction. We report here a fatal case of SJS due to phenytoin in a 37 year old male patient presenting at emergency room with a positive history of tuberculosis and recent onset of generalized tonic clonic seizures.

O 22.

Evaluation of Prescribing Pattern in Indoor Patients of Tertiary Care Rural Hospital

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Aim: To find out the prescribing pattern in indoor patients of Shree Krishna Hospital, Karamsad.

Objectives: To evaluate the prescribing pattern of consultants in terms of rationality

Materials and methods: As per NABH requirement, audit of prescriptions is the routine practice in our institute. With the consent of Quality Control Group, indoor case files are collected randomly from department of medical record. Case files are analyzed for parameters like patient's demographic details; final diagnosis; drugs prescribed to the patient with its dose, dosage form, frequency, duration; number of unnecessary drugs, irrational drugs and hazardous drugs. Each case file is evaluated for their final status of appropriateness.

Results: In last 3 months, 50 case files were evaluated. Final diagnosis was recorded in all cases. The average number of drugs per case was 6.5. About 73.85% of the drugs were prescribed by brand names. From all prescribed formulations about 21.85% FDCs were prescribed. Out of total 325 prescribed formulations; main formulations were 97, of which 90% were appropriately chosen, while complimentary formulations were 107, amongst which 98% were appropriately chosen. About 20% of the drugs were unnecessary and 10.46% of the drugs were irrational.

Conclusion: Though, the Hospital is having its own formulary developed on the basis of WHO Essential Medicine List & Standard Treatment Guidelines are in place, there is a need for monitoring for compliance.

O 23.

Knowledge, Attitude and Practice of Pharmacovigilance in Mahadevappa Rampure Medical College, Gulbarga, Karnataka

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Context: ADRs are a growing problem throughout the world causing significant patient morbidity and mortality, therefore, its monitoring has become exceedingly important in today's practice of medicine. Spontaneous reporting of ADRs which is the primary source of data, has played a major role in the detection of unsuspected, serious, and unusual ADRs previously undetected during the clinical trial phases. The Pharmacovigilance Program of Indian (PvPI) was started with an aim of generation of ADR database in the Indian population subset.

Aims: The aim of our study is to deduce by a survey the knowledge, attitude and practice of pharmacovigilance amongst the various cadres of medical healthcare professionals (interns, postgraduate students and teaching faculty) in a medical college.

We intend to investigate whether our healthcare professionals are inclined to, and are properly equipped to spontaneously and properly report ADRs.

Methods and Materials: This questionnaire based survey was conducted in Mahadevappa Rampure Medical College (MRMC), Gulbarga, Karnataka on 100 participants comprising of Interns, Postgraduate students and Teaching faculty of various departments.

Results: A majority (64%) of the doctors had a basic idea about pharmacovigilance and what it deals with. Amongst the factors discouraging participation in the pharmacovigilance program,. 41% of the responders replied that bureaucratic hassles were the biggest deal breaker in their opinion.

Conclusion: Our study revealed that the doctors in this tertiary care hospital were inadequately aware about the aim and methods of pharmacovigilance. Moreover, the primary tool of pharmacovigilance, that is spontaneous ADR reporting, was poorly understood by a vast majority of the participants.

O 24.

Is there a need for dedicated training hours on Pharmacovigilance in the Nursing curriculum in India?

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Introduction: Patient safety can be endangered by adverse drug reactions (ADRs) leading to considerable morbidity and mortality. Nurses primarily being involved in medication administration must be aware of adverse drug reaction monitoring activities in order to develop a culture of safe usage of drugs. Unfortunately the nursing curriculum in India has no dedicated training hours for ADR monitoring in patients resulting in the poor capturing and monitoring of ADRs.

Objectives: To assess the knowledge change of nurses regarding pharmacovigilance (PVG) activities before and after planned training programme with a structured questionnaire and to identify the strategies to improve the awareness among nurses regarding PVG.

Initiative: A prospective interventional study using dedicated hours of pharmacovigilance training was conducted to investigate the level of awareness regarding PVG among nurses from October to November 2013. Training module was prepared and validated by the consultant clinical pharmacologist and set of senior trained nurses for training of all 410 nurses of Peerless Hospital, Kolkata. All the nursing staffs were

administered a validated questionnaire pre and post training to evaluate the change knowledge and attitude regarding PVG.

Observation: Post-training, awareness about PVG among the nurses increased from 34.39 % to 89.78 % (P<0.001). 71.86 % of nurses also felt that pharmacovigilance should be incorporated into the nursing curriculum to improve ADR reporting in India (P= 0.00082). Post training 82.93% Nurses' felt that it one of the mandatory responsibility of a nurse was to report an ADR. After the completion of training, reporting of ADRs in our Hospital has increased considerably. (From nil to average 4-5 cases per month).

Conclusion: The present study suggests that awareness about PVG among nurses is poor and leads to low capturing of ADRs. Hence, the authors strongly feel that dedicated hours on ADR monitoring and PVG reporting should be included in the Nursing curriculum to improve PVG activities in the country and augment patient safety.

ABSTRACTS FOR POSTER PRESENTATIONS

P 1

To Evaluate the Role of Oral Propranolol vs Oral Prednisolone in The Management of Paediatric Haemangiomas: A Prospective Study of 50 Patients Using the Haemangioma Activity Score.

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Introduction: Haemangiomas are the most common benign tumor of infancy. Infantile haemangiomas occur in approximately 1-2% of infants at birth. These tumors are commonly managed by oral corticosteroids or Vincristine and at times only by observation, however recently oral propranolol has been shown to have dramatic results in infantile haemangiomas. This is our prospective study of 50 children on oral propranolol compared with oral corticosteroids. Potential explanations for the therapeutic effect of propranolol are Vasoconstriction, decreased expression of VEGF and bFGF genes through the down regulation of the RAF mitogen activated protein kinase pathway and triggering of apoptosis of capillary endothelium.

Material and Methods: A total of 50 infants were included in this study, 25 were treated with oral propranolol (2mg/kg) and 25 with oral steroids (oral prednisolone 1mg/kg), and the results were compared at 3 and 6 months. Drugs were stopped in case of significant side effects. Patients were followed up for a period of 6 months after stopping the drugs for any recurrence.

Results: There was significant decrease in size of hemangiomas in propranolol group as compared to prednisolone group as assessed by Haemangioma Activity Score (HAS). There was no recurrence of hemangiomas after stopping propranolol .No significant side effects occurred in patients receiving Propranolol.

Conclusion: Oral propranolol is more effective than prednisolone in infantile hemangiomas and is well tolerated by patients without any significant side effects. It should always be tried in patients of infantile hemangiomas if there are no contraindications for use of beta blockers.

P 2.

Biosimilars: A New Challenge in The World of Pharmacovigilance

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Introduction: Biosimilars / 'follow on' biologics are medicinal products similar to already patented biotech products, but are manufactured by new companies after the patent expiry of originator product. Biosimilars, are new hope due to their, low price, effectiveness similar to originator product and they require shorter time to develop, which helps in facing challenges like shift in disease pattern, product demand and rapidly increasing healthcare cost . Pharmacovigilance programms for biosimilars would require a more refined expertise to identify safety signals because of their manufacturing complexities & lack of widespread awareness amongst healthcare providers. Pharmacovigilance processes should be designed to adequately address the specificity of the respective biosimilars.

Objective: Here we present innovations & strategies that describe a risk management system, the so-called **"Risk Management Plan"** which contains two parts: ***pharmacovigilance*** and ***risk minimization***. We have made an attempt to make clear how the safety of a product would be monitored and measured to reduce risk.

Methodology: The method followed here ,is secondary data analysis. The findings are based on literature review , internet search of journals, report and relevant organization working in area of biosimilars.

Conclusion: Based on their size, complexity , variability & manufacturing changes between the originator and biosimilar products, this might lead to a difference in safety profile (e.g. immunogenicity), which brings about a new Pharmacovigilance challenge. But once proven safe and effective, biosimilars will be an option

for a number of patients and thus may reduce the overall cost of delivering the lifesaving biotechnology medicines.

P 3.

Pentavalent Vaccine Induced Seizure in a 2 Month Old Neonate: Case Report

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Immunization is one of the most important public health interventions and preventive strategy to control the infectious diseases especially in children. The pentavalent vaccine is a combination of five vaccines in one (DPT+Hep B+Hib). Hypotonic hyporesponsive episodes (HHEs) and seizures are recognized adverse reaction to whole-cell and acellular pertussis-containing vaccines and to HiB and hepatitis B vaccines. Manifestations following administration of vaccine include the following: with or without fever occurring within 3 days of immunization and persistent, severe, inconsolable screaming, or crying for 3 or more hours within 48 h of immunization. Usually, these are not associated with permanent sequel. Neurological complications are thought to be primary due to the pertussis component of the vaccine.

Here we report a case of vaccination induced seizures in a 2 month old neonate whom this life threatening adverse effect was related in a temporal fashion to the administration of intramuscular pentavalent vaccine as part of his regular immunization.

This case emphasizes the occurrence of seizures consequent upon pentavalent vaccine use, an adverse reaction that has been described with use of pertussis component of the vaccine. This case highlights the importance of the continuous monitoring of vaccine-related adverse events of pentavalent vaccine.

P 4.

Study of Antioxidant and Renoprotective Potential of *Nigella Sativa* in Acute Kidney Injury (AKI) induced by Antineoplastic Drug Cisplatin in Experimental Animals.

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Objective: To study antioxidant potential and renoprotective potential of *Nigella sativa* oil (NSO) against cisplatin induced AKI in albino wistar rats.

Methods: 24 healthy adult albino rats of either sex (150-200 g) were randomly divided in four groups of six animals each. Group I (Normal control) and Group II (Negative control) were administered normal saline (0.2 ml/day i.p) for 9 days. Group III and IV (test groups) were administered NSO (1 and 2 ml/kg p.o) daily for 9 days respectively. On 5th day group II, III and IV were administered cisplatin (6 mg/kg, i.p single injection). On 10th day (24 hrs after last dose of medication) rats were sacrificed, and blood, urine collected for biochemical tests. Kidney was removed for histology and lipid peroxidation-antioxidant test.

Results: Cisplatin caused nephrotoxicity as evidenced by elevated blood urea, serum creatinine, blood urea nitrogen and urine glucose and decreased creatinine clearance in Group II as compared to Group I. Administration of NSO in group III and IV caused dose dependant reduction in the rise of blood urea, serum creatinine, blood urea nitrogen and urine glucose and an increase in creatinine clearance as compared to group II. There was increase Catalase, GSH and decrease MDA level in group II while NSO treatment reversed the changes towards normal values. Histopathological examination of kidney revealed protection in group III and IV compared to group II.

Conclusion: *Nigella sativa* oil has renoprotective activity against cisplatin induced acute kidney injury in rats.

P 5.

Pattern of Adverse Drug Reactions associated with various Chemotherapeutic Regimens at Oncology Department of Tertiary Care Teaching Hospital

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Aim: To evaluate the pattern of ADRs occurring in cancer patients visiting oncology department of tertiary care teaching hospital

Objective: To detect the prevalence of adverse drug reactions (ADRs) in department of oncology.

Method: A prospective observational study was conducted at Mahatma Gandhi Memorial hospital (MGMH), Warangal, Andhra Pradesh, India from March 2012 to August 2012. Patients were interviewed about symptoms related to their drug therapy. Detected and suspected ADRs were analyzed for causality, severity, preventability and predictability using appropriate validated scales and were reported. Total 116 patients associated with hospitalizations were interviewed.

Results: A total of 439 ADRs were detected, documented, assessed and reported during the study period, the incidence was found to be 88.79%. The prevalence of ADRs mostly occurred in the age group between 41-50 years (30.75%) and most of the ADRs were seen in females (67.42%). Gastrointestinal system was the most commonly affected (54.44%); multiple drug therapy was identified as the major predisposing factor (39.65%). The possible ADRs according to WHO scale were 57.4% and according to Naranjo were 50.34%. The ADRs which are mild were 58.08%, 87% were preventable and 91.57% were predictable.

Conclusion: The study was its kind in providing a baseline data regarding the safety profile of chemotherapeutic drugs in India. So, similar studies covering more patients from different regions are needed to validate the findings of this study.

P 6.

Concept of Pharmacovigilance in Unani System of Medicine

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Ensuring the safety and efficacy of pharmaceuticals and biotechnology products is one of the top challenges in healthcare today. Worldwide movement for the improvement of patient safety is gaining momentum; hence the subject of pharmacovigilance or drug safety becomes even more prominent in the present day scenario. Since centuries Unani systems of medicine is practiced in this continent. It is regarded as the safest system of medicine. However with the scientific ethos everything is rejected or accepted in the light of available clinical data only. Hence, to create pharmacovigilance program for ASU (Ayurveda, Sidha, Unani) drugs become essential for giving them credibility. Unani drugs are obtained from three sources, plants, animals and minerals. Some of these single crude drugs contain adverse effects (*Muzarrat*) such as the drugs of 3rd and 4th degree (Toxic). If these drugs are used in proper dose according to the degree of temperament (*Darjat-e-Mizaj*) of a drug, according to the temperament of patient and disease, along with proper purification as well as rectification, (*Muddabar and Musleh*), as and when required, they are supposed to be non-toxic and free from any adverse effect. Unani medicine has many ways to avoid adverse drug reactions and can be safely used in the patients, to prevent and cure the diseases. This indicates a very vast concept and scope of pharmacovigilance in Unani medicine. Its details will be discussed in full length paper.

P 7.

Acute Delirium in an Elderly Women Following Zolendronate Administration – A Case Report.

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Zolendronate is a third-generation bisphosphonate having distinctive profile of high potency as well as prolonged duration of action. Intravenous zolendronate is the recently approved bisphosphonate for the treatment of osteoporosis and has an attractive once-yearly regimen for the treatment of osteoporosis. Here we report, for the first time, a case of acute delirium following zolendronate administration for osteoporosis. An 86 year old female patient presented to orthopaedics OPD with complains of pain and unable to bear weight on left thigh with history of fall from bed 2 months back. She was diagnosed as fracture neck femur with severe osteoporosis and treated conservatively. She was given zolendronate IV 5mg infusion over 30 minutes. After 10-12 hrs of zolendronate infusion, Patient became confused, disorientated and agitated. A septic work-up was negative. Electrolyte disturbances were excluded with normal sodium, potassium, calcium and magnesium levels. Computed tomography of the brain was unremarkable. A metabolic cause could not be found, for the change in her mental state. Patient was referred to medicine department where she was diagnosed as drug induced acute delirium probably due to zolendronate. Patient was advised injection Haloperidol and injection Torsemide. In the following 48 hours her confusion was cleared and mental state was improved. According to the Naranjo probability scale the effect of zolendronate in our patient was scored 6 indicating a probable likelihood of causing delirium and also it was probable cause of acute delirium according to WHO causality scale.

P 8.

A Comparative Survey Study on Current Prescribing Trends in Proton Pump Inhibitors and H2 Receptor Antagonists among Practitioners in Private Set Up and Tertiary Care Teaching Rural Hospital

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Background: Acid peptic disorders result from excessive acid secretion or diminished mucosal defense. They are common entities present in daily clinical practice that, owing to their chronicity, represent a significant cost to healthcare. The histamine-2 receptor antagonists revolutionized the treatment of acid peptic disorders owing to their safety and efficacy profile. The proton-pump inhibitors (PPIs) represent a further therapeutic advance due to more potent inhibition of acid secretion.

Aim: Our work aimed to compare the pattern of using proton pump inhibitors and H2 receptor blockers in private practitioners and tertiary care teaching rural hospital.

Materials and Methods: The prospective survey study included a total of 50 medical practitioners; 25 from private set up and 25 from tertiary care teaching rural hospital. The feedback questionnaire that contained various questions related to antiulcer agents, were distributed to find out the various indications for which consultants prescribed them, dose and frequency, choice of preparation, and any recorded adverse effect.

Results: It was observed that proton pump inhibitors and H_2 receptor antagonists were prescribed for GERD, peptic ulcer and non-ulcer dyspepsia. Proton pump inhibitors were preferred over H_2 receptor antagonists for above indications except in pediatric patients in whom H_2 receptor antagonists were effectively used because of availability of liquid formulations.

Conclusion: The proton pump inhibitors are more potent and effective than H_2 receptor antagonists in treatment of acid-peptic disorders. Major concern is related to overprescribing and irrational use of these drugs.

P 9.

Central depressant activity of Myristica fragrance (Nutmeg) in rats

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Objective: To investigate the central depressant activity of ethanolic extract of *Myristica fragrans* seeds.
Materials and Methods: *Myristica fragrans (Nutmeg)* seeds were purchased from local market and authenticated by competent authority. Ethanolic extract of the drug was prepared. Central depressant activity of the extract in dose of 200 and 400 mg/kg was studied in rats by using pentobarbitone induce-hypnosis potentiation test. The ethanolic extract was administered 1 hour prior to pentobarbitone injection (30mg/kg i.p.). Sleeping time was measured as interval between abolition and reappearance of righting reflex. Sleep latency and duration of sleep was compared between Test and Control groups.
Results: *Myristica fragrans* Ethanolic extract increased the duration of sleep and decreased the sleep latency significantly.
Conclusion: Ethanolic extract of *Myristica fragrans (Nutmeg)* seeds has central depressant activity in rats.

P 10.

A Randomized Clinical Trial to Evaluate the Efficacy of A-Keto Analogues of Essential Amino Acids Supplementation in Patients of Chronic Kidney Disease.

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Objective: To evaluate efficacy of α-Keto analogues of essential amino acids (KAA) supplementation in patients of Chronic Kidney Disease.
Material and Methods: A prospective comparative study was conducted in patients of Chronic Kidney Disease at a tertiary care centre of north India. Patients were randomly divided into two interventional groups. Group I (Control) was advised conservative management while Group II (KAA) given conservative management along with KAA (600 mg, thrice daily) for 12 weeks. Haemoglobin percent, blood glucose, blood urea, serum creatinine, 24-hour total urine protein, 24-hour total urine volume, glomerular filtration rate were measured at 0, 4, 8 and 12 weeks of treatment.
Results: Both groups showed gradual improvement in the above mentioned parameters as compared to their pre-treated values which was more marked in KAA supplemented group. There was reduction in: fasting blood glucose (12.51% &20.78%), post-prandial blood glucose (14.80% & 20.89%), blood urea (25.55% &38.09%), serum creatinine (25.00% &39.52%) and TUP (19.80% &38.34%) in Group I & Group II respectively. There was increase in: haemoglobin concentration (12.64% &19.77%), TUV (19.41% &33.32%) and GFR (22.60% &49.20%) in Group I& Group II respectively.
Conclusion: α-Keto analogues of essential amino acids (KAA) supplementation improved the therapeutic effect of conservative management in patients of Chronic Kidney Disease.

P 11.

A Cross Sectional Drug Utilization Study amongst Hypertensive Patients in A Tertiary Care Teaching Hospital at Jaipur.

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Introduction: Drug Utilization research defined by WHO in 1977 as "marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social, and economic consequences". The principal aim of drug utilization study is to facilitate rational use of drugs in population. Without the knowledge of how drugs are being prescribed and used, it is difficult to evaluate rational use of drugs and to suggest measures to change prescribing habits for the better.

Objective: The purpose of this study is to investigate the current trend and pattern of prescribing antihypertensive drugs and to identify, whether such pattern of prescription is appropriate and in accordance to international guidelines for pharmacotherapy of hypertension.

Material and Method: It is a retrospective cross sectional study. Data was collected from patient's medical record.

Results: 1275 prescription records were assessed, out of which, 561 were females and 714 were males. Most of the patients were in the age group of 50 - 65 years. Average number of drugs per prescription was 4.6. Drugs mentioned in WHO-EML (Essential Medicine List) were 59% and drugs mentioned in NLEM (National List of Essential Medicine) 2011 were 74%. Drugs prescribed as fixed dose combinations were 26%. Drugs prescribed by generic names were 82% while drugs prescribed by brand names were 18%.

Conclusion: This study will give us an overall pattern of prescribing prescription amongst hypertensive patients and also a broad idea about rational use of drugs in these patients.

P 12.

Assessment of Knowledge, Attitude and Practice (KAP) of Pharmacovigilance among Healthcare Professionals in India

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Background: Adverse drug reactions are a major cause of morbidity, mortality, hospital admissions and economic burden. Spontaneous reporting of ADRs has remained the cornerstone of pharmacovigilance. Pharmacovigilance activities in India have increased over the last 15 years. The aim & objective of this study is to assess knowledge, attitude and practice of pharmacovigilance amongst healthcare professionals in India.

Method: A retrospective analysis of studies of pharmacovigilance reported in India since 2002 to 2014 was done. All studies evaluating knowledge, attitude and practice of pharmacovigilance in India were assessed. Common questions (18 questions) in all the studies were selected under the categories of knowledge, attitude and practice.

Result: A total of 65 Indian studies (national, international journals) were included. Knowledge about the definition and importance of pharmacovigilance was 52% and 42% respectively. Knowledge about International Drug Monitoring Centre (Uppsala) and the pharmacovigilance centre in India was 19.2% and 57.5%. The definition of ADR was known by 64.9%. Knowledge about how and where to report ADRs was 51.9% and 51%. Very few, 33.3% healthcare care professionals keep records of ADRs and 25.4% have attended ADR training workshops. About 59.9% think that reporting of ADR is a professional obligation. Majority felt that ADR reporting is important, 82.6% and 75.8% necessary. Reasons for underreporting included legal considerations by 28%, unavailability of ADR forms by 50 % and lack of time by 33.3%.

Conclusion: There is limited awareness amongst healthcare professionals in India about pharmacovigilance activities. Majority of health care professionals consider ADR reporting as important. There is a need to increase educational interventions to improve knowledge, attitude and practices of pharmacovigilance.

P 13.

ADR Analysis Request E-Form: A Mobile App

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Introduction: Adverse drug reaction (ADR) monitoring is being done across the globe under various national and international pharmacovigilance programmes. The major hurdle in these programme is the disconnect between the clinician and the reporter of the ADRs. Many ADRs still go unreported due to inability or hesitancy of the clinician to fill the cumbersome ADR reporting form. To address this problem we have devised an ADR analysis request form and incorporated in an mobile app.
Mobile App: The ADR analysis request e-form consists of fewer columns from which basic information regarding the patient and problem is gathered. The information would be used to follow-up the case. The information consists of Name, age, sex, ward/ bed and hospital identification number of the patient. In addition to it, data regarding the reaction, medicine(s), date of start and stop of medicine are also collected. The whole data is compiled in the form of a mobile software based on JAVA platform and can be used of android Operation system. For easier uploading of the ADRs analysis request, some additional features also incorporated in the app. These features include drop down menu, function of sending/ uploading the request using various platforms (email, SMS or WhatsApp) and one time saving of the data of the clinician or sender.
Advantage of the App: 1) Fast input of data which requires less than 30seconds, 2) Decrease the number of unreported ADRs, 3) User can send the data using one of the various options (email, SMS or WhatsApp)

P 14.

Evaluation of Prescribing Pattern in Outdoor Patients Of Tertiary Care Rural Hospital

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Aim: To find out the prescribing pattern in outdoor patients of Shree Krishna Hospital, Karamsad.
Objectives: To evaluate the prescribing pattern of consultants in terms of rationality.
Materials and methods: The present study is cross sectional, observational ongoing study. As per NABH requirement audit of prescription is routine practice in our department. With the consent of Quality Control Group outdoor prescriptions are collected randomly from various outdoor patient departments. Prescriptions are analysed for data like patient's demographic details, final diagnosis, drug prescribed to the patient with its dose, dosage form, frequency, duration, number of unnecessary drugs, irrational drugs and hazardous drugs. Each prescription is evaluated for their final status of appropriateness.
Results: In last 5 months, 106 prescriptions were evaluated. Final diagnosis was recorded in 56.6% prescriptions. The average number of drugs per prescription was 3.49. About 76.76% of the drugs were prescribed by brand name. From all prescribed formulations about 25.94% FDCs were prescribed. Out of total 370 prescribed formulations, main formulations were 202, of which 78.3% were appropriately chosen, while complimentary formulations were 78, among which 52.83% were appropriately chosen. About 24.32% of the drugs were unnecessary and 5.4% of the drugs were irrational.
Conclusion: Though, the Hospital is having its own formulary developed on the basis of WHO Essential Medicine List & Standard Treatment Guidelines are in place, there is a need for monitoring for compliance.

P 15.

Role of Clinical Pharmacist in Optimisation of Drug Therapy Outcomes at A Tertiary Care Hospital

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Background: Clinical pharmacists work directly with physicians, other health professionals and patients to ensure that the medications prescribed for patients contribute to the best possible health outcomes. However this role of Clinical pharmacist and the concept of pharmaceutical care services is completely new to most of the physicians, nurses and even pharmacists presently working in our government health facilities. Present study being the first of its kind in the state will pave way for more advanced, systematic and coordinated pharmaceutical care services in future.

Objective: To identify and resolve patients drug related needs and problems and thereby optimise drug therapy outcomes.

Methods: Medication use data was collected and reviewed. Drug-related needs and problems of patients were assessed. Patient specific Pharmaceutical care plans were formulated and medication interventions proposed and followed.

Results: Based on the assessment of patient specific clinical data which included medical and medication history and their current drug therapy, a total of 258 interventions were made, besides imparting patient education and counselling to 177 patients. Pharmaceutical Care Services including patient counselling offered to the study patients proved beneficial in terms of better patient compliance, their improved health-related quality of life, optimized therapeutic outcomes.

Conclusion: Pharmacists can improve the quality of drug therapy by improving the organizational structures through which drug therapy is provided particularly by means of rendering their pharmaceutical care services.

P 16.

Analysis of Spontaneous Adverse Drug Events Reported At Peripheral ADE Monitoring Centre of Tertiary Care Teaching Hospital

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Objective: To evaluate the ADEs reported at this centre under Pharmacovigilance Programme of India.

Methodology: As our department is one of the peripheral "Adverse Drug Reaction Monitoring Centres" (AMC), healthcare professionals of Shree Krishna Hospital are supposed to send intimation to Pharmacology department when they came across ADE. On intimation residents of Pharmacology department used to collect history of the same and fill ADR forms. Pharmacology residents also survey actively to collect the ADE as part of their academic curriculum. Descriptive statistics were performed to analyze the ADEs in various parameters.

Results: We have reported 36 spontaneous adverse drug events from May 2014 to Sept 2014. Majority of the adverse events were seen in female patients i.e. 20 (55.5%). Ten (28%) ADEs were in patients of age group 21-30 years. One ADE was life-threatening and one was needed hospitalization. Out of 36 ADEs, 19 (53%) were probable, 16 (44%) were possible and one was certain. Active therapeutic intervention to treat ADE was needed in 19 (53%) cases. Commonest drug responsible for ADE was Metronidazole. Eighteen (50%) of total ADEs were of augmented type while remaining 18 (50%) ADEs were of bizarre in nature.

Conclusion: Adverse drug reaction monitoring is important to promote safe use of medicines. Clinicians and other healthcare professionals should be aware of ADR reporting to enhance patient safety. As less reporting is observed, continuous reinforcement is required to inculcate the culture of ADR monitoring amongst them.

P 17.

Screening Of Used Eye Drop Containers for Microbial Contamination

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Background: Contamination of eye drops poses a potential cause of avoidable ocular infections. Apart from the risk of infection, microbial contamination may alter the pH of the solution thereby reducing the efficacy of drug.

Aims: This study was aimed to identify the pattern of the bacterial and fungal contamination of used/opened eye drop containers and residual medicine at our teaching hospital.

Methods: Fifty five used eye drop containers were obtained from patients attending out- patient and in-patient departments of Ophthalmology. We filled Case record forms for each container and then sent them for microbiological investigations to microbiology dept. The residual medicine was cultured in brain heart infusion broth for 48 hours at 35C and then sub- cultured on blood agar, Sabaurods-Dextrose agar, McConkey agar. Bacterial and fungal Isolates were confirmed both by conventional and automated methods.

Result: We found 14.5% multiple dose ophthalmic solution contaminations with various bacteria, like staphylococcus (9.09%), pseudomonas (3.63%), and E .coli (1.81%). We did not find any contamination by fungi. We also observed that, there was no contamination with eye drop containing antimicrobial agents.

Conclusion: Our data show a contamination rate of 14.5%, which is the lower range of data published on the contamination of eye drops elsewhere (0.07% to 35.8%)

P 18.

Klebsiella Endocarditis Leading To Brain Abscess in a Child with Tetralogy of Fallot

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Though congenital heart disease (CHD) predisposes to Infective endocarditis and brain abscess, endocarditis due to gram negative bacteria is uncommon. Among gram negative bacteria, Klebsiella species are very rare cause of bacterial endocarditis. Here we describe a case of a two and half year's male child who presented to us with fever and cyanotic spell with initial echocardiography revealing TOF with no evidence of endocarditis. The child developed fever on day 8th after being afebrile during 1st seven days of hospital stay while on empirical IV antibiotics and initial culture being sterile. Repeat echocardiography was done and blood culture from three different sites 12hrs apart were sent. A CECT head was done on later date which revealed a ring enhancing lesion in left parieto occipital region suggestive of brain abscess. One Repeat blood culture also came out to be positive for klebsiella species. A diagnosis of klebsiella Endocarditis (? Hospital acquired) with septic emboli to brain was made and sensitive antibiotics were started.

P 19.

Electronic Nicotine Delivery System & Safety issues: Current Status.

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Context: Electronic Nicotine Delivery System (ENDS) of which electronic cigarettes are the most common prototype, are a recent development in tobacco harm reduction. E-cigarettes (ECs) are made up of a cartridge, atomizer, battery and an LED light. E-cigarette is also known as an e-vaping device, were introduced to the Chinese market in 2004 and to the US market in 2007, now becoming popular in India. The studies have revealed that e-cigarettes are not free from adverse effects and the use of e-cigarettes by teenagers, especially middle-school children, has increased resulting in the criticism of e-cigarettes worldwide.

Objective: To review the studies on ENDS / e-cigarettes - to assess the adverse effects and regulatory guidelines regarding safe use of e-cigarettes.

Method / Search Strategies: We searched the PubMed electronic database by using defined key words related to e-cigarettes and appraisal of published articles from peer reviewed journals. The search was limited to articles written in the English language till date.

Results: The studies have revealed that there is tremendous growth in the e-cigarette market and millions of people currently using them. ENDS are shaped to look like their conventional tobacco counterparts e.g. cigarettes, cigars, pipes, hookahs, they also take the form of pens, and USB memory sticks. It is estimated that there are approximately 466 brands and 7764 flavour of e-cigarettes, & US $3 billion was spent on ENDS globally in 2013. There are two views, some experts welcome ENDS as a pathway to the reduction of tobacco smoking, while others do not support their use, hence ENDS are the subject of a public health debate. There are reports from the studies that e-cigarettes cause pneumonia, congestive heart failure, disorientation, seizure, hypotension, and other health problems.

Conclusion: E-cigarettes were marketed as less harmful alternatives to smoking, currently the use of e-cig is apparently booming as a "gateways devices" for smoking among young people. ENDS are the subject of a public health dispute because of safety issues. There is lack of consistent, scientific research on ENDS also reports are not evidence-based. There are health risks to users, non-users and bystanders. Appropriate legislative and regulatory measures to prevent the use of e-cigarettes are necessary. There is need for well-designed studies & pharmacovigilance programme for Electronic Nicotine Delivery System.

P 20.

Pattern of adverse drug reactions reported to the regional Pharmacovigilance center at a Tertiary Care Teaching Hospital in Bhopal

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Objective: To characterize the pattern of ADRs reported & assess the causality of collected ADRs by Naranjo's & WHO-UMC scale in a tertiary care teaching hospital in Bhopal.

Methods: The study was conducted based on the ADRs reported between April 2014 and September 2014 (6 months) to the pharmacology department. Evaluation of the data was done for various parameters which

included patient demographics, drug and reaction characteristics, and outcome of the reactions. Assessment was also done for causality.

Results: Total of 79 ADRs, which were reported during the 6 months period among which 49 (62.02%) were in males and 30 (37.97%) in females. Dermatology department reported 56 (70.88%) out of 79. Most common ADRs reported were acneiform eruptions 43 (54.43%). Among the total ADRs, topical steroids [n=39, (49.36%)] were responsible for most of the reactions followed by antimicrobial drugs [n=14, (17.72%)]. The causality assessment showed 69 (87.34%) of the ADRs to have a 'probable' relationship with the suspected reaction. Majority of the ADRs were non-serious and only 11 cases were serious and required hospitalization.

Conclusion: The results suggest that healthcare professionals (HCP) at this institution are cognizant of PV. However a closer liaison between the HCPs and the hospital PV centre, periodic reinforcement of the HCPs regarding the need for PV can further improve spontaneous reporting. The data will also help in designing strategies for framing policies towards safer use of drugs in future.

P 21.

A Study on Assessment of Medication Related Problems in Cardiovascular patients at General Medicine Department of a Tertiary Care Teaching Hospital

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Objectives: The objectives of the study were to evaluate the number and nature of drug related problems (DRPs) with cardiac drugs, to prevent actual and potential DRPs, to provide pharmacist interventions for identified DRPs, to evaluate pharmacist intervention mediated outcomes and to improve the overall patient care.

Method: A prospective, observational and interventional study was conducted among 189 patients with cardiovascular disease who were aged 18 years or older and admitted to the general medicine ward. During the six months study period the nature, prevalence and incidence of DRPs were studied and documented using the PCNE (Pharmaceutical Care Network Europe foundation) classification system.

Results: A total of 189 patients with a mean age of 57.22 years were screened for DRPs. Among them 130 patients have at least one DRP. A total of 416 DRPs were identified of which improper drug selection (23.31%), untreated indication (19.95%) and drug interactions (16.10%) were the most frequently occurring DRPs. Adverse drug reactions accounted for 10% and anti-hypertensive drugs were most commonly associated with adverse drug reactions. Calcium channel blockers were the most commonly implicated class of drugs in DRPs followed by anti-platelet agents and amlodipine presented a high drug risk ratio. Pharmacist interventions were mostly on drug choice, drug interactions and 68% of them were accepted, resulting in prevention of DRP occurrence.

Conclusion: The current study demonstrated the importance of routine medication review and the need of a pharmacist in a multidisciplinary team in prevention of drug related problems with cardiac drugs.

P 22.

A comparison between implementation of regulations pertaining to Pharmacovigilance between India and Europe

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Aim: There is variation in the pharmacovigilance system from country to country with Europe being the most advanced and India still being in its infancy. This necessitates the utmost need for effective regulations for monitoring adverse drug reactions for strengthening our drug regulatory system.

Methods: The publications related to pharmacovigilance in European Union and CDSCO, India were studied and the monitoring processes were compared.

Results & conclusion: Comparing the implementation of regulations relating to pharmacovigilance of the two countries, it is observed that India is far behind in strictly implementing the regulations. The reasons for this difference could be lack of sufficient funding, trained staff, and adequate training programme.

P 23.

Sterile Abscess following Pentavac Immunization: a Case Report

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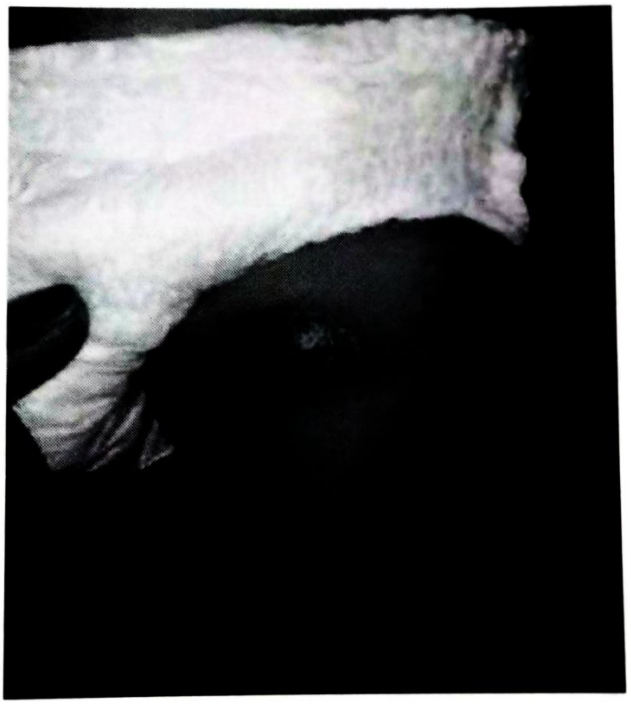
Adverse reactions are quite common after DPT vaccination. They are mainly local and few systemic reactions. Local reactions are usually pain, swelling, induration and redness at the site of intramuscular injection. Among systemic reactions fever, fretfulness and drowsiness are commonly seen. Rare ones include sterile abscess at the injection site, the incidence being 6-10 per million doses. Here we report a case of sterile abscess occurring in a two month old baby following Pentavac (pentavalent vaccine containing DPT, H. influenza B and Hepatitis B) immunization.



P 24.

Role of Pharmacovigilance in the Newly Found Controversy of Oral Contraceptive Pills and Intraocular Pressure Changes

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Aim: The association between female sex hormones and intraocular pressure changes in eye has been long known. However, the report of increased risk of open angle glaucoma in the females taking oral contraceptive pills (OCP) for three years or more has come up as a recent finding, which requires further studies to probe the causal association between estrogen, progesterone and intraocular pressure (IOP) rise, if any. The aim of this study is to create awareness about this recently reported glaucoma risk with OCPS so that effective pharmacovigilance programme can be initiated to prevent this.

Methods: In this study, adequate information was searched using the internet databases like PubMed and Medscape.

Results: The American Academy of Ophthalmology in New Orleans, has announced recently, that women who have taken oral contraceptives for three or more years are twice as likely to suffer from glaucoma. The study indicates that glaucoma may be considered as a part of the risk profile for a patient on oral contraceptive pills, together with other existing risk factors.

Conclusion: The association of OCPs with risk of glaucoma is a reason for alarm, especially in a country like ours, where OCPs are the most commonly used method for birth control and the population taking these pills is generally unaware of the impending risks. With proper pharmacovigilance, the association between OCPs and IOP can be demonstrated.

P 25.

Prescription Auditing of patients admitted at a ward of tertiary care hospital of Western UP

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Aim: To analyze and auditing the prescribing pattern of inpatients admitted at Dermatology Ward of Jawaharlal Nehru Medical College Hospital, A.M.U., Aligarh, from the period of January 2012 to October 2014.

Material and Methods: Permission to access medical records of the past 2 years of all patients admitted in the Dermatology ward from January 2012 to October 2014 was obtained by competent authority. Of the 72 patients, prescriptions of only 70 patients (25 female, 45 male) were available in the Central Record Section (CRS). These prescriptions were analyzed after making a standard criterion using WHO and other researchers' guidelines. Following modified parameters were taken to analyse and auditing prescription:

1. Patient details like name, age, sex and address.
2. Completeness of diagnosis, legibility & spelling mistakes.
3. Details of the consultant like name, signature and contact number.
4. Use of generic name, mean number of drugs per prescription, number of antibiotics per prescription, route of administration and provision of proper instructions.

Results: Only 25.71% of prescriptions contained the full names of patients, while their age, sex and address were present in 98.57% of the prescriptions. 97.14% prescriptions were found written with a diagnosis and 98.57% prescriptions contained the signature of the concerned doctor. Only 1.4% had the doctor's phone number. None of the drug names were in generic form. A mean number of 7.37 drugs were written per prescription. Insufficient instructions were mentioned on all prescriptions for both oral and topical drugs. 4.27% prescriptions were illegible, however, spelling mistakes were not found of the prescribed drugs.

Conclusion: As per WHO, drug use indicators are simple as a supervisory tool to detect problems in performance by individual doctors. We can conclude by stating that there is always a scope of improvement in prescribing patterns and hence, promotion of rational drug use among practitioners.

P 26.

Safety Profile of Paclitaxel

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Objective: To assess Safety profile of Paclitaxel.

Methods: Literature source is one of the tool for collecting safety information of drug by the Market Authorization Holder (MAH). Literature search conducted for the period of 01-01-2012 to 31-08-2014 using term paclitaxel International Non-proprietary Name (INN) in electronic Database (PubMed). Individual Case Safety Reports (ICSRs) of Paclitaxel were screened for valid ICSRs. We prepared line listing as per ICH E2D guideline. Pivot tables were prepared for the assessment of ICSRs e.g. Country wise ICSRs distribution, no. of SADRs in male and female, SOC wise ADRs distribution etc. Suspected ADR terms were coded using MedDRA.

Result: Till now (study is in progress) 272 Individual case safety reports (ICSRs) have been screened. Japan has 47%, USA 11% and India 5% share of valid ICSRs. Female and male share 61% and 39% of valid ICSRs respectively. Till now suspected ADRs for paclitaxel belong to 16 system organ class (SOC) with maximum 14% suspected ADRs belong to nervous system disorders, infections and infestations 11%, Skin and subcutaneous tissue disorders 11% Blood and lymphatic system disorders 11%, 26 SADRs were found, Breast, Lung, Cervical and Gastric Cancer were most common indication for PTX.

Conclusion: Since PTX is anticancer chemotherapy drug which is used for cancer treatment such as breast, cervical, lung cancer, advanced cases of cancer, metastasis cases, benefit outweigh risk of ADRs however physician should take account of the SADRs due to PTX while chemotherapy and cases in which PTX chemotherapy is ineffective.

P 27.

ADR –Monitoring in Unani Medicine

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Adverse Drug Reactions (ADR) are any noxious, unintended and undesired effect of a drug, which occurs at a dose used in humans for prophylaxis, diagnosis, therapy or modification of physiological functions. It may be differentiated from Adverse Drug Events (ADE) as in ADE these are the any untoward medical occurrence that may present during treatment with a drug but which does not necessarily have a causal relationship with its use.

Unani System of Medicine (Greco-Arab medicine) has an age-old concept and principles of drug management. It includes the basic concepts of Drug Monitoring which initially monitors the Drug before prescribing it to the patient and there are various procedures mentioned in the Unani classical literature where Avicenna (980-1037 A.D) has mentioned in Al-Qanoon that says that Drug Monitoring starts from the Day of Collection of the drug till its use in the patient and follow up is also given to the patient. Drug also causes the adverse effects beside its therapeutic usage, this concept was well known to the Unani Scholars this is evident from the fact that Ibne Sina in his book of al-Qanun under the heading, "On General Means of Treatment". He has said that treatment should be done in three ways: "one of them is regimen and nutrition;

the second, application of drugs; and the third, manual treatment, i.e., surgery". Treatment with drugs must take into account the following rules: choice of drugs by their quality, selection of drugs by their quantity and this rule includes change in weight, potency and properties; and the time of administration of drugs. So, if we follow the basics of Unani medicine we can escape from ADR in multi ways and this is the prime differentiation and safety measure of Unani System of Medicine.

P 28.

Amelioration of Cisplatin Induced Neuropathic Pain Using *Nigella Sativa*

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Aim/ Objectives: Clinical utility of anticancer drugs is limited by their adverse effects. So, we studied amelioration of cisplatin induced neuropathic pain using *Nigella sativa* seed ethanolic extract. Tramadol was used as standard drug for comparison.

Material and Methods: Wistar rats were given cisplatin (2 mg/kg) i.p. for 4.5 weeks to induce neuropathic pain. They were divided in 3 groups viz. - control (distilled water), tramadol (20 mg/kg) & *Nigella sativa* (1000 mg/kg) of 6 rats in each group. Pain assessment was done at 0, 30, 60, 90, 120, 240 minutes by hotplate and tail flick apparatus.

Results: *Nigella sativa* 1000 mg/kg group exhibited higher reaction time on hotplate and tail flick test which was statistically significant compared to control group at 90, 120 & 240 minutes. However, tramadol group at 60, 90, 120 & 240 minutes showed a better effect than *Nigella sativa* 1000 mg/kg group.

Conclusion: *Nigella sativa* possess analgesic activity against cisplatin induced neuropathic pain and can be used for treatment of neuropathic pain. However, further clinical studies are required to advocate its clinical use in cancer patients for treatment of chemotherapy induced pain.

P 29.

Association of New onset diabetes with HMG –Co A reductase inhibitors.

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Background: HMG Co A reductase inhibitors (Statins) are one of the most widely prescribed groups of drugs in the world. These cholesterol-lowering drugs received a US Food and Drug Administration warning, in February 2012, regarding increased risk of incident diabetes and impaired glycemic control in patients who already have diabetes.

Methods: Relevant clinical trials, experimental studies as well as meta-analysis were reviewed using PubMed search. Associations of different statins, at different doses as well as gender differences were studied.

Results: Although a number of questions remain unanswered, the available evidence supports that statins do increase the chances of New Onset Diabetes (NOD). In this regard some statins appear to be more strongly related (e.g., simvastatin, rosuvastatin and atorvastatin) than others (e.g., pravastatin). Women and elderly persons appear to be at increased risk.

Conclusion: It is difficult to weigh benefit; in terms of prevention of adverse cardiovascular events, versus risk of NOD although benefits appear to outweigh risks in moderate to high Cardiovascular Disease (CVD) risk population. Their use in low CVD risk population for primary prevention is controversial. Clinicians using statins should be more cautious and vigilant regarding their use and carefully balance benefits with risks.

P 30.

Sociodemographic Determinants of Elevated Blood Lead Levels In Children of Aligarh

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Introduction: Exposure to lead is a public health concern, particularly for young children. Lead poisoning is the number one environmental disease among children in developing countries. Aligarh, being the hub of a variety of industries like lock, knobs, polishing, battery repair etc., is feared to be home to children with risk of exposure to lead.
Objective: To determine the sociodemographic correlates of elevated blood lead levels in children aged 6 months to 12 year attending the Pediatric OPD.
Methods: Informed consent of parents or legal guardian was taken. Questions pertaining to child's eating or sucking habits of non-food items, the type of housing and family's use of ethnic remedies or cosmetics were asked and the responses entered. Thereafter the site for venepuncture was aseptically prepared and blood sample drawn. Blood lead level (BLL) was done at the department of Biochemistry, K.G.M.U., Lucknow by Lead Care II Analyzer. Blood lead level above 10 mg/dl was taken as significantly elevated (WHO).
Results: A total of 60 children were included in the study. There were 37 males and 23 females. Elevated blood level was found in 22 (36%). Age was seen to significantly affect BLL. Only one child was below one year of age, 11 and 10 children were in the age group between 1 to 5 year and more than 5 year respectively. No significant difference in BLL was found in children with or without pica. Recent plumbing or painting in the household or use of kohl by the child or the mother was also not found to significantly affect the BLL.

P 31.

Drug Utilization Study of Anti-Microbial Agents in Hebbal Primary Health Centre in Gulbarga District, Karnataka.

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Context: WHO describes drug utilization as the marketing, distribution, prescription and use of drugs in society with special emphasis on the resulting medical and social consequences. Antibiotics are a commonly prescribed group of drugs and the problem of their overuse is a global phenomenon. Primary Health Care (PHC) is integral part of any country's health care delivery system, its importance is vital when considered for the developing countries. To prevent overprescribing amongst PHC practitioners, detailed data on antibiotic utilization should be obtained.
Aims: To evaluate prescription pattern and criteria for selection of antimicrobial agents (AMAs) in PHC, to analyze rationality among the prescriptions and to monitor Adverse Drug Reactions (ADRs) encountered during the course of the study.
Methods and Materials: This prospective, observational and analytical study was done on 300 consecutive patients of either gender and of any age, to assess the pattern of antimicrobial agent (AMA) use in patients attending Hebbal PHC in Gulbarga district, Karnataka. Approval and clearance from the institutional ethics committee was obtained before starting the study.
Results and Conclusion: From our study we see that amongst the single AMA prescribed, most common was Cefixime (~11%), a 3rd generation cephalosporin. Cefixime was also implicated in a few ADRs and GIT symptoms (7%) and rash (3%) were observed. In the combinational AMA therapy used, the most commonly used AMA combination was Ofloxacin + Ornidazole (~10%).

Rational use of antibiotics is an area where physicians can harmonize their efforts with a multidisciplinary team for assuring best possible drug use. The results indicate that a satisfactory standard has been maintained in several areas in the studied PHC. This study needs to be extended and repeated over time to maintain good quality healthcare in the PHC.

P 32.

Study of *Nigella sativa* Oil as Add on Therapy in Patients of Chronic Kidney Disease

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Objective: To study the effect of *Nigella sativa* oil as add on therapy in patients of chronic kidney disease.
Material and Methods: This is a prospective comparative study conducted in patients of Chronic Kidney Disease attending Renal Clinic of J.N.M.C.H., Aligarh (March 2014-October 2014). 46 Patients were randomly divided into two interventional groups. Group I (Control, 21) was given conservative management while Group II (Test, 25) was given conservative management along with *Nigella sativa* oil (2.5 ml, OD, p.o.) for 12 weeks. Haemoglobin percent, blood urea, serum creatinine, blood glucose, 24-hour total urinary protein, 24-hour total urine volume and glomerular filtration rate were measured at 0, 6 and 12 weeks of treatment.
Results: Patients in both groups showed gradual improvement, as was evident from the parameters mentioned above in both the groups compared to their pre-treated values but it was more marked in *Nigella sativa* supplemented group. There was reduction in: fasting blood glucose (2.05% & 15.21%), post-prandial blood glucose (5.42% & 14.51%), blood urea (8.52% & 31.11%), serum creatinine (0.65% & 29.78%) and total urinary protein (37.17% &43.84%) in Group I & Group II respectively. There was increase in haemoglobin concentration (4.91% & 6.18%), total urine volume (17.83% &19.03%) and glomerular filtration rate (15.35% & 54.16%) in Group I and Group II respectively.
Conclusion: *Nigella sativa* oil (2.5 ml OD, p.o., as add on therapy) with conservative management improves therapeutic output in patients of Chronic Kidney Disease.

P 33.

Survey on management of GERD: Clinical experience with esomeprazole + levosulpiride

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Background: Gastroesophageal reflux disease (GERD) results from continued exposure of the esophageal mucosa to gastric secretions, particularly acid and pepsin. A significant percentage of patients with GERD also have delayed gastric emptying. Though proton pump inhibitors (PPIs) are known to decrease acid secretion, they do not have any effect on the lower esophageal sphincter (LES) tone or gut motility. Hence, in patients not responding to PPI alone addition of a prokinetic agent such as Levosulpiride increases LES pressure and promote gastric motility.
Objectives: This survey was aimed to determine usage profile of fixed dose combination of esomeprazole + levosulpiride and physician's clinical experience with it in the management of GERD.
Methods: This survey was based on the clinical experience of 40 randomly selected physicians on an aggregate patient basis in the management of GERD from different parts of India. Prescription Event Monitoring (PEM) Forms comprising of various questions were filled up by these physicians. Data from 378 patients were analyzed.

Results: Of the patients diagnosed with symptomatic gastroesophageal reflux disease 63 % were males and 37 % were females. Physicians observed that 100% of the patients got relief from symtoms at the end of treatment with fixed dose combination of esomeprazole + levosulpiride. Antacids were the most common co-prescribed drugs (In 7.67% patients). Adverse effects like loose motions and fever with headache were noticed in only 0.79% of patients. As per physician's opinion, this combination was effective in 99.21% of patients.

Conclusion: This survey highlighted that addition of prokinetic agent like levosulpiride with PPI esomeprazole offered better symptomatic relief in patients suffering from GERD. Physicians also opined that this combination is effective in management of GERD with good safety profile.

P 34.

Radiation Therapy: Paradoxical Hypertrichosis

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We all know that alopecia is a widely accepted side-effect rather the adverse effect of radiation therapy even in this era where modern, precise and accurate treatment delivery systems are available to spare the normal tissue. But, here is an unusual clinical circumstance where a patient presented paradoxical hypertrichosis upon treatment with radiation therapy for non-small cell adenocarcinoma of left-lung (stage III). However the phenomenon of 'paradoxical hypertrichosis' is very rare and only very few cases are reported worldwide. But this topic may trigger research in the arena of dermatology. The poster presents a plausible hypothesis for this unusual phenomenon.

P 35.

Survey to understand role of angiotensin receptor blockers (ARBs) in the management of Hypertension

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Background: The manner in which blood pressure (BP) is reduced influences outcome, and antihypertensive therapy should induce smooth and sustained BP control throughout the 24-h dosing interval. The studies also suggest that, in order to improve the cardiovascular risk profile of patients with hypertension, optimal antihypertensive therapy should provide sustained BP reduction and smooth BP control over the full 24-h period. In the patients treated with losartan, measurement of blood pressure at trough (24 hours post dose) relative to peak (5-6 hours post dose) demonstrated relatively smooth BP reduction over 24 hours.

Objectives: This survey was aimed to determine usage profile of different angiotensin receptor blockers (ARBs) in hypertension and physician's clinical experience with these ARBs in the management of hypertension.

Methods: This survey was based on the clinical experience of 43 randomly selected physicians on an aggregate patient basis in the management of hypertension from different parts of India. Prescription research survey (PRS) questionnaire forms comprising of various questions were filled up by these physicians based on their clinical experience.

Results: Fifty two percentage of all hypertensive patients taking medications are on ARBs. Majority (57.5%) of physicians use ARBs as first line of therapy for newly diagnosed hypertensive patients. Losartan is a preferred ARB by most of the physicians (69.77%). Physicians also opined that smooth reduction of blood pressure is most important factor in choosing antihypertensive drug followed by safety of the drug. Sixty nine percent of physicians perceived losartan for smooth reduction of BP.

Conclusion: This survey highlighted that smooth reduction of blood pressure is a most important factor in choosing antihypertensive drug in hypertension. Losartan is preferred drug for smooth reduction of BP.

P 36.

A Fall That Struck His Heart

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A 5yrs old male child presented with h/o fall from height and sustained lacerated wound on the right side of the chest which got infected and subsequently drained by the CVTS team. The child was continued on i.v. antibiotics but continued to run high grade fever with tachypnea followed by generalized swelling of the body. The child was investigated and showed B/L pneumonitis and positive pus culture for Staph aureus. Echocardiography revealed massive pericardial effusion (purulent) with tamponade which was drained with Pigtail catheter and subsequently the child improved. This case showed that how innocuous wound can lead to life threatening complication in the form of cardiac tamponade especially in children with staph aureus infection.

P 37.

Meroanencephaly in a newborn – A rare anomaly

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Introduction: Meroanencephaly is a rare form of anencephaly characterized by malformed cranial bones and a median cranial defect, through which protrudes abnormal tissue, called the area cerebrovasculosa. Area cerebrovasculosa denotes abnormal spongy, vascular tissue admixed with glial tissue ranging from a thin membrane to a large pseudoencephalic mass that is composed of connective tissue, hemorrhagic vascular channels, glial nodules, and disorganized choroid plexuses. Its actual incidence is unknown. Very few cases have been reported in the world literature. Here we present a case of Meronencephaly cared for in our Neonatal Intensive Care Unit.

Case Report: A male baby was born at term by normal vaginal delivery to a primigravida mother who did not have any antenatal visits or folic acid supplementation during pregnancy. The baby weighed 1.785 kilograms and cried poorly following birth. He showed gross malformation of the cranium in the form of meroanencephaly and bilateral proptosis. No history of teratogen exposure could be elicited. Antenatal ultrasound was never done which might have picked up the defect. He was on intravenous fluid for three days after which he was shifted to oral feeds which he tolerated well. The baby was discharged on eighth day on oral feeds. The vital need for folic acid supplementation prior to conception was advised and emphasized upon the family.

A rare case of Meroanencephaly in a male baby

P 38.

Safety evaluation of Indacaterol, an Ultra-long-acting β_2-adrenergic receptor agonist, in comparison to Tiotropium in patients of COPD.

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Introduction: Indacaterol is an inhaled ultra-long-acting β_2 agonist given in once daily dose in patients of COPD for maintenance therapy. These agents increase the compliance of patients with COPD. In the present study we evaluated the safety of Indacaterol in comparison to Tiotropium

Method: This is a randomized, prospective, open labelled and parallel group study. Eligible patients were enrolled and randomized according to the table generated by random allocation software into two groups (20 patients in each group).

Group I patients received Indacaterol in the dose of 150µg once daily and Group II patients received Tiotropium 18µg once daily for 12 weeks. Patients were followed fortnightly up to twelve weeks.

Result: One patient of Indacaterol group and two patient of tiotropium group complained of cough which appeared 15 to 20 seconds after the inhalation for 5 to 8 seconds. Two patients from group1 (Indacaterol) presented with mild headache within two weeks and similar complaints were found in two patients of group2 (Tiotropium) within four weeks of treatment.

No interventions required for above complaints. No any patients of either group presented with tremor, palpitation, and muscle spasm as recognised by previous studies with β_2- agonist drugs.

Conclusion: Once daily dose of 150µg was well tolerated in this study and also provides sustained bronchodilation. Because our study included only small number of patients so more studies are required to evaluate various safety parameters.

P 39.

A Case of Multiple Pyemic Abscess with Septicemia and Pneumonitis In A 10 Months Old Child Due To Community-Acquired Methicillin resistant Staphylococcus Aureus

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A ten month old male child presented to our speciality with c/o fever on and off since 2 month swelling over right thigh region for past one month following which he developed multiple abscesses all over the body (pinna, breast and back) and difficulty in breathing in the form of fast breathing and chest wall retraction and shock.

On investigation counts were very high (49000/micro litter) and chest x-ray suggestive right lung fluffy infiltrates. Abscesses were drained and culture sensitivity showed oxacillin resistant staph aureus strain sensitive to Vancomycin and after starting sensitive antibiotic the child showed dramatic improvement. *Staphylococcus aureus* resistant to methicillin was initially described as a typical micro-organism obtained in nosocomial infections. However, in recent years CA-MRSA infections is a cause of skin and soft tissues, but serious infections such as pneumonia and sepsis may occur. This report describes a case of sepsis in a child, complicated by pneumonia secondary to soft tissue lesions by CA-MRSA.

P 40.

Multiple intracardiac mass creating a hypoplastic left heart situation.

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2- month- old boy weighing 2.5 kg was admitted to our institute with fast breathing, and central cyanosis since 15 days of life. On examination HR 170/m, RR 88/m, CRT<3, Temp 99°F, MAP-32 mmHg with SPO2 43 %, 69 % in room air & with O2 respectively. CVS examination showed S1, S2 Normal with PSM Grade 3 at left parasternal area. Respiratory examination showed tachypnea, intercostal & subcostal retractions, with diminished B/L air entry, and basal crepts. Other systemic examinations were normal.
Echocardiography showed situs solitus, atrioventricular and ventriculoarterial concordance, normally related great arteries, with normal pulmonary & systemic venous drainage. PFO (left to right shunt) seen. Large mass was seen filling LA, affecting LA filling and contractility (1) Minimal flows seen across mitral valve. LV was hypertrophied, with small mass also seen floating in it (2). Multiple muscular VSD jets were seen. Left Arch, with hypoplastic Ascending aorta almost atretic (3) with minimal antegrade flows , smallish transverse arch, & PDA continuing as descending aorta seen and retrograde flows filling the transverse arch.(4)

P 41.

Mortality Risk Assessment of Stemi Patients Using Dynamic Timi Risk Score

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Background: Cardiovascular disease has emerged as a major health burden in developing countries and is a subject of great concern for its significant contribution to mortality. Although there are multiple methods of risk stratification of ST-Elevation Myocardial Infarction (STEMI), the Dynamic risk score provides an initial risk stratification and reassessment at discharge.
Aim: Our main aim was to assess one year mortality rate in STEMI patients admitted into ICU cardiology department MGM Hospital.
Methodology: A prospective observational study was conducted on patients diagnosed with STEMI from March to October, 2013. Dynamic TIMI Risk Score was used to assess the 1 year mortality risk for the patients who were diagnosed with STEMI.
Results: Out of 80 patients 81% were males and the mean age of the study subjects was 53.81±12.09 **(95% CI: 51.12 TO 56.50)** years. 40% of patients had history of Hypertension and 17.5% had Diabetes Mellitus.44% patients belonged to KILLIP II class and 39% patients are diagnosed either with anterior wall Myocardial Infarction or Left Bundle Branch Block. Of the total in hospital events 13(42%) patients suffered with arrhythmias, 10(32.25%) with recurrent myocardial infarction and 7 (22.5%) with major bleed. Dynamic TIMI risk showed that 16(20%) patients had high, 25(31%) had moderate and 39(49%) had low 1 year mortality risk.
Conclusion: Risk stratification of STEMI patients is a continuous process and dynamic TIMI risk score can be used to estimate 1 year mortality at the time of hospital discharge.

P 42.

Spectrum of cyanotic congenital Heart disease presented in a tertiary care hospital.

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Case 1: A day 1 baby presented with severe respiratory distress and cyanosis, and was not maintaining saturation (<60%) with 100% oxygen. ECHO was done which showed **Tricuspid atresia with pulmonary atresia**. Baby was surviving due to open PDA .So was started with PGE1 infusion and O2 % FiO2was reduced.

Case 2: A baby presented with cyanosis at birth. Clinical examination revealed single loud S2, ESM murmur at pulmonary area. ECHO was done which showed **Corrected TGA with restrictive VSD with severe PS.** Patient was refereed to higher centre for Pulmonary ballon valvulotomy.

Case3: A baby was presented with cyanosis at and fast breathing at 1 day of life. X ray chest showed snow storm appearance, ECHO showed Left sided deviated IAS which caused pulmonary veins to drain in RA creating **TAPVC**. Patient was referred for surgery where a patch was made and IAS was Shifted to normal location so that now pulmonary veins drained to normal atria i.e. LA

Case 4: A baby presented to us in shock and cyanosis at day 8 of life. CVS examination was normal. ECHO was done for ruling out any congenital anomaly. And we founded multiple intracardiac mass filling LA and LV. And Aortic arch became atretic. This created a **hypoplastic left heart situation.**

Case 5: A newborn presented with severe cyanosis at birth. Hyperoxia test was positive. ECHO was done and showed small restrictive perimembranous **VSD and severe PS** with gradient of 66 mmHg. Patient was started with PGE1 infusion.

P 43.

A Rare Case Report of Dress Syndrome Caused By Vancomycin

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Introduction: Drug reaction with eosinophilia and systemic symptoms syndrome (DRESS) is a distinct severe adverse drug reaction characterized by potentially life-threatening hypersensitivity reaction with extensive rash, fever, and internal organ involvement including liver and kidney, occurring most commonly two to six weeks after initiation of a medication.

Case Presentation: A 62-year-old female was admitted in a tertiary care hospital with severe fever, progressive maculopapular skin rash, eosinophilia and acute renal insufficiency. History revealed that she had valvular heart disease, for which prosthetic valve replacement was done about 5 years back and she was treated for Prosthetic valve endocarditis in a private clinic about 1 month back, where treatment was done with vancomycin (2 g/day) due to infection by methicillin-resistant Staphylococcus aureus. No drug allergy was reported. Approximately 3 weeks later, she started developing the symptoms. Diagnosis was confirmed using haematological, LFT findings, renal profile and excluding the other causes. According to the RegiSCAR scoring system, our case could be classified as definite DRESS scoring 6 points. There were no lymph nodes enlargements. Methylprednisolone (1g/day) and antihistaminics were administered to achieve the cure.

Conclusion: The diagnosis of DRESS is challenging because the pattern of cutaneous eruption and the types of organs involved are various. There is scarcity of published case reports of DRESS with vancomycin in the literature from Indian perspective. Further studies are required for early diagnosis of a case of DRESS as well as to formulate better treatment protocol to diminish morbidity and mortality from it.

P 44.

Opipramol: Drug review and our clinical experience

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Opipramol is an antidepressant and anxiolytic used in Germany and was recently launched in India. It is an iminostilbene derivative, belonging to dibenzazepine group and was developed by Schindler and Blattner in 1961. Although it is structurally similar to tricyclic antidepressants (TCAs) especially imipramine but it does not classed as TCAs because opipramol does not act as reuptake inhibitors, instead acts as a sigma receptor agonist. Opipramol is typically used in the treatment of generalized anxiety disorder (GAD) and somatoform disorders

Adverse drug reactions: Opipramol is a well-tolerated drug and produces fewer side effects than SSRIs and SNRIs. The frequently (≥1% to <10%) reported adverse reactions with opipramol especially at the beginning of the treatment includes fatigue, dry mouth, blocked nose, hypotension and orthostatic dysregulation. The adverse reactions reported occasionally (≥0.1% to <1%) includes dizziness, stupor, micturition disturbances, accommodation disturbances, tremor, weight gain, thirst, allergic skin reactions (rash, uriticaria), abnormal ejaculation, erectile impotence, constipation, transient increase in liver enzyme activities, tachycardia and palpitations.

Our Clinical experience: we used opipramol for the treatment of general anxiety disorder in 15 patients in a dose of 150mg/day to 300mg/day. Drug was well tolerated by most of the patients and mild gastrointestinal symptoms was complained by 4 patients and only 3 patient reported dizziness. No significant improvement in the symptoms of anxiety was reported by the majority of the patients in a 2week period. As, the drug was recently launched in India so there is limited data on its usage. However, double blind placebo control trial was needed to validate its efficacy.

P 45.

Acute Kidney Injury Associated with the Use of Nephrotoxic Drugs in Children with Complicated Malaria

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Background: Malaria is a significant cause of morbidity and mortality in children and adults, especially in tropical countries. Acute Kidney Injury (AKI) is among the commonest complications of malaria in children. Use of nephrotoxic drugs may aggravate kidney injury in children with complicated malaria.

Objective: To study the association of nephrotoxic drugs to acute kidney injury in children being treated for complicated malaria.

Methods: It was a cross sectional study done in the Pediatric ward of a referral teaching hospital Children aged up to 14 years admitted for complicated malaria were included. Diagnosis and species of malaria were confirmed by peripheral blood smear or quantitative buffy coat (QBC) methods and the stage of parasitemia was determined. Patients were categorized into complicated and uncomplicated malaria as *per* WHO criteria. Concomitant use of nephrotoxic drugs was noted. Presence of AKI among the patients was assessed using the Acute Kidney Injury Network (AKIN) criteria. Other risk factors for AKI such as presence of vomiting, diarrhoea, dehydration, use of diuretics and coexisting infections were also noted. All patients were followed up to discharge to note persistent derangement of renal functions. Patients with abnormal serum creatinine at discharge were further examined at 1-month and 3-month follow-up visits for persistence of derangement.

Results: A total of 153 patients of complicated malaria were studied. Most patients (n=100; 68.2%), had received one (n=67, 67%) or more than one (n=33, 33%) nephrotoxic drugs, before or during the course of

hospital admission. Mean (S.D) duration of nephrotoxic drug administration was 5.1 (3.3) days. The nephrotoxic drugs administered included aminoglycosides (n=97, 97%) antiepileptics (n=23, 23%) and other drugs like vancomycin and piperacilline (n=10, 10%).Of the risk factors associated with AKI that were studied, use of nephrotoxic drugs had an independent and significant association, OR 3.3 (95% CI: 1.5-7.5; P = 0.004). Additionally, there is significant association of nephrotoxic drugs with persistence of renal function derangement (P=0.009) as measured by elevated serum creatinine levels on follow-up.
Conclusion: Use of nephrotoxic drugs in patients with malaria is a significant independent risk factor for AKI and is also associated with persistence of elevated serum creatinine on follow-up, which underlines the need for judicious use of antibiotics.

P 46.

Rifampicin Induced Pleural Effusion: A Case Report

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A 24 year old patient was admitted with high grade fever and body ache for last 3 days. His X- ray chest PA view showed bilateral effusion. His routine investigation like haemogram, blood sugar, blood urea, urine routine and microscopy were in normal range. History of present illness revealed that he was on antitubercular treatment for last one week for Koch's abdomen. X-ray chest PA view was normal at that time. He was put on antibiotics but there was no response. It was thought that patient had drug induced fever and effusion. So all the medicine were stopped, steroids were started, within three days fever subsided and effusion were cleared. After gap of 7 days ATT was again started but patient again developed high grade fever. So ATT was again stopped and fever subsided. After few days only rifampicin in the dose of 450 mg once daily was started, patient again developed fever and effusion. So it was confirmed that rifampicin was the drug which caused fever and pleural effusion. We are reporting this case because there is no case report in literature in which rifampicin cause pleural effusion.

P 47.

A Study on Prevalence, Anthropometric and Biochemical Parameters in Children with Beta-Thalassemia Major

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Background: Biochemical parameters and bone mineral status regarding the bone mineral status and its prevalence has been extensively investigated in adult thalassemia patients but data in children are scarce. The aim is to assess the anthropometric parameters, calcium, phosphorous, hepatic and renal functioning status in children with beta thalassemia major receiving packed red cells transfusion with chelation therapy.
Materials and Materials: In this Case control study from February 2014 to July 2014, in a 1000 bedded tertiary care teaching hospital, a total of 63 patients with a mean age of 6.77±2.49 years and a sex–age matched control group with a mean age of 7.15±2.78 years were included. Anthropometric and Serum biochemical analyses were measured and Statistical analyses by ANOVA and independent samples T-test were carried out ($P<0.05$).

Results: In thalassemia major, mean age was 6.77±2.49 and had significantly higher AST, ALT, P, and ferritin levels while they have significantly low ALP compared to controls. Phosphorous levels were higher than normal ranges (4.34mg/dL) in 54 patients while AST (normal ranges for patients aged 1–9 years 15–55 U/L and for patients aged over 10 years 5–45 U/L) were high in 28 patients and ALT (normal ranges 5–45

U/L) were high in 34 patients. They also had higher AST, ALT, ALP, and Ca, but the difference was not significant (P<0.003).

Conclusion: Our results showed that patients with thalassemia major had low calcium and high potassium and ferritin levels showing a significant hepatic and renal impairment, so an early detection and attention towards their care is essential.

P 48.

A Study of Utilization Patterns of NSAIDS

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Background: Nonsteroidal anti-inflammatory drugs (NSAIDs) are prescribed widely in INDIA[1]. Nonsteroidal anti-inflammatory drugs cause both minor GI side effects such as abdominal pain and vomiting and serious GI events such as ulcers and bleeding[2].

Objective: The objective of this work is to analyze prescribing patterns of NSAIDS and concurrent use of gastro protective agents from a private clinic.

Methodology: This is a prospective observational study. We collected data from Abhinav Ortho care Hospital located in Warangal.

Results: We collected 1036 prescriptions of which 630 were males and 406 were females. Mean age of patient was 42.73±10.38. Patients with Joint Pains were highly prevalent (36.3%). Tablet Aceclofenac 100mg was mostly prescribed accounting for 60%. Most patients (55%) were co-prescribed with pantoprazole 40mg followed by rabeprazole (27.6%). The mean duration of NSAID prescription was 11.78±6.18.

Conclusion: Though the prescribing patterns of NSAIDS are rational, there is a need to study NSAIDS usage patterns at multi-centered level so as to assess exact patterns.

P 49.

A Study to Evaluate the Efficacy of Neem (*Azadirachta indica* A. Juss.) in the Treatment of Dermatophytosis

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There has been a steady rise in the incidence of cutaneous fungal infections and an increasing rate of treatment failure or relapse. Among this list Qooba (dermatophytosis) is one of oldest and commonest skin ailments, which poses a considerable worldwide health problem. This disease has been very well described in the Unani system of medicine under the heading of Qooba and there is a treasure trove of effective drugs for its treatment. One of them is Neem. So this study was designed to evaluate the efficacy of Neem (*Azadirachta indica* A. Juss.) in patients of dermatophytosis. This study was conducted in the Department of Moalajat, AKTC, Aligarh. This was a randomized standard control clinical trial in which Neem was taken as a test drug while Fluconazole was taken as a standard control. All the patients were randomly allocated into 2 equal groups (test and control), comprising of 50 patients in each group. The patients of the test group were advised to take capsule Neem 500 mg (aqueous extract) orally twice daily for 6 weeks and to apply Roghan-e-Neem (Neem oil) on the affected areas for the same duration. Similarly, the patients of the control group were given fluconazole 150 mg once a week for 6 weeks and were also advised to apply its gel (0.5%) twice daily for the same duration. Statistical evaluation showed significant improvement in both the groups, however no statistical difference was found between the two groups.

P 50.

Antibiotic Prophylaxis in Caesarean Section-Single dose versus Multi Dose Regimen

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Introduction: Caesarean section is the most common surgical procedure performed widely nowadays. Infection is one of the most common complications associated with caesarean delivery. Single dose regimen is as effective as multi dose regimen. Duration of stay was smaller in single dose regimen as compared to multi-dose regimen. This study has been conducted in Department of Obstetrics and Gynaecology, JNMCH, AMU, Aligarh.

Methods: Total 200 patients undergoing emergency/elective caesarean section were taken into study and followed in post-partum period for any post-op infections morbidity

Results: There was no significant difference between the groups related to fever, wound infection, endometritis.

Conclusion: There is no added benefit in using multi-dose regimen. Single dose is safe, cost effective, having less adverse effects and decreases the financial and mental burden of patient party due to less hospital stay.

P 51.

Pharmacoenvironmentology and Environmental Risk: Current status

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Objective: To review the current scientific status of the work ever taken in relation to Environmental Pharmacology (Pharmacoenvironmentology).

Method: Literature search was conducted through online database search engines (PubMed, BioMed Central and EMBASE) using keywords 'Pharmacoenvironmentology', 'Environmental Pharmacology' and 'PharmEcovigilance' published until August 2014.

Observation: We observed one article on PubMed and BioMed Central on "Pharmacoenvironmentology" two articles on "PharmEcovigilance" on PubMed and one article on "Environmental Pharmacology" on PubMed. No article was found on EMBASE.

Conclusion: The terms 'Pharmacoenvironmentology', 'Environmental Pharmacology' and 'PharmEcovigilance' are not well accepted. Pharmacoenvironmentology is all about tracking of metabolic excretion of drugs to the environment. Its widespread awareness among healthcare providers, at regulatory level and public should be the starting point to check elimination of drugs into the terrestrial and acquatic environment.

P 52.

Amelioration of Gentamicin induced Nephrotoxicity by root extracts of Bauhinia variegata

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Introduction: Kidney is an important excretory organ in human body. It serves wide range of functions. Gentamicin is a commonly used antibiotic and is a known nephrotoxic agent, but no specific drugs are available for prevention of renal damage. Therefore, there is a great need to explore nephroprotective agents which are safe and efficacious. Gentamicin damage is mainly free radical mediated. *Bauhinia variegata* have potent antioxidant properties. Present study evaluate nephroprotective effect of *Bauhinia variegata* on Gentamicin induced damage.

Aims and objectives: To evaluate nephroprotective activity of *Bauhinia variegata* root extracts by biochemical and histopathological examination.

Materials and methods: Thirty albino wistar rats were taken and divided into six groups (n=5). Control rats received normal saline (i.p) per day for 7 days. Nephrotoxicity was induced in rats by i.p Gentamicin 80 mg/kg/d for 7 days. Four test groups were treated with *Bauhinia variegata* root ethanolic and aqueous extracts in doses of 200 and 400 mg/kg p.o for 7 days along with Genatamicin. On 8th day rats were sacrificed and biochemical parameters were evaluated along with histopathological examination of kidneys.
Results: Results showed there was significant elevation in serum urea creatinine and decrease in serum total proteins, potassium in gentamicin treated group in comparison to normal control group. In plant root treated test groups there was significant decrease in serum urea , creatinine and elevation in serum total proteins and potassium when compared with Gentamicin treated group.
Conclusion: Root extracts of B. variegata has significant protective effect on Gentamicin induced damage.

P 53.

A Case of CSF Positive *Staphylococcus aureus* Meningitis

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Department of Paediatrics, JNMC, AMU

Introduction: Meningitis due to *Staphylococcus aureus* accounts for 1-9% of cases of bacterial meningitis and is associated with mortality rates of 14-77%.
Case Report: A seven month old male child was admitted with complaints of fever since 5 days, history of abnormal movement and unconsciousness since 6 hours. On examination, GCS score was low (GCS-6). Neck rigidity and pathological reflexes were found. Investigation of cerebrospinal fluid (CSF) revealed clusters of gram positive cocci and culture report showed Staphylococcus aureus, but CFS biochemistry and cells were within normal range. Ceftriaxone and Vancomycin were given according to culture and sensitivity. Child was successfully recovered.
Conclusion: Staphylococcal meningitis is uncommon but severe disease and requires correct diagnosis and prompt adequate treatment.

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