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Short Communication

PHARMACOVIGILANCE AT SKIMS SRINAGAR (J&K) — A CASE STUDY

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Abstract

Pharmacovigilance is an emerging discipline that encompases several vital issues concerning safe and rational use of drugs and pharmaceuticals. In view of the huge annual inflow of patients running into lakhs in number, use of large quantities of prescription and non-prescription products and paucity of any drug information services at Sheri-Kashmir Institute of Medical Sciences, a tertiary care centre at Srinagar (J&K), establishment of an in-house pharmacovigilance centre there becomes inevitable. Such an endeavour will further help in knowing more about the drug utilization patterns at SKIMS and adverse drug reaction profiles among Kashmiri population. Various prospects, constraints and perspectives related to this endeavour are discussed.

Key Words : Pharmacovigilance, Adverse Drug Reactions, SKIMS

It was not until the disaster caused by thalidomide in 1961 that the first systematic international efforts were initiated to address drug safety issues. The Erice Declaration of 19971 called for all the players in healthcare including public health administration, health professionals, the pharmaceutical industry, government, drug regulators, the media and the consumers to strive towards the highest ethical, professional and scientific standards in protecting and promoting safe use of medicines and in establishing a new culture of transparency, equity and accountability in communicating drug safety information. Of late, sustained efforts in this area have led to the advent of a new discipline named Pharmacovigilance which means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Recently its concerns have been widened to include herbals, traditional and complementary medicines, blood products, biologicals, medical devices, diagnostic products and vaccines. **2, 3, 4** Pharmacovigilance is needed for the prevention of drug-induced human sufferings and to avoid financial risks associated with unexpected adverse effects. Its major objectives are: **5, 6.**

- Early detection of hitherto unknown adverse reactions and interactions.
- Detection of increases in frequency of known adverse reactions.
- Identification of risk factors and possible mechanisms underlying adverse reactions.
- Estimation of quantitative aspects of benefit/risk analysis and dissemination of information on the need to improve drug prescribing and regulation.

Pharmacovigilance activities are specifically

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aimed to improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions, contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use, and promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

Sher-i-Kashmir Institute of Medical Sciences (SKIMS), Srinagar is a 500-bedded teaching-cum-service referral centre, offering primary, secondary and tertiary care facilities. During the year, 2002, a total of 3,11,182 patients attended different speciality poly- and referral clinics at SKIMS;6,129 patients were admitted by super speciality disciplines for various surgical procedures;529 patients were admitted in surgical intensive care unit for life support and intensive monitoring.7 Calculating between the period 1996 to 2002, at an average, over twenty four thousand patients get admitted, 1.7 lack patients attend referral clinic, over seventy thousand patients attend polyclinic and over thirty thousand patients attend emergency department at SKIMS every year. Considering the fact that SKIMS has been established towards the end of 1982, it is estimated that during its life span of 20 years up to ending 2002, it might have admitted about 5 lac patients, treated over 30 lack patients at its referral clinic, over 14 lac patients at its polyclinic and over 6 lac patients at its emergency department.

However this huge inflow of patients does not run commensurate to the information and data collected/available on the pattern of adverse drug reactions (ADRs) and interactions in Kashmiri population or on drug utilization patterns at SKIMS. This becomes evident from the fact that upon literature search for published ADR reports and drug utilization patterns using various database resources like Medline, Toxline, Chemical, Biological and Pharmaceutical Abstracts between 1966 to 2004, reports not exceeding a two-digit figure in number from entire Kashmir could be retrieved depicting a very grim scenario of ADR monitoring and reporting from the valley. It is astonishing to know that even such a large population of patients catered by SKIMS over the past twenty years could not be utilized for collection of some valuable information on how drugs behave in this part of the globe or on what drug utilization patterns at SKIMS are like, due to the lack of any systematic pharmacovigilance activities.

One may ask as to what is the need to monitor effects of drugs in our valley when such activities are already in progress in other parts of the world and information on drug utility and safety is made available worldwide by premier research institutions like FDA, WHO etc. However in spite of all that, pharmacovigilance is needed in every country and every region because there are differences between countries and even regions within countries in the occurrence of ADRs and other drug related problems. This may be due to differences in drug production, distribution and use, genetics, diet, traditions of the people, pharmaceutical quality and composition of locally produced pharmaceutical products, use of non-orthodox drugs like herbal remedies which may pose special toxicological problems when used alone or in combination with other drugs, prescribing and dispensing practices etc.**8,6** As such it is most likely that drugs having been used successfully elsewhere may prove detrimental and dangerous to the population here. As a result of complete dearth of any sustained efforts in the valley, several drugs that have been either banned abroad or several ADR reports on their use continue to pour in from across the globe, are being used unabated without any monitoring. Some of

these drugs include Phenylbutazone, Phenacetin, Cefloridine, Analgin etc. Drugs belonging to Quinolone group that are not recommended for use below 18 years of age, are routinely being prescribed without any proper monitoring of their adverse drug reactions. Similarly a number of drugs to be used with greater caution in pregnancy (Class C, D or X) are being used either advertantly or inadvertantly. Further the data derived from within the valley may have greater relevance and educational value. Information obtained from other parts of the country or the world may not be relevant to this part where above-mentioned factors differ.

Drug and Pharmacy department of SKIMS dispenses around 1000 prescriptions daily for in- and out-patients and around 200-250 prescriptions for employees per day making an annual sale of drugs/surgicals to the tune of approx. Rs. 1.5 crore7 and thereby taking the total number of prescriptions dispensed per year to over four lacks. Given this rate, it is estimated that over 80 lack prescriptions might have been handled by the Drug and Pharmacy department over the past 20 years but sadly so, not even 80 reports of adverse events at the rate of a mere ten reports per year are available in the literature from entire SKIMS though this figure of dispensed prescriptions represents only a small fraction of total number of prescriptions actually written by the physicians at SKIMS due to the fact that majority of prescriptions get filled from outside in open drug markets. Does it mean that drugs do not show any usual or unusual adverse drug reactions here? Surely the answer is in negative, for, the harm caused by medicines has been shown to be significant. Morbidity and mortality from drug-induced diseases have of late been recognized as an important item on the public health agenda in developed and developing countries. Recent studies have shown that ADRs are responsible for 11.5% of hospital admissions in Norway, 13% in France and 16% in UK**9,10,11**;6.5% of hospital patients suffer serious ADRs**12** and 0.1-0.3% of hospital patients suffer fatal ADRs. The annual national cost of drug related morbidity and mortality has been estimated at $76.6 billion with the majority ($ 47 billion) related to hospital admissions associated with drug therapy or absence of appropriate drug therapy.**13** Another recent study has indicated that out of a total of 356 ADR reports reviewed, 25.2% were attributed to CNS agents, 12.6% to CVS agents, 24.5% to anti-infectives, 12.1% to blood formation and coagulation products and remaining 25.6% to other categories of drugs.**14** Situation becomes even more grievous in view of the fact that even medicines that do not need a prescription (over-the-counter medicines) can cause problems. Vaccines, health foods and herbal products may also cause adverse reactions.**15** The reasons for non-reporting are non-existence of systematic and organized pharmacovigilance and drug information services/activities within SKIMS or any other hospital of the valley. Since there is no dearth of well-qualified pharmacy professionals working under the immediate supervision of an experienced hand at SKIMS, the respective section needs to be encouraged and promoted to actively participate and contribute through their expertise in this field.

The huge inflow of patients makes SKIMS an ideal case for immediate initiation of pharmacovigilance activities in order to ensure safe, rational and effective drug therapy to its patients. Recently Central Drug Standards Control Organization (CDSCO), Government of India has taken up a project in association with and under the financial assistance of WHO, wherein national, zonal and regional pharmacovigilance centres are to be established throughout India. SKIMS could well provide a centre under this scheme. In this direction, Dept. of Clinical Pharmacology

can serve as the epicentre of all drug safety monitoring studies/programs in collaboration with the Dept. of General Medicine and some other institute/department outside SKIMS like Department of Pharmaceutical Sciences, The University of Kashmir. Dept. of Clin. Pharmacology, SKIMS can provide all necessary inputs for launching of a Pharmacovigilance center at SKIMS. Academic centres of clinical pharmacology and pharmaceutical sciences could play an important role through training, teaching, research, policy development, clinical research, ethics committees, and the clinical services they provide. Appointment of an ADR advisory committee comprising amongst others of independent experts in general medicine, epidemiology, pediatrics, pathology and clinical pharmacology is likely to instill confidence amongst pharmacovigilance staff and it can be expected to make a substantial contribution towards public health.

There is a need for a reconsideration of pharmacovigilance practice in the light of the lack of clear definition of boundaries between food, medicines (including traditional medicines, herbal medicines and natural products), medical devices, and cosmetics. Some other issues of relevance to pharmacovigilance include substandard medicines, irrational drug use, overdoses, medication errors, lack of efficacy reports, increasing self-medication practices, increasing use of traditional and herbal medicines with other medicines, illegal sale of medicines, use of medicines for indications that are not approved and for which there is inadequate scientific basis, case reports of acute and chronic poisoning, assessment of drug-related mortality, abuse and misuse of medicines, polypharmacy and adverse interactions of medicines with chemicals, other medicines, and food. There are other aspects of drug safety that have been rather neglected until now, which should be included in monitoring latent and long-term effects of medicines. These include detection of drug interactions, measuring the environmental burden of medicines used in large populations, assessing the contribution of 'inactive' ingredients (excipients) to the safety profile, systems for comparing safety profiles of similar medicines, surveillance of the adverse effects on human health of drug residues in animals, e.g., antibiotics and hormones.**5**

The entire cost of a pharmacovigilance system, compared with the national expenditure on medicines or the cost of ADRs to the nation is very small.**16** Moreover, keeping in view the fact that about 30-80% of ADRs may be preventable,**17** comprehensive ADR monitoring, evaluating and reporting programs need to be undertaken that should focus on the assessment of incidence, prevalence, category, severity, preventability, costs and burdens of ADRs. This would help ensure that patients receive safe medicines and mortality/morbidity due to ADRs is considerably reduced.**18** Pharmacovigilance is a clinical discipline in its own right-one that contributes to an ethos of safety and serves as an indicator of the standards of clinical care practiced within an institute. By way of pharmacovigilance, healthcare practitioners could make good use of their patients' positive and negative experiences of treatment and thereby contribute to the medical sciences and towards an improved understanding of disease and of the medicines.

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A Survey Report Indicating Drug Abuse Among Adolescents of Pantnagar : An Alarming Situation

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Abstract

Adolescence is a developmental transition between childhood and adulthood. The biological changes that signal the end of childhoold produce rapid growth in height and weight, changes in body proportions and form and the attainment of sexual maturity. But adolescene is also a social and emotional process. It has been said that "adolescene" begin in biology and ends in "culture". The question of selfhood crests in adolescene and is related to social and emotional maturity. This phase of "search for identity" is not at all easy and often accompanied by emotional turmoil, which results in experimentation with drugs. Adolescents may be involved with legal or illegal drugs in various ways. They use drug for many reasons including curiosity, because it feels good, to reduce stress, to feel grown up or to fit in. Adolescents abuse a variety of drugs legal and illegal including alcohol, tobacco, and prescribed medications (ex Ritalin and Oxycontin), inhalants, cough, cold, sleep and diet medications, marijuana, stimulants, clubs drugs, depressants, heroin, steroids and many more. The use and abuse of illegal drugs is increasing, especially among young generation.

Hence to explore the alarming situation and fact sheet of drug abuse among adolescent of Pantnagar the survey was conducted. 150 students were selected by stratified random sampling. Among the representative sample 50 students were 8th graders, 50 were from high school and 50 were from intermediate classes. The questionnaire was applied to know the extent and type of drug abuse. It also tries to find out the reason of developing the habit of drug abuse. Findings are really shocking. Adolescents are at risk for developing serious alcohol and drug problems. Various environmental situations are responsible for the problem of drug abuse.

Introduction

It is generally considered that adolescene begins at about age 12 or 13 to end in the late teens or early 20's. It is a developmental transition between childhoo al changes of adolescene have many psychological ramifications. One of the great paradox of adolescene is the conflict between a young person's yearning to find an individual identity to assert a unique self and over whelming desire to be exactly like his or her friend.

This stressful situation leads to adolescent depression. Along with it many other factors are also contributing towards it.

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i. A family history of substance abuse

ii. Low self esteem

iii. Individual's feeling that they don't fit in or are out of the main stream.

Adolescent have a tendency to feel indestrubctible and immune to the problems that others experience. All these factors contribute to "emotional turmoil" which results in experimentation with drugs. A drug is any chemical that produces therapeutic or non-therapeutic effects in the body. Where as drug abuse is simply excessive use of a drug or use of a drug for purpose for which it was not medically intended. Drug abuse can lead to drug dependence or addiction. Drug addiction means compulsive use of a substance despite negative consequences, which can be severe.

Adolescence is a time for trying new things. They can use drugs for many reasons inclueing curiosity, because it feels good, to reduce stress, to feel grownup or to fit in. The exact cause of drug abuse is not known. However the genetic make up of the individual, the pharmacology of particular drug, peer pressure, emotional distress, anxiety depression and environmental stress are all factors, which seem to be involvecd. According to the "Brown University Child and Adolescent Behaviour Letter" vol. 18, No. 4, April 2002, A statistics (1) on teens depression indicate that one in eight adolscents may suffer from depression. Of all these adolescents struggling with emotional and behavioral problems a mere 30% receive any sort of intervention or treatment. The other 70% simply struggle through the pain of mental illness or emotional turmoil. The consequences of untreated depression lead to drug abuse.

Adolescents abuse a variety of drug legal or illegal- Alcohol, Tobacco, Prescribed medication (such as Ritalin and Oxycontin), Inhalants, Over-the counter-cough, cold, sleep and diet medications (such as coricidin), Marijuana, Stimulants (such as crack, amphetamines, dextroamphetamine), Club drugs (such as Ketamine, Rohypnol (Rophies), Depressents, Heroin, Steroids, Opiates and Narcotics (such as poium, codeine, Demerop)

The use of illegal drugs is increasing, especially among young adolescents. Drug use is associated with a variety of negative consequences including inceased risk of serious drugs use later in life, school failure and poor judgment, which may put teens at risk of accidents, violence, unplanned and unsafe sex and suicide.

Warning Signs of Adolescent's Drug Abuse

Physical	Fatigue, repeated health complaints, red and glazed eyes, and a lasting cough.
Emotional	Personality change, sudden mood changes, irritability, irresponsible behaviour, low self-esteem, poor judgement, depression and a general lack of interest.
Family	Starting arguments, breaking rules, or withdrawing from the family.
School	Decreased interest, negative attitude, drop in grades, many absences, truancy and discipline problem.
Social Problem	New friends who are less interested in standard home and school activities, problems with the law, and changes to less conventional styles in dress and music.

In a more scientific way the signs and symptoms vary according to the type of drug.

Objectives

So keeping in mind the seriousness of the problem of drug abuse among adolescents, a survey was conducted with the following objectives:

1. To explore the type of drug excessively used by adolescents.
2. To know the extent to which the drugs are being used.
3. To find out the possible reasons of drugs abuse among adolescents.

The goal of the survey was to collect data on life time, 30-days and daily basis.

Type of Drugs	Symptoms of use	Symptoms of with drawl
Opiates and Narcotics		
	• Needle marks on the skin in some cases (calles "tracks") • scares from skin abscesses • constricted pupils (pinpoint) • relaxed and/or euphoric state ("nodding") • coma, respiratory depression leading to come and death in high doses • rapid heart rate	• anxiety and difficulty in sleeping • sweating • goose bumps (piloerection) • runny nose (rhynorrhea) • stomach cramps or diarrhea • dilated pupils • nausea and vomiting • excessive ssweating • increase in blood pressure, • pulse, and temperature
Central Nervous System Stimulants	• euphoria (exaggerated feeling of well-being • dilated pupils • rapid heart rate • restlessness and hyperactivity	• fatigue and malaise • depression • vivid and unpleasant dreams
Central Nervous System Depressants	• slurred speech • lack of coordination • decreased attention span • impaired judgement	• anxiety • tremors • seizures • increase in bolld pressure, and temperature • delitirum

"Life time" refers to use at least once during a respondent's life time.

"30-day" refers to an individual's drug use at least once during the month preceding their response to the survey.

"Daily" refers to the intake of drug at least once in 24 hours.

Methodology

The campus of Govind Ballabh Pant University of Agriculture and Technology, Pantnagar was selected for the study. Both inter colleges of campus i.e. (Government Inter College and Campus School) were selected for the study. A total of 150 students were selected by stratified random sampling. Samples were divided into 3 categories purposively and they are 8th graders High Schoolers and Intermediate students. 50 respondents from each category were selected. (Diagram-i)

A pre-tested questionnaire was applied to know

the fact. Questionnaire does not contain the column for name of the respondents so as to secure their privacy. After collecting the information, data was analyzed statistically.

Results and Discussion

* **Trends in Prevalence of various drugs for 8th graders, High Schoolers and Intermediate students. (In percentage)**

Key findings of the survey

- All the categories students used tobacco in the form of panmasala excessively.
- Cigarette smoking was also common among all the categoreis.
- Alcohol and other drug abuse was relatively low among all the categories.

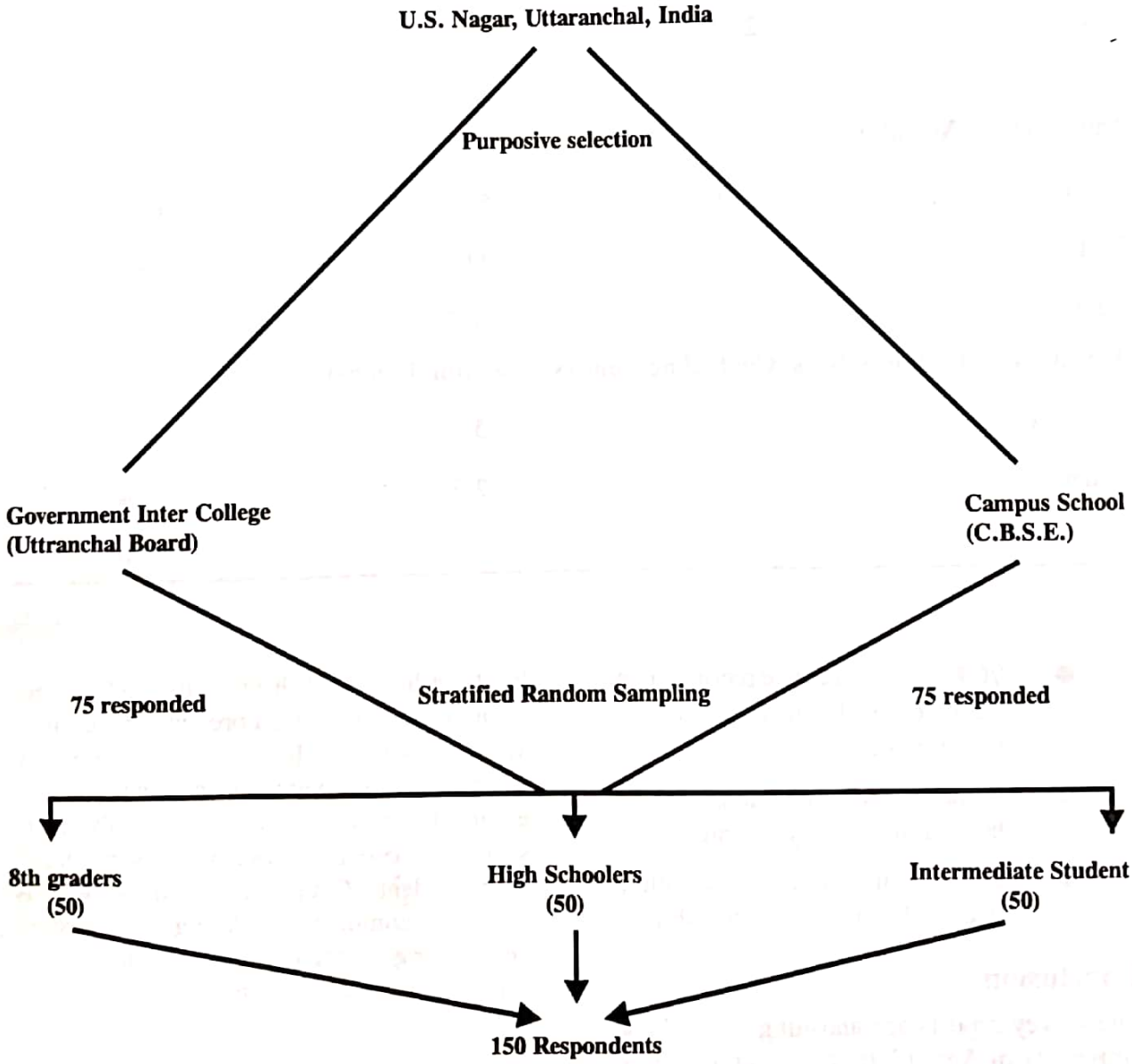

Diagram 1: Showing the sample selection

	8th graders	High Schoolers	Intermediate students
Cigarette smoking			
Life time	40.9	56.8	58.7
30-day	15.3	22.8	56.0
Daily	2.7	4.3	8.0
Alcohol Intake			
Life time	4.0	5.6	9.6
30-day	2.5	3.1	7.3
Daily	-	-	1.2
Tabacco (Pan Masala)			
Life time	47.2	58.2	60.2
30-day	38.7	42.0	58.2
Daily	25.2	38.2	49.2
Any other drug (Painkillers, Central nervous system Stimulations)			
Life time	-	5.9	8.0
30-day	-	2.3	3.4
Daily	-	-	1.0

- 76% respondent have reported that main reason for drug abuse was peer pressure.
- Some of the respondents (27%) have family history of drug abuse.
- 6% respondent reported other reasons for initiating drug abuse.

Conclusion

The survey reports are alarming. G.B. Pant University of Agriculture and Technology is an apex institution but campus results are really shocking. More than 62% adolescents have life-time history of drugs abuse, 34.3% are using drugs daily. Strict preventive measures are recommended for university administration. Along with creating good environment for study, the administration should take care of emotional and mental health of the students. Counseling cell for students is strictly recommended. Along with student counseling a regular session of parent counseling should be there.

ADVERSE DRUG REACTION REPORTING AND MONITORING

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Introduction

Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality and have a direct impact on the costs of health care. Adverse drug reaction (ADR) monitoring and reporting programs encourage adverse drug reaction surveillance, improve ADR documentation and provide a mechanism for monitoring the safety of drug use in patients, as well as stimulating the education of health professionals regarding potential ADRs. Therefore it is essential that pharmacists have knowledge of the adverse effects of drug, including their predictability and reversibility, their frequency and severity, their predisposing factors and recognition, their relationship to dosage and duration of treatment, and their prevention. Pharmacists in organized health care systems should develop comprehensive, ongoing programs for monitoring and reporting adverse drug reactions. It is the pharmacist's responsibility and professional obligation to report any suspected ADRs. ADR monitoring and reporting programs encourage ADR surveillance, facilitate ADR documentation, promote the reporting of ADRs, provide a mechanism for monitoring the safety of drug use in high risk patient populations, and stimulate the education of health professionals regarding potential ADRs.

How common are adverse drug reactions?

- 5-10% of the hospitalized admissions attributed to ADR.
- Up to 30% of the hospitalized patients experience ADR.
- 0.3% of ADRs are fatal in nature.
- ADR related expense has been estimated is US to be up to 30 billion US$ in 1 year and it can go high as up to 130 billion US$.

Definition

An adverse drug reaction has been defined by the World Health Organization as: "any response to a drug which is noxious and intended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function".

Classification

Adverse drug reaction has been classified as Type A or Type B reaction as shown below:

1. Type A (Augmented) reactions: These reactions results of an exaggeration of the normal pharmacology of the drugs, e.g. low blood glucose (hypoglycemia) with sulphonylurea or dizziness due to a fall in blood pressure with antihypertensive agents. Such reactions are usually predictable from the pharmacology of the drug, generally dose dependent, and whilst they are common, they generally do not cause serious illness. Such ADRs generally resolve when the dose of the drug is reduced. Examples include teratogenicity, chloroquine retinopathy.

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Type A reactions may result from the following causes

- ❒ Pharmaceutical, (changes in the formulations resulting in enhanced bioavailability).
- ❒ Pharmacokinetic, (changes in absorption, distribution, metabolism or elimination) commonly due to drug-disease or drug-drug interactions.
- ❒ Pharmacodynamic, (changes in drug receptor sensitivity or homeostatic mechanisms).

2. Type B (Bizarre) reactions: These reactions are qualitatively abnormal and unrelated to the known pharmacology of the drug, e.g. allergic reaction to penicillin, lupus like syndrome with hydralizine and aplastic anemia from chloramphenicol. Type B reactions are generally not dose dependent, and comparatively often cause serious illness and even death. Treatment of such reactions usually involves drug withdrawl. Type B reactions often arise due to hypersensitivity or an idiosyncratic mechanism, and because of this they are difficult to predict.

Causes of Type B reactions include

- ❒ Pharmaceutical, e.g. use of the wrong incipient in a drug formulation.
- ❒ Pharmacokinetic, e.g. formation of toxic metabolites or electrophillic compounds.
- ❒ Pharmacodynamic, e.g. altered target organ sensivity.

Predisposing factors

Factors predisposing to ADRs may relate either to the properties of the drug or to the characteristics of the patient. A number of factors have been reported to associate with an increased risk of adverse drug reactions, including:

1. Multiple drug therapy: There is an exponentially increase in the risk of adverse effects with the number of drugs taken. It has been stated that patients taking more than eight medications can expect to suffer at least one adverse effect. The increase incidence of adverse effects is due in part to increased severity of disease and potential for drug interactions in patients taking multiple medicines.

2. Age: The very old and the very young appear to be at greater risk of adverse effects due to differences in pharmacokinetic handling of many drugs and sensitivity to their pharmacological actions.

3. Gender: For as yet unknown reason, women tend to be more susceptible to certain adverse drug reaction than men. This is true in case of aplastic anaemia induced by chloramphenicol and agranulocytosis with phenylbutazone.

4. Intercurrent diseases: Many illness are associated with changes in pharmacokinetic handling of drug, particularly renal and hepatic diseases. Still other diseases may predispose patients to particular adverse effects, for example rash associated with the use of amoxicillin in patients with glandular fever.

5. Pharmacokinetic differences: There may be increased toxicity from a drug because of genetic factors (e.g.

difference in enzyme activity) or environmental influences (e.g. high alcohol intake).

6. Race and genetic polymorphism: Race and genetic polymorphism may account for alterations in both drug handling and their effects on end organs (e.g. G-6-PD deficiency haemoilytic anaemia with quinine).

Adverse drug reaction risk factors

When assessing the appropriateness of any drug, it is important to consider all the potential risks associated with the use of the drug and to balance these against the predicted benefits for individual patients. The following are the risk factors:

- ❒ Cross reactivity
- ❒ Teratogenicity
- ❒ Carcinogenicity
- ❒ Mutagenicity
- ❒ Pregnancy and other reproductive issues
- ❒ Effects on lactation
- ❒ Drug interactions
- ❒ Dental precautions
- ❒ Interference with diagnostic tests or procedures

What needs to reported?

The Committee and Safety of Medicine (CSM) monitor adverse drug reactions using drugs, which should be more carefully monitored. CSM guidelines are:

- ❒ Any suspected minor or major ADR should be reported for newer drugs or new indications or combinations of older drugs.
- ❒ Any suspected minor or major ADR should be reported for pediatric use of drugs.
- ❒ Report any serious suspected reactions even if well recognized.
- ❒ Do not be discouraged from reporting ADRs because you feel the reaction is too well known or because the patient may be on more than one drug.

Who can report an ADR?

- ❒ Coroners
- ❒ Dentists
- ❒ Doctors (including pre-registration house officers)
- ❒ Nurses
- ❒ Pharmacists
- ❒ Patients

Detection and monitoring of adverse drug reactions

Type A reactions to drugs are generally detected before the drugs are marketed; hence post marketing surveillance is usually more important for detecting and documenting Type B reactions and identifying predisposing factors for both Type A and Type B reactions.

In assessing whether or not an adverse drug reaction has occurred, it is important to establish a cause and effect relationship. Causality may be established using the following criteria:

- ❒ Timing
- ❒ Dose
- ❒ Nature of reaction

- Dechallenge /rechallenge
- Alternative aetiologies

Documentation of ADRs is primarily aimed at preventing the patient from unwanted re-exposure to the same (or) related drug. However, provision of ADR data recording authorities and pharmaceutical companies, and publications of reports in the medical pharmaceutical literature contribute the compilation of the adverse drug reaction profiles of individual drugs.

Pharmacist's Role in ADR Detection and Monitoring

Pharmacists should exert leadership in the development, maintenance, and ongoing evaluation of ADR programs. They should obtain formal endorsement or approval of such programs through appropriate committees (e.g., a pharmacy and therapeutics committee and the executive committee of the medical staff) and the organization's administration. In settings where applicable, input into the design of the program should be obtained from the medical staff, nursing staff, quality improvement staff, medical records department, and risk managers. The pharmacist should facilitate:

1. Monitor patients most susceptible to ADR
   - Those with multiple disease process
   - Patients treated with large number of drugs
   - Geriatric and pediatric patients
   - Compromised ability to handle drugs
   - Patients with abnormal investigation results
   - Previous documentation of allergy or ADR
   - Pregnancy and lactation
   - Prolonged therapy
2. Monitor drugs which are susceptible to ADR
   - Predictable dose related adverse effects
   - High incidence of adverse effects
   - Low therapeutic index or potential for multiple interactions
   - Inappropriate dosing
3. Documentation
   - Patient medical record
   - Use of relevant alert notices / stickers attached to medication administration records
4. Reporting
   - To the regional or the national centers
   - Use of manufacturers in the case of trial or non-marketed drugs, newly marketed drugs
5. Education
   - Medical
   - Nursing
   - Pharmacists
   - Patient

Benefits of ADR monitoring and reporting system

An ongoing ADR-monitoring and reporting program can provide benefits to the organization, pharmacists, other health care professionals, and patients. These benefits include the following:

1. Providing an indirect measure of the quality of pharmaceutical care through identification of preventable ADRs and anticipatory surveillance for high-risk drugs or patients.

2. Complementing organizational risk-management activities and efforts to minimize liability.

3. Assessing the safety of drug therapies, especially recently approved drugs.

4. Measuring ADR incidence.

5. Educating health care professionals and patients about drug effects and increasing their level of awareness regarding ADRs.

6. Providing quality-assurance screening findings for use in drug-use evaluation programs.

7. Measuring the economic impact of ADR prevention as manifested through reduced hospitalization, optimal and economical drug use, and minimized organizational liability.

Conclusion

Adverse drug reactions are an inevitable risk associated with the use of modern medicines. ADR represent an important clinical issue. The associated morbidity and mortality is of great concern both to the health care professionals as well as the patients. Number of ADRs have increased during the course of time may be due to increased awareness from the treating physicians and also from the patients as well. Majority of ADRs and predictable and most of the reactions are preventable. There is a greater need for careful monitoring of patients especially those who are at risk for prevention of potential ADRs. A successful ADR reporting and monitoring system is one mechanism to positively affect quality of patient care. The pharmacist is an important member of the health care team.

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CLINICAL TRIAL OF AN HERBAL FORMULATION AND ASSOCIATED ADVERSE DRUG REACTIONS IN PATIENTS OF BRONCHIAL ASTHMA

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Introduction:

Prevention is better than cure, as elsewhere in medicine, application of the same principal has given new dimension to the study of Pharmacovigilance or ADR monitoring.

Traditional Herbal Medicine constitutes a major part of consumption often in combination with Orthodox Medicine. 65 - 80% of the world population uses traditional medicine as their primary health care. The use of such medicinal plants extracts for the treatment of various disorders has been based largely on historical and anecdotal evidence (1). Experience passed on from generation to generation has demonstrated the safety and efficacy of traditional medicine. It is a common belief that such drugs are mostly safe and do not cause any harm or side effect. De Smet has shown that many adverse reactions to herbal remedies remain unnoticed, since personal experience is not a reliable basis for the exclusion of uncommon reaction to herbal remedies in the population (2). While ingestion of alternative medicine, even in overdose, generally produces minimal toxicity, life threatening events from severe intoxication may also occur. As with other poisoning, an understanding of these agents mechanism of toxicity is key in planning specific management strategies (3). ADR analysis thus becomes a challenge and poses even more difficulties in monitoring.

Many traditional systems of Medicines are practiced worldwide. Indian government. has recognized Ayurveda, Yoga, Unani, Siddha and Homeopathy as Indian system of Medicine. These system are practiced all over India along with conventional / Allopathic system of Medicine. As far as Pharmacovigilance is concerned a very quaint situation has been created. Pharmaceutical industries started launching these drugs without proper scientific research. Even the physicians of Indian system of Medicine started posing their drugs as equally safe. This opened doors to huge global market with no strict regulation in place. Use of some herbal supplement has been reported to cause oral manifestations including apthous ulcer, lip, Tongue irritation, gingival bleeding by Fever few and Ginko biloba, oral and lingual dyskinesia with Piper methysticum (4).

Therefore it is essential that claims about pharmacological action and therapeutic uses of various drugs should be validated scientifically and equally subjected to the rule of Pharmacovigilance of ADR Monitoring. Present study is a step in that direction.

Material and Methods:

The present study was undertaken by department of Pharmacology in collaboration with Department of TB and Chest Diseases, Jawaharlal Nehru Medical College, Aligarh

Muslim University, Aligarh. Department of TB and Chest Diseases standardized methodology to evaluate the patients of Bronchial Asthma including the respiratory test revealing spasmodic involvement (Pulmonary Function Test - PFT).

Total 180 patients were selected from the OPD of T.B. & Chest Diseases and herbal formulation 'Asthma 5' 400mg was administered in tablet form orally. Dosage was 2 tablets twice a day or thrice a day as per condition of the patient. The response of drug was assessed as per protocol including clinical assessment form and ADR monitoring form. Patients were followed up to 90 days.

All patient male and female from 7 to 75 years of age who has undergone PFT showed pulmonary obstruction and 15% increase in FEV1 following bronchodilator, were included in the study. Patients of diabetes mellitus, myocardial infarction, severe hepatic or renal damage or patients on oral steroid therapy were excluded.

Assessment of clinical response and ADR: PFT was performed on first day then after administration of drugs on 7th day, 15th day, 30th, and 90th day. Mainly four parameters were studied PEFR (Peak Expiratory Flow Rate), FVC (Forced Vital Capacity), FEV1 (Forced Expiratory Volume in One Second).

Increasing in value of PEFR as compared to the first day along with symptomatic relief in the condition of patients was considered as improvement. Naranjo ADR probability scale was applied on the reported cases of Adverse Drug Reaction and result were indicated as highly probable (Hpr), probable (Pr), Possible (Po) and or doubtful (Do).

Result:

In total 180 patients were recruited in the study out of them 57% (104) were males and 43%

Table 1.

ADRs	Out of 180	Naranjo Scale
Increased sleep (2)	1%	Do Po
Myalgia (5)	3%	Pr Po Do
Flatulence / distention in abdomen (1)	1%	Do
Headache (3)	2%	Po Do
Increased coughing & expectoration (8)	4%	Pr Po Do
Malaise (5)	3%	Po Do
Fatigue (4)	2%	Po Do
Rhinitis (1)	1%	Do
Increased breathlessness (3)	2%	Po
Palpitation (1)	1%	Po
Tremors (2)	1%	Po Pr
Dysentery (5)	3%	Do Po
Dryness (3)	2%	Po Do
Constipation (2)	1%	Po Do
Itching (2)	1%	Do Pr
Heart Burn (1)	1%	Do
Sweating (1)	1%	Po
Dryness in soles and Palms (1)	1%	Po

were females. In 66% (119) patients history of allergy was positive and in 34% (61) negative. 32% (57) patients were lost to follow up. 14% (26) patients were followed up to 7th day while 16% (29) patients followed up to 15th day, 18% (33) patients followed up to 30th day and 20% (35) patients followed up to 90th day.

Out of total 123 patients who reported in follow ups, 76% (94) showed improvement but 23% (29) either showed no improvement or even decrease in values of PFT, however, 20% (36) patients reported ADR.

Adverse events of mild to moderate degrees were reported. Most of them subsided by their own or by reducing the dose. Very few of them required intervention. More than 2 patients complained the same adverse events and also, the same patients reported 2 or more than 2 adverse events. Drug Reaction which were reported were assessed according to Naranjo ADR probability scale (Table 1).

Discussion:

Herbal medicines are used in Health care around the World and may increase in importance. There is much uncertainty, however, with regard to their composition, efficacy and safety. There is substantial evidence that Herbal medicine can cause serious adverse drug reactions but more data are needed as regard their nature, frequency and preventability (5).

So, Revisiting of traditional system of medicine through research is the dire need of the day.

1. Textual Research / Literary reviews
2. Drug Research / Pharmacological and toxicological profiles, precise Identity and composition.
3. Clinical research / Premarketing surveillance and post marketing surveillance.

In order to minimize the adverse drug reaction associated with herbal medicine following steps (6) should be taken at the level of:

A. Physician:

(i) Awareness of use or misuse of traditional medicine by patients.

(ii) Awareness of traditional medicine information centers.

(iii) Prompt reporting of any suspect adverse event.

(iv) knowledge of the potential of traditional medicines.

B. Pharmaceutical Company:

(i) introduce package inserts with details of ingredients, indications, adverse effects, precautions, contraindications.

C. ADR Monitoring Centre:

(i) Record and monitor ADRs to traditional medicines.

(ii) Harmonize the use of certain accepted and important terms in traditional medicine.

(iii) Computerized herbal substance registration for drug monitoring programme.

(iv) Research and Evaluation of herbal medicines without a long history of use or which have not been previously researched. This should follow WHO's Research guidelines for evaluating the safety and efficacy of herbal medicine. For herbal medicines with a well-documented history of traditional use and for conducting research and evaluating safety and efficacy the *General guidelines for methodologies on research and evaluation of traditional medicine, 2001 WHO* may be used

(v) Methodologies for quality control of herbal preparations and finished herbal products.

(vi) Conduct studies to prove causal relationship between drugs and adverse effect

(vii) Run symposia, workshops.

(viii) Publish information booklets.

D. Regulatory Level:

(i) Frequent checks at the site of manufacturing.

(ii) Federal legislative acts to regulate herbal products such as Dietary SHealth and Education Act (DSHEA) 1994 of USA

(iii) Random sampling of raw material, in-process material and final product.

(iv) Insistence on maintaining documentation of procedures and verification.

E. Patient

(i) Do not take traditional medicines if pregnant or attempting to become pregnant

(ii) Do not take traditional medicines if you are nursing

(iii) Do not give traditional medicines to your baby

(iv) Do not take a large quantity of any one traditional medicine

(v) Do not take any traditional medicine on a daily basis

(vi) Buy only preparations listing the herbs and other ingredients (no guarantee of safety or correctness, but better than nothing).

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PRESCRIBING PRACTICES IN A TERTIARY CARE HOSPITAL IN NORTHERN INDIA

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Abstract

Rational drug use is a function of prescription practices having medical, social and economic implications. A retrospective prescription audit of 200 prescriptions was carried out in a tertiary care hospital. The data collected was used to evaluate the WHO drug use indicators: average number of drugs prescribed; percentage of drugs prescribed by generic name; percentage of drugs prescribed from essential drug list and percentage of antimicrobials prescribed. The average number of drugs prescribed per prescription was 7 and 42% of drugs were prescribed by generic name. Antimicrobials were the most prescribed group of drugs 46% and 66% of drugs were prescribed from the essential drug list. The findings of the study indicate a need for improvement in prescribing.

Key words: Prescribing pattern, drug use indicators, tertiary hospital.

Introduction:

The importance of modern therapeutic agents for diagnostic, curative and preventive purpose and their contribution to health care requires no emphasis. However, it is important to realize that every medicine is potentially hazardous. The inappropriate use of drugs represents a potential hazard to patients and unnecessary expense. Excessive and inappropriate use of drugs in hospitals contributes to the development of drug resistance and increased hospital costs[1]. The outcome of medical care and expense therein are sequent to the prescribing practices. This necessitates a periodic review of patterns of drug use in a health care setup to ensure safe and effective use of drugs.

Drug prescribing pattern study is the study of drug prescriptions written by physicians. This kind of study is helpful in exploring the most commonly used group of drugs and individual drugs, number of injectable used, whether the drug is prescribed by generic or brand name etc[2]. It also provides the information about the number of investigations being sent as this can make a big difference in deciding the cost effectiveness of the therapy. Thus, it can be said that drug prescribing pattern studies help to ascertain the principles of "Rational Drug Use".

Estimates of prescribing prevalence would be more meaningful if frequency of prescribing is combined with the total quantities of drug per prescription. For purposes of comparison with studies conducted elsewhere, the ATC/DDD (Anatomic-Therapeutic-Chemical classification/Defined Daily dose) ethodology is of great value compared to the traditional units of measurement of drugs by weight or cost. The ATC/DDD methodology was developed to measure drug use in early 1970 in Norway. The ATC index assigns code letters and number to all drugs on an ATC basis. The DDD is assumed average dose per day for a drug used on its main indication in adults[3,4].

In view of the plethora of problems associated with drug prescribing, the present study was designed to analyse the prescribing pattern of drugs in a tertiary care hospital.

Materials and Method

This was a retrospective study conducted in 200 patients admitted in the department of surgery, Christian Medical College and Hospital, Ludhiana. The demographic profile of patients i.e. name, age, sex and clinical diagnosis, duration of hospitalization, drugs prescribed (name, dose, frequency and duration) and the results of culture sensitivity tests were recorded in customized data collection forms. The data collected was analyzed using standard WHO drug use indicators i.e. average number of drugs prescribed per prescription, percentage of drugs prescribed by generic name, percentage of drugs prescribed from essential drug list and percentage of antimicrobials prescribed[2].

Culture sensitivity tests performed for antimicrobials use in individual patients were analysed to find out whether the selection of antimicrobials was according to the sensitivity of organisms or not. ATC code was given to different drugs. Drug utilization was expressed as DDD/1000 patients/day for each drug[5].

Result and Discussion

A total of 200 prescriptions containing 1390 drugs were audited. Out of 200 patients, 145 (73%) were male and 110 (55%) patients were in the age group of 21-50 years (Table I). Average number of drugs prescribed per prescription was[7], which is very high as compared to other studies. In earlier studies in India the average number of drugs prescribed per prescription was between[3,5,6-8]. Five drugs were given to 16% patients; six drugs to 31% patients; seven drugs to 27% patients and more than seven drugs to 9% patients. The high number of drugs per prescription shows trend towards polypharmacy. It is preferable to keep the average number of drugs per prescription as low as possible to decrease drug interactions, hospital costs, drug resistance and improve compliance.

The most commonly prescribed drugs were antimicrobials in 46% of patients followed by NSAID, GIT drugs, narcotic analgesics, anticoagulants, anxiolytics and miscellaneous drugs (Fig. 1).

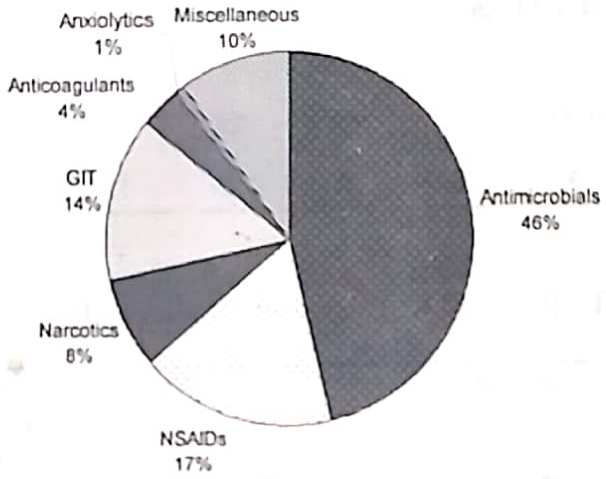

Fig. 1: Percentage of various groups of drugs prescribed.

All patients received two or more than two antibiotics (2 antibiotics-4%; 3 antibiotics-64%; 4 antibiotics-20%; 5 antibiotics-2%). Majority of patients (84%) received 3 to 4 antimicrobials, which is a matter of concern. Antimicrobials were indicated mainly for prophylactic use. The average duration of antimicrobial therapy was 9 days. The prescribing frequency was higher for metronidazole, cephalosporins and aminoglycosides in all age groups (Table I, II). The only combination used was of amoxycillin and clavulanic acid (10%).

Culture and sensitivity tests were carried out in 124 patients (62%) prescribed antimicrobials. Seventy-one specimen (36%) showed growth of pathogenic organism on culture, but only 47 patients (24%) received antimicrobials according to sensitivity report

Table I : Age-wise prescribing frequency for chosen drug categories in males and females

Age (years)	No. of patients	Cephalo-sporin	Amino--glycoside	Metroni-dazole	Quinol ones	-Peni-cillin	NSAIDs	Narcotic	GIT	Anticoag-ulants	Others
MALES											
<20	28	22	26	28	13	4	33	11	26	4	11
20-50	77	75	73	77	26	2	98	57	66	20	48
>50	40	33	29	40	7	2	46	18	53	11	53
FEMALES											
<20	7	4	4	7	4	0	9	9	9	0	0
20-50	33	29	29	33	4	2	37	22	26	9	13
>50	15	11	22	15	2	4	15	11	4	4	13

TABLE II: Culture and sensitivity tests for antimicrobials prescribed

Antimicrobials	No. of patients	Culture/ Sensitivity done	Culture Positive	Receiving antibiotics according to sensitivity	Not receiving according to sensitivity
Cephalosporins	187	124	71	44	27
Aminoglycosides	178	111	62	47	15
Quinolones	55	45	23	14	9
Amoxycillin+Clavulinic Acid (Augmentin)	15	13	6	4	2

(Table II). Expensive and 3-4 antimicrobials were prescribed even when microorganisms were insensitive. Cephalosporins were prescribed to 187 patients (94%), but only 44 (22%) cultures were sensitive to the drug. Newer and expensive antimicrobials were frequently prescribed. The tendency to over prescribe antimicrobials is similar to earlier reports from other developing countries[9,10]. Although one can justify the use of newer antimicrobials on the assumption of development of resistance to the existing antimicrobials, but in majority of cases, newer antimicrobials were used without culture reports. Metronidazole was prescribed to all the patients (100%) mainly as a prophylactic use for anaerobic infections.

The problem of antimicrobial overuse and misuse is a global phenomenon. In India, the prevalence of use of antimicrobial agents vary from 24-67%[11]. Information about patterns of usage of antimicrobials drugs is necessary for a constructive approach to problems that arise from the multiplicity of antimicrobials now available.

Analgesics were prescribed to 25.6% of patients, which is comparable to other studies[11,12]. The prescribing frequency of

NSAIDS and narcotic analgesics was higher in the age group 20-50 years in both males and females (Table I). The most frequently prescribed NSAID was paracetamol (65%). Amongst GIT drugs, ranitidine was most commonly prescribed drug (43%). Anticoagulants were given as prophylactic therapy. Miscellaneous drugs included antidiabetics, antihypertensives, steroids, multivitamins and sodium bicarbonate injections.

In our study, prevalence of prescribing is also expressed as DDD/ 1000 patients/day. Table III shows ATC and DDD/1000/day for various drugs. In this study DDD/1000/day obtained for several drugs is comparable to other studies e.g. cefotaxime, but higher for few drugs e.g. metronidazole[1-5].

All drugs were given initially by parenteral route (100%), which was changed to oral route after 2-3 days, but antimicrobials were given by parenteral route for the entire duration of antimicrobial course. Parenteral drugs are costly and the cost of drugs is a major factor influencing treatment in developing countries. Since, the use of drugs was prophylactic in

Table III : ATC code, DDD/1000/day and prescribing frequency (%) of selected drugs

Drug	ATC Code	Prescribing frequency (%)	DDD/1000/day
ANTIMICROBIALS			
Cefuroxime	J01DA06	7.93	85
Ceftriaxone	J01DA13	11.37	40.56
Cefpirome	J01DA37	1.37	2.5
Ceftazidime	J01DA11	4.82	25.83
Cefotaxime	J01DA10	1.72	4.58
Ceftizoxime	J01DA22	1.37	2.5
Amikacin	J01GB06	18.96	101.67
Streptomycin	J01GA01	2.06	5.42
Tobramycin	J01GB01	6.2	17.78
Augmentin	J01CR02	3	16.67
Ofloxacin	J01MA01	5.17	18.33
Levofloxacin	J01MA12	3.44	17.11
Metronidazole	G01AF01	31	333.33
NSAIDs			
Paracetamol	N02BE01	64.82	57.75
Diclofenac	M01AB05	24.07	24.17
Piroxicam	M01AC01	6.48	17.78
Valdecoxib	M01AH03	6.48	17.78
NARCOTIC ANALGESICS			
Morphine	N02AA01	50	16.11
Tramadol	N02AX02	36.5	11.66
Pentazocine	N02AD01	17.3	0.16
GIT DRUGS			
Ranitidine	A02BA02	43.67	23.33
Pantoperazole	A02BC02	27.58	29.44
Metoclopramide	A03FA01	10.34	4

patients due for surgery, parenteral route was preferred. The drug administration by parenteral route should be decreased and patient switched over earlier to oral administration. The patients were hospitalized for a time period ranging from 7-62 days, average hospitalization period was 17 days.

The percentage of drugs prescribed from essential drug list was 66%. This must be increased to lower the cost of treatment. The percentage of drugs prescribed by generic name was 42% only, that could result in more expensive prescribing as the branded drugs are usually costlier. Moreover, brand names can create confusion during dispensing. Other studies have shown drug prescribed by generic name to be between 19% - 35%[13,14].

Third world countries spend approximately 30-40% of their total health budget on drugs, some of which are useless and expensive and double their expenditure on drugs every four years, while GNP doubles every 16 years[15]. Although irrational prescribing is known throughout the world, it becomes more important to prescribe rationally in developing countries because of small amount of funds available in the overall health budget for drugs. The findings of the present study indicate a considerable scope for improving the prescribing pattern of drugs and minimizing the misuse of antimicrobials. This can be facilitated by various intervention strategies like providing feedback, prescriber education, introduction of hospital formulary and control of institutional regulatory authorities.

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A SERIOUS ADVERSE DRUG INTERACTION OF TWO TRADITIONAL MEDICINES - A CASE REPORT

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Introduction

If history repeats itself, then the use of herbal remedies is no exception. During the late 1800s, pharmacies sold a number of leaves, roots, teas, powders and liquid extracts. It has been estimated that 25% of the patients who seek medical attention for a serious medical problem are utilizing unconventional therapy and 70% of those patients do not disclose their use to their physician (1-2). Countless patients are being simultaneously treated with Western and Traditional medicine. It is common for a patient to seek herbal treatment while taking several prescription medications. Thus safety has become a major issue. As herbal remedies grow in popularity it becomes increasingly important that users and their health care practitioners know of the potential interactions between herbs and pharmaceutical drugs. Many herbs have powerful effects, which may be increased or counteracted by pharmaceutical drugs and vice versa.

Many medicinal herbs and pharmaceutical drugs are therapeutic at one dose and toxic at another. Interactions between herbs and drugs may increase or decrease the pharmacological or toxicological effects of either component. Synergistic therapeutic effects may complicate the dosing of long-term medications e.g., herbs traditionally used to decrease glucose concentrations in diabetes could theoretically precipitate hypoglycaemia if taken in combination with conventional drugs.

A "possible interaction" refers to the possibility that one substance may alter the bioavailability, or the clinical effectiveness of another substance, when two or more substances are given concurrently. The net result may be an increase or decrease in the effect of one or both substances. Most of the possible interactions may be classified in two major categories: pharmacokinetic and pharmacodynamic interactions (3,4). Pharmacodynamic types of herb-to-drug interactions are best identified by analyzing the therapeutic effect of the herbs and drugs. Concurrent use of herbs and drugs with similar therapeutic actions will undoubtedly pose potential risk of herb-to-drug interactions. The increase in treatment effect interferes with optimal treatment outcome: the desired effect becomes more unpredictable and harder to obtain with precision. The highest risk of clinically significant interactions occur between herbs and drugs that have sympathomimic effects, cardiovascular effects, diuretic effects, anti-coagulant effects, and anti-diabetic effects (5).

Experimental data in the field of herb-drug interactions are limited; case reports scarce, and case series rare. This lack of data is also true of drug-drug interactions: published clinical studies are mainly case reports (controlled trials are scarce, since the random assignment of patients to trials that examine

unintended effects is not ethical). The true prevalence of drug interactions is substantial but unknown.

Many reports of herb-induced interactions lack crucial documentation on temporal relations and concomitant drug use. Perhaps the most serious problem encountered in analyzing such reports is the consistent absence of any effort (beyond that of reading the label) to establish a positive identification of the herb involved, and to exclude the effect of contaminants or adulterants.

In clinical practice, polypharmacy is common, and to the mixture physicians prescribe, patients add various over-the-counter medications, vitamins, herbs, and foods. All ingested substances have the potential to interact. Following case report poses another type of problem i.e. adverse drug interaction of two traditional medicines viz. Unani and Homeopathy.

Case Report

Many aboriginal drugs of different systems of medicines are extant in India. Experts of these different systems of Medicine are entitled only to advice their own drugs. Sometimes scheduled H drugs are misused by consumers and start taking these drugs without prescription as over the counter. There are many reasons that could be cited for over the counter use of drugs. Drug Interaction is one predictable reaction that may occur because of two or more drugs. If two drugs of different systems are used then chances of adverse events due to drug interaction are increased. As part of phase IV clinical trial of the drugs used in vitiligo, following adverse drug reaction was noted. Roots of *Ruta graveolens* Linn., which is commonly known as *Suddab* in Unani System of Medicine is widely used for the treatment of vitiligo. A patient 32 years old female was advised to take Suddab. The plant roots were procured from local suppliers, washed for any extraneous material, dried and pulverized. The patient was administered 1.5 gm of the root powder orally (dose related to extent of disease) twice a day with water. The powder mixed with vinegar was also applied locally over the affected parts of body and the patient was asked to take sunbath for 4-5 minutes after application. No other drug was administered concurrently or applied locally. The same patient without informing the investigator started taking another OTC drug of Homeopathy system of medicine. The compound was later found to be Arsenic formulation. Two days after the consumption of Suddab and Arsenic, patient developed serious reactions that led to disability: loss of hairs, hyperpigmented patch over the face, dark colored skin and marginal repigmentation at the periphery of the white spot (see fig. 1). Naranjo ADR Probability Scale Evaluation (6), when assessed the likelihood of the reactions with the above drugs gave an idea about a score of 6. Hence "Use of the Naranjo ADR Probability Scale indicated a 'probable' relationship between the adverse effects and drug-drug interaction in this patient." Similarly, WHO Causality Categories (7)

when evaluated also confirms its 'probable' link.

Discussion

Homeopathic medicine is commonly believed to be relatively harmless. However, treatment with improperly used homeopathic preparations may be dangerous. Chakraborti D et. al. reported three case reports. Case 1 presented with melanosis and keratosis following short-term use of Arsenic Bromide 1-X followed by long-term use of other arsenic-containing homeopathic preparations; Case 2 melanotic arsenical skin lesions were

developed after taking Arsenicum Sulfuratum Flavum-1-X (Arsenic S.F. 1-X) in an effort to treat his white skin patches. While in case 3, Arsenic Bromide 1-X for 6 days was consumed in an effort to treat his diabetes and developed an acute gastrointestinal illness followed by leukopenia, thrombocytopenia, and diffuse dermal melanosis with patchy desquamation. Within approximately 2 weeks, he developed a toxic polyneuropathy resulting in quadriparesis. Arsenic concentrations in all three patients were significantly elevated in integument tissue samples. In all three cases, arsenic concentrations in drinking water were normal but arsenic concentrations in samples of the homeopathic medications were elevated (8).

Phytophotodermatitis is a phototoxic reaction, occurring in skin exposed to sunlight after contact with plants like *Ruta graveolens* Linn because of furanocoumarins. Typical reactions are mild, showing erythema with post-inflammatory hyperpigmentation. Wagner AM et. al. reported a similar reaction in a 6-year-old boy presented with marked, symmetric, painful erythema and edema of both hands that rapidly developed into dramatic bullae covering the entire dorsum of the hands. The history revealed that the hands had been bathed in limejuice for a prolonged period in the preparation of limeade. This report documents an unusual bullous presentation of phytophotodermatitis resulting from contact with furanocoumarins in local limes. This study was conducted to identify and measure the inciting substances from the rind and pulp of the limes. Psoralen, xanthotoxin, bergapten, and isopimpinellin content were measured by gas chromatography and high-pressure liquid chromatography. It was found that the rind contained 6- to 182-fold concentrations of all furanocoumarins measured when compared with pulp. Bergapten was the most abundant substance in the rind. Hydration of the skin during the preparation of limeade combined with increased levels of bergapten in local limes to produce a dramatic bullous reaction (9). Pharmacognostically it is also important to identify the authentic *Ruta graveolens* Linn (Suddab) as another drug in its place is erroneously marketed which further complicate the efficacy and safety issues of the drug (10).

The above studies show that when individual use of Ruta graveolens Linn and Arsenicum may produce skin reaction. Their simultaneous use may further aggravate the condition and this same happened in our case report.

Conclusion

Historically, herbs and drugs were rarely prescribed together. Patients now commonly seek care from several physicians for the same ailment. The result is that a patient may be concurrently using multiple drugs, herbs, and vitamins. The difficulty lies in predicting the unwanted side effects, and/or interactions, of these medications. It is imprudent to assume that no interactions will occur. The solution to this dilemma lies in understanding drug-drug and drug-herb interactions, and to utilize appropriate measures to prevent their occurrence. With some general insights in pharmacology, however, one can foresee possible interactions and exercise precautions to avoid incompatibilities.

In general, the manufacturers of new products are not required to submit proof of safety and efficacy to the Drug Administration before marketing. For this reason, the adverse effects and drug interactions associated with herbal remedies are largely unknown. Herbal remedies may sometimes interact with other medicines making these medicines more or less effective. This makes it particularly

important to tell doctor or pharmacist if one is taking an herbal remedy with other medicines such as prescribed medicines (those provided through your doctor or dentist).

Herbal may not always mean herbal - reportedly 'herbal remedies' containing heavy metals. The adulteration of ethnic medicines with heavy metals is a significant international problem. The inclusion of these metals, or salts containing them, poses a serious risk to public health. Consumers are advised to be alert to possible effects and follow the general safety advice if any are experienced whilst taking an herbal remedy.

Arsenic used therapeutically in homeopathic medicines and Ruta graveolens (Suddab) in Unani Medicine can cause clinical toxicity if the medications are improperly used.

Acknowledgement

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SAFETY PROFILE OF PREMEDICATION WITH ORAL CLONIDINE ON INDUCTION DOSE OF PROPOFOL AND PERIOPERATIVE NONINVASIVE HAEMODYNAMIC STABILITY

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Introduction:

The frequent occurrence of cardiovascular reaction to laryngoscopy and tracheal intubation has attracted the attention of anaesthetists for about four decades. Though these changes usually have no dangerous consequences but can cause serious problems with pre-existing hypertension and coronary artery disease[1].

Various techniques have been adopted to suppress this pressor response. The preventive measures recommended include increasing the depth of anaesthesia and doses of anaesthetic drugs along with the use of many pre-medication adjuvants.

Clonidine (imidazole compound)[2] is basically an antihypertensive agent, which acts by stimulating alpha 2 adrenergic inhibitory neurons in the medullary vasomotor center resulting in decreased sympathetic nervous system activity manifested by decease in systemic blood pressure, heart rate and cardiac output. Its ability to modify function of potassium channels in the central nervous system makes its responsible for profound decrease in anaesthetic drug requirement. Clonidine is rapidly and almost completely absorbed after oral administration and reaches a peak plasma level within 60-90 minutes by this route.

Material and Methods:

The study comprised of 60 ASA I and II patients of either sex aged between 18 to 55 years undergoing different elective surgical procedures under general anaesthesia. Patients with history of cardiovascular and respiratory diseases, smoking, obesity, chronic drug intake and obstetrical patients were not included in the study. A written consent was obtained from all the patients.

The patients were allocated randomly into two groups of 30 each- Group I and II on the basis of premedication received. Before giving premedication; patient's baseline pulse rate, blood pressure (systolic and diastolic) and respiratory rate were recorded.

Group I (control) received tramadol 1.5 mg/kg, midazolam 0.05 mg/kg and metoclopramide 0.15-mg/kg intravenous injection (ivi.)

Group II (study) received oral clonidine 5 mg/kg as premedication 60 minutes before induction along with tramadol 1.5mg/kg, midazolam 0.05 mg/kg and metoclopramide 0.15 mg/kg ivi.

The patients of both groups were preoxygenated with 100% oxygen followed by induction with propofol ivi. (Sleep dose).

The parameters for induction were:

1. Loss of response to verbal command
2. Loss of eyelash reflex

After induction, intubation with cuffed endotracheal tube of appropriate size was facilitated with the help of suxamethonium chloride in the dose of 1.5mg/kg.

Anaesthesia was maintained with N_2O (60%) and O_2 (40%), vecuronium bromide 0.08mg/kg ivi. and controlled manual ventilation using Bain's coaxial anaesthesia breathing system. Injection ephedrine 5mg ivi. bolus was given if systolic blood pressure was below 20% of baseline value and injection atropine 0.3 mg ivi. was given if pulse rate was below 60bpm anytime throughout the study.

At the end of surgery, residual paralysis in both the groups was reversed with neostigmine 0.04mg/kg and atropine 0.02mg/kg.

Following parameters were recorded during perioperative period in both the groups:

1. Pulse rate
2. Blood pressure (systolic and diastolic)
3. Respiratory rate (in the pre and post operative periods)

Statistical analysis:

Statistical analysis was done using unpaired t-test between the groups and paired t-test within the group. All the values were expressed as mean ± S.E. A $p<0.05$ was considered statistically significant.

Observations:

The two groups were comparable with respect to age, weight and sex distribution of patients as well as duration of surgery or anaesthesia (Table I). The surgical procedures chosen amongst the two groups of patients were cholecystectomy and genitourinary surgeries. Total dose of propofol required for induction in the study group was significantly less as compared to the control group (fig. 1).

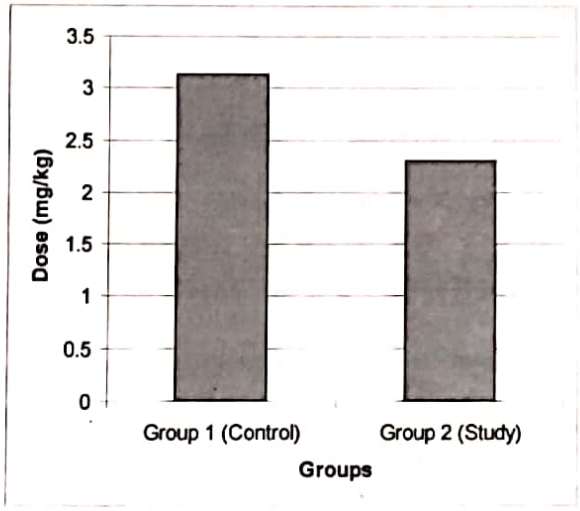


Fig.1: The dose of induction agent (Propofol) required in the two groups (Mean±S.E)

Table 1: Demographic Data

	Group I (Mean±S.E.)	Group II (Mean±S.E.)
Age (years)	30±10	31±12
Weight (kg)	50±10	48± 8
Sex (M/F)	13/17	16/14
Duration of surgery (min.)	118±18	119±20
Duration of anaesthesia (min.)	140±15	143±18

In this study, we also found that increase in pulse rate, SBP and DBP was of short duration in the study (clonidine) group as compared to control group along with less perioperative haemodynamic lability during surgery (figs.2, 3,4). Moreover, clonidine was much capable of reducing pressor responses and the effect of noxious stimuli in the study group when compared to the control group.

Table II: Side Effects

	Group I (Control) (n=30)		Group II (Study) (n=30)	
	No.	% Age	No.	% Age
Hypotension	0	0	3	10
Bradycardia	1	3.3	4	13.3
Rebound hypotension	0	0	0	0
Nausea and Vomiting	2	6.7	1	3.3
Sedation	0	0	1	3.3

FIGURE 2 : CHANGES IN PULSE RATE AT VARIOUS INTERVALS IN TWO GROUPS OF PATIENTS

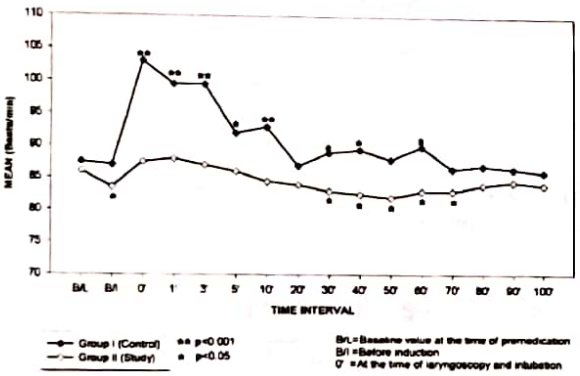
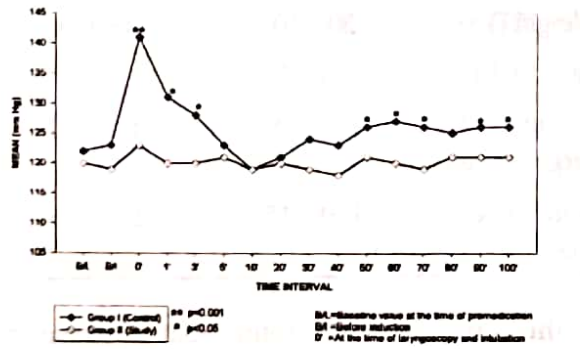
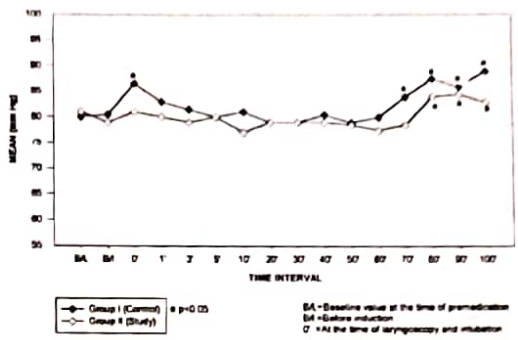


FIGURE 3 : CHANGES IN SYSTOLIC BLOOD PRESSURE AT VARIOUS INTERVAS IN TWO GROUPS OF PATIENTS



Hypotension was present in 10% of patients while bradycardia was found in 13% of patients in the study group. The incidence of nausea and vomiting was less in the study group (3.3%) as compared to control group (6.7%). Excessive sedation was reported in one case in the study group.

FIGURE 4 : CHANGES IN DIASTOLIC BLOOD PRESSURE AT VARIOUS INTERVALS IN TWO GROUPS OF PATIENTS



Discussion:

It has been a widely held view among the anaesthesiologists that during anaesthesia with endotracheal technique, there may be marked circulatory derangements. Prevention of tachycardia in response to laryngoscopy and intubation and the slowing of pulse rate induced by clonidine share a complex underlying mechanism. It consists of at least two different components. Centrally, the activation of alpha2 adrenoceptors causes both a reduction in peripheral symapathetic tone and an increase in vagally induced reflex bradycardia. Peripherally, stimulation of presynaptic alpha adrenoceptor leads to diminished release of norepinephrine from the nerve endings towards the vasculature and a reduction in peripheral sympathetic tone towards the heart[3]. Clonidine may, therefore, represent an effective and specific agent to blunt this cardiovascular response, which may result in myocardial ischemia and dysfunction in susceptible individuals.

On analysing the data from Figure1, we find that clonidine premedication significantly ($p < 0.05$) decreases the propofol dose requirement for induction of anaesthesia. Our data was comparable with the data of Richards et al.[4] and Imai et al.[5]. This may be due to the effect of clonidine on the substantia gelatinosa of the dorsal horn of the spinal cord, reducing the efficacy of synaptic transmission of nociceptive stimuli at that level. Clonidine also

reduces the tonic activity of the locus coeruleus, which modulates the stimuli arising in the CNS. When this system is depressed, sleepiness with EEG synchronization and a reduction in the efficacy of the input signal results, which reduce the anaesthetic requirements.

The data regarding the pulse rate changes at various time intervals showed that there was marked increase in pulse rate in the control group when laryngoscopy and intubation was done. In control group, the rise in pulse rate persisted up to 10 minutes while in the study group this rise was present at 0 minutes interval only.

Changes during the intraoperative period showed that lability in pulse rate from baseline values varies from highly significant ($p < 0.001$) to insignificant ($p < 0.05$) values during 10 to 100 minutes time interval in control group while it remained insignificant to just significant ($p < 0.05$) during the same interval in the study group. Batra et al.[6] in their study showed that the rise in pulse rate following intubation was highly significant in the control group, but it was just significant in clonidine treated patients.

On analysing the available data regarding blood pressure changes, we can see that there was marked perioperative lability in systolic blood pressure (SBP) and diastolic blood pressure (DBP) in the control group while clonidine markedly attenuates the variability in SBP having little response to lability of DBP in the study group during the perioperative period. The results of the study were comparable with the results of Flacke et al.[7], Pouttu et al.[8] and Nishina et al.[9].

By studying these observations, we come to the result that clonidine is a good premedication drug for providing better perioperative haemodynamic stability and decreasing the dose of anaesthetic agents.

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ADVERSE DRUG REACTIONS IN INDIAN SYSTEM OF MEDICINE-PERSONAL EXPERIENCE

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General notion in Indian society is that-Ayurvedic medicines are very safe and do not produce adverse drug reactions. In literature and in my personal experience of clinical practice in Indian System (Ayurved) only, we found that in this system also there are ADR's of grade I & II in certain formulations eg.

1. Guggulu preparations produced dryness of mouth, weight loss and loosness of muscles and tendons.
2. Karpoor Ras contains opium is contraindicated in bronchitis and should not be given in children and old age.
3. Chitrakadi Bati is contraindicated in pregnancy and bleeding piles as it may cause bleeding.

Amaroli, also called urine therapy is the use of one's own urine as food, medicine, restorative, transforming agent and immune system booster. It is also known as Shivambhu or Auto Urine Therapy. According to Hindu philosophy and religious practice 'urine therapy' involves any method of ingestion or injection of a person's own urine for the purpose of health improvement or as a way to promote or maintain health. Amaroli comes from the root word 'Amaroli' which means immortal, undying and imperishable. Aamaroli is therefore a technique designed to bring about immortality. Urine therapy has been in practice since the time immemorial ad its use is mentioned in many scriptures and ancient texts including Bible. Urine has been mentioned as 'Amrita' in Vedas.

Urine is not a dirty or toxic substance rejected by body. Medicinally it referred as 'plasma ultra-filtrate' which contains excess water, salts, vitamins, mineral, cozymes, antibodies and urine. Urine therapy has been used extensively in many ill health conditions like jauncdice, mental illness, beginning stage of dropsy, skin diseases, immuno-therapy for cancer patients.

Despite of numerous benefits and advantages urine therapy deserves some special attention. Monitoring is required and Amaroli should not be used if patient is under some sort of medical treatment or in patients with liver, kidney or heart disease, problem in protein metabolism and salt imbalance or pus filled urine. Consumption of white sugar, refined flour, tinned food, spicy food, milk, intake of alcohol and tobacco should be avoided during this therapy.

So, it is concluded that Amaroli is a key to good health and will prove to be a boon to improve health care if practiced with propter monitoring.

COMMON MEDICAL ERRORS

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1. Medical Erros cause 44,000 to 88,000 deaths annually in U.S.A.
2. 8th commonest cause of death, more common than death due to Accidents or AIDS.
3. This causes financial loss of 17-29 billion dollars annually.
4. In critical patient, an average of 178 activities performed per day and 1-7 errors per patient performed daily (Donchin et. al.)

   A Report of Institute of Medicine 1999, U.S.A.

Types of Erros

A. Error of Omission - Failure of a planned action to be completed as intended.

B. Error of commission - Use of a wrong plan to achieve an aim.

Place of Errors

1. Error in Practice
2. Error in Production
3. Error in Procedure
4. Error in System

Adverse Effect

This is not an error. This is known effect which can manifest all of sudden in unknown way.

Types of Errors

i. Medication Errors

ii. Health Care System Errors

iii. Diagnostic Errors

iv. Procedural Errors

v. Equipment Errors

vi. Surgical Errors

vii. Reporting Errors

viii. History taking Errors

ix. Drug intake Errors

x. Teelephonic Consultation Errors

i. Medication Errors

1. Errors in Prescription

a. Error in prescription.

b. No error in prescription, but incomplete

c. Prescription is wrong

d. Prescription is right but dosage wrong.

2. Errors in Dispensing

3. Errors in Drug Administration

a. Interchange of name of Patient/ medication.

b. Route of medicine changed

c. Mode of administration changed

d. Mixing of non-compatible drugs.
e. Loading of drugs wrongly.
f. Wrong mode of administration.
g. Speed of administration wrong.

ii. Health Care System Errors

a. Lack of informational technology.
b. Wrong selection of staff.
c. Lack of dialogue in between staff.
d. Lack of knowledge.

iii. Diagnostic Errors

a. Poor resolution.
b. Poor standardization
c. Poor calibration

iv. Procedural Errors

a. Ward procedure
b. Diagnostic Procedure

v. Equipment Errors

a. Faulty monitors
b. Faulty infusion pumps

vi. Surgical Errors

a. Wrong side surgery
b. Foreign body inside
c. Removing viscera without consent

vii. Reporting Errors

a. Errors in name
b. Errors in decimal or zero
c. Errors in units
d. Errors in reporting X-Ray's.

viii. History Taking Errors

a. Not taking H/o allergy to drug
b. Not taking H/o concurrent illness
c. Not taking H/o previous drug dosages
d. Not taking H/o drugs already taken
e. Not taking personal history

ix. Drug intake errors

a. Drug before meal or after meal.
b. Drug to be diluted
c. Drug to be mixed with milk

x. Telephonic Consultation Erros

a. Erros in description of disease/ symptoms
b. Errors in noting down drugs.
c. Errors in not identifying patient.

Types of Errors

I. Medication Erros

1. Errors in Prescription

a. Prescription is Illegible-Flying words or Chineese style

i. Similar speliling drugs

Lanoxin	Lasix
Daonil	Depsonil
Aldactone	Amiodarane
Combutal	Carbatol
Depsin	Dapasone
Dilatin	Dilcontin
Macox	Moclox

ii. Dosage form written illegible

OD looks like BD

QID looks like OD

TDS looks lik HS

iii. Strength written illegible

Tab Diazepam 5.0mg written 50 mg.

Tab Lanoxin 0.25 mg written 25 mg.

Tabl Acitrome 1.0 mg written 10 mg

b. Prescription is Incompleted

i. Not mentioning strength

Tab Alprazolam 0.25 mg, 0.50 mg or 1.00 mg

Tab Haloperidal 0.25 mg, 0.50 mg, 1.0 mg

25 mg 5 mg 10 mg

ii. Not mentioning dosage

Forget to write dosage to be taken

iii. Not mentioning instruction

About drug intake- either empty stomach, with meal or after meals

iv. Not mentioning time

Tab Lasix to be taken in morning

Tab Dulcolax to be taken at bed time

Tab Diazepam to be taken at bed time

v. Not mentioning method of application

1. Liniments, antiscabial lotion to apply locally but patient taking orally.
2. Vaginal suppository, laxative suppository, Eye caps taking orally.
3. Rectal ointments being applied around rectum only.
4. Nitrodermal patches applying only on hear area.
5. Insulin injection being injected on forearm at one site only repeatedly.
6. Not instructing to close eye after eye drops installation.
7. Not mentioning the distance of infra red lamp during radiation therapy.
8. Not mentioning weight of traction to be applied during lumbar traction.
9. Not mentioning to move fingers after plaster.
10. Not mentioning about to change of posture in bed ridden patient.
11. Not mentioning to do calf exercise in long term bed ridden patient.

vi. Not mentioning how to use it

1. Mouth washes to be diluted.
2. Potassium solution, alkalizer to diluted with water to avoid bitter taste.
3. Keratolytic liniment to be applied on lesion, not on normal skin area.
4. Cleaning mouth with water immediately after mouth wash.

vi. **Not writing name completely**

Betadine solution/lotion/mouth wash.

vii. **Not equalising dosage when converting injectable to oral forms**

Tab Lasix contain 40 mg Frusemide

Inj. Lasix contains 20 mg Frusemide

viii. **Not mentioning day of start & end of pill - specially in hormone therapy.**

ix. **Intravaginal contraceptive to put intravaginally before contact.**

Patient taking orally before contact.

c. **Presciption is wrong**

i. Sugar based cough syrups, antacids to diabetic patients

ii. Magnesium based antacides to renal failure patients

iii. Laxative at bed time for good motion in morning, followed by loperamide in day to stop motion in day time.

iv. Use of contraindicated drugs

Beta blocker in bronchial asthma

Alfa blocker in Blaucoma

Frunsemide in hypopotasemia

v. Using drugs having interactions

vi. Prescribing insulin without mentioning strength 40 IU, 100 IU vials.

vii. Wrong use of syringe in Insulin administration

d. **Prescribed Dosages are Wrong**

i. Adult dosage to pediatric or Geriatric patients

ii. Not considering dosages as per weight

iii. Failure of dose adjustment in renal failure patient

2. Errors in Dispensing

a. Similar package of drugs- similar types of bottles of syrups, tab or cap.

b. Not mentioning clearly for local application

c. Certain ampoules to be taken orally

d. Difference in pharamacological formulation in tab and injectable form.

Tab Anafaten

Inj Anafaten

e. Change of formulation but name remaining some.

Tab Anxiocalim-previously Herbal preparation but now Alprazolam

Cap Doxy-previously Doxycycline but now Azithromycin

3. Errors in Drug Administration

a. **Interchange of medicine due to similar name of patient.**

i. Name is same - Mr. Ram Pyare taking medicine of Mrs. Ram Pyari, finding sanitary pad in his packet usually in outdoor.

ii. Similar name of indoor patient 'Nipple shielding Creams' given to Mr. Krishna instead of Mrs. Krishna.

b. Route of medicine changed

i. I/M injection given I/V-Inj chloroquine given I/v isseverely cardiotoxic and fatal

ii. Oily injection like analgesic to be given I/m only eg. Inj. Paracetamol

c. Mode of administration changed

i. I/v drug to be given after dilution given as bolus eg. Inj. Adrenalin

ii. Paraldehyde injection to be given with glan syringe only.

iii. Drugs to be given in infusion given as I/V push - Dopamine Injection

iv. Insulin infusion with fluid in plastic bottle.

d. Mixing of Non-compatible drugs

i. Ifepsolin is given with normal saline only and not with 5% dextrose, it precipitates.

ii. Inj magsulf given in 5 dextrose bottle.

e. Loading of dosages wrong

Insulin loaded in syringe, having air bubble in it.

f. Wrong mode of administration

i. Subcutaneous injection given deep to muscle.

ii. Intramuscular injection given at wrong site causing nerve paralysis

iii. Iron preparation not given deep intramuscular

g. Speed of administration

i. Sedative drug given intravenous bolus fastly, can cause respiratory depression.

ii. Fluid given fast in Severe Anamia, Congesting Heart Failure.

iii. Fluid given slowly in severe dehydration.

ii. Health Care Sstem Errors

a. Lack of informational technolyg -Registration, record maintaining filings in wards and lab - not appropriate, wrong orders to patient.

b. Wrong selection of staff - Expert of one field working in another.

c. Lack of dialogue in between staff - instruction not passed over properly to next duty staff due to lack of staff

d. Lack of knowledge in his/ her field

iii. Diagnostic Errors

a. Poor resolution in imaging technique like ultrasound, CAT Scan may miss the diagnosis.

b. Poor caliberation in biochem labl equipment can give false results.

c. Poor EKG machine standardization may give false EKG interpretation.

d. Errors in procedure

1. Word procedures

i. Mismatched size of Foley's catheter may cause urethral rupture.

ii. Wrongly placed Ryles Tube in trachea can cause respiratory failure.

iii. Absorption of irrigating fluids post prostate surgery can cause fluid over load.

2. **Diagnostic procedure- Endoscopic procedure may fail due to wrong track adapted by endoscope causing injjury.**

vi. **Procedural Errors**

a. Ward procedure- Wrong size foley's catheter can rupture the urethral passage.

b. Diagnostic procedure - Lumber puncture can cause complication

v. **Equipment Errors**

a. Different monitory devices giving false reading like false HR on monitor, erroneous BP recording by instrument.

b. Faulty infusion pumps not supplying instructed dosages properly.

vi. **Surgical Errors**

a. Wrong site operated

b. Foreign body left inside

c. Removing any organ during surgery without patient's consent.

vii. **Reporting Errors**

a. Errors in name - Due to same name report of one patient handed over to other patient.

b. Errors in decimal or zero - Not placing decimal makes the report abnormal. Serum Bilirubin 0.2 mg is normal while 2 is abnormal

c. Errors in units - Alkaline phosphatase has diferent normal values in King Armstrong unit or unit/liter

d. Errors in reporting X-Ray's - X-Ray Chest describe only findings of lungs. No comment on spine in X-Ray Chest. That can be erroneous.

viii. **History Taking Erros**

a. Not taking H/o allergy to drug - Patient may be allergic to any drug.

b. Not taking H/o concurrent illness - Patient might be having diabetes, hypertension or coronary artery disease.

c. Not taking H/o previous drug dosage - It is prudent to know the dosage of drug taking already specially in Diabetes mellitus, Hypertension and Renal Failuer cases.

d. Not taking H/o drug already taken - New drug being prescribed should not have interaction with previously taking drug.

c. Not taking personal History - History of Smoking, Tobacco, Alcohol, etc.

ix. Drug Intake Errors

a. Drug before meal or after meal - Refampicin should be taken before meal. Drugs causing gastric irritation should be taken after meal.

b. Drug to be diluted - Alkalizers, Potassium Solutions should be diluted due to bitter taste.

c. Drug to be mixed with milk - Calcirol packed should be taken with milk.

xi. Telephonic Consultation Errors

a. Errors in description of disease/symptoms - Description on Telephone can give a false impression about disease.

b. Errors in noting down drugs - Drugs written wrongly on Telephonic consultation.

c. Errors in not identifying patient - patient discussed on phonse may be wrongly recognized due to confusion or similarly of name.

IS THERE A NEED OF PHARMACOVIGILANCE IN PHARMACY CURRICULUM?

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The present curriculum of Bachelor of Pharmacy framed by the statuary body, AICTE, is oriented towards pharmaceutical products. This can conveniently be evidenced by the employment attained by the pharmacy graduates in the areas of production, formulation, quality control and marketing. The enormous growth attained by pharmaceutical industries in India during last century for export of indigenous products and also medicinal formulation for local consumption, testify self reliance and self sufficiency. The technical human resource produced by institutions imparting pharmaceutical education cater the needs for manpower in all sectors of pharmaceutical industry.

Curriculum Vs Scenario

The scenario of 'generalized therapy' has undergone metamorphosis to 'individualized therapy' by the development of 'gene therapy', 'biomolecules', 'biotechnology' as they are new tools of drug development. By these novel approaches the indepth cause of various diseases is under identification and these approaches have deviated the 'product oriented' pharmacy practice approach. The present curriculum of B.Pharm is insufficient to impart the conceptual knowledge of 'patient oriented' pharmacy practice approach. The first recognition of this neglegance was in 1991 when the education regulations were amended to include the subjects of hospital and clinical pharmacy, community pharmacy and health education, drug store and business management in Diploma of Pharmacy curriculum.

As evident from the syllabus of various subjects like:

- Clinical pharmacology
- Community pharmacy and Health Education
- Dispensing Pharmacy
- Hospital Pharmacy
- Pathophysiology and Pharmacotherapy

Students are exposed the pharmacodynamics and other aspects of drug through the existing curriculum, but the 'pharmacovigilence' aspects are neglected in terms of its meaning. The rational approach need to be instilled in the curriculum. Clinical pharmacology syllabus as prescribed by AICTE imparts knowledge about ADRs and their monitoring, drug-drug interactions, about concepts of pharmaco-therapy, management of various disorders, concepts of essential drugs and rational drug use. Hospital and community pharmacy curriculum deals with various aspects of essential drugs and rational drug use. Hospital and community pharmacy curriculum deals with various aspects of patient handling in various sections of hospitals; dispensing of medicaments in hospital and to some concepts of clinical pharmacy practice. These subjects are directly concerned with the handling the patients who are the ultimate "drug users" and they are the subjects who are benefited or adversely affected with drug. Thus the pharmacovigilance is already included in pharmacy curriculum but it lacks the specificity. The subject needs to gain a

specific foothold in the curriculum so as to promote effective, safe and rational drug therapy. Pharmacovigilance can thus form a major part of the subject "clinical pharmacy practice" in D. Pharm or can be treated as a separate subject in the degree course.

Suggestions

In order to impart complete knowledge of drug's benefits as well as adverse effects, the curriculum needs to be changed or revised so as to resolve some of the shortcomings such as the application of Biopharmaceutics, Pharmaco-kinetics and Pharmacodynamics be included in the syllabus. Adverse effects resulting from combined medicaments must gain attention apart from ADRs of single drug entity. Practical aspects of Pharmacovigilance must be included in the syllabus, for which students should be allowed to deal with various case studies related to various aspects of the subject. Students must get practical training in hospitals under supervision of qualified faculty where they are trained in various aspects of pharmacovigilance. The Libraries of the institution must have their own Drug Information Centre, and must have various services of drug informatics made available to students. The institute imparting education of pharmacovigilance has to be collaborated with a hospital (300 beded) which should be encouraged to have its own pharmaco-vigilance cell, a unit of drug information centre, where reports of ADRs and other such events are placed. Students undergoing course study are given opportunity for being acquainted with mechanism of filing ADR's reports. Students must be encouraged to deal with patients in a manner as following;

Students must be taught to:

1. Take a through drug history
2. Be knowledgeable about the action of drugs being used
3. Identify the patient risk factors
4. Educate patient
5. Play a role in monitoring therapy
6. Know about/impart individualize therapy

The institutions who will impart training in Pharmacovigilance must collaborate with health care providers who contribute to post marketing surveillance, so as to keep the informations updated.

The next important aspect is, who should be the recipient of pharmacovigilance education? The students of D.Pharm. have superficial training in their final year classes, but in reality that doesn't impart them complete vigilance of drug . For diploma holders, a separate certificate course in clinical pharmacy practice which covers all the aspects of pharmacovigilance is recommended. Inclusion of Pharmacovigilance at Degree level is again difficult, because the tenure of four years does'nt provide sufficient space for addition of any new subject. A new subject can be introduced in place of some subject which is liable to be deleted from the curriculum. Due to expansion of various tributaries of pharmacy branches like bio-technology, bioinformatics, herbal technology etc. further addition of any new subject will overburden the students. Therefore in the final year Pharmacovigilance alongwith Pharmacy practice can be treated as a optional subject for a students who opt to make career in clinical pharmacy practice/ community pharmacy. For them the 90 days Industrial training can be replaced by professional training in clinical pharmacy practice at a Medical Hospital (>300 bedded hospital). Looking into consequences of drug misuses, poor health outcomes from drug treatment, recognition of ADRs after launching a drug into market i.e. it is mandatory for students of pharmacy to ensure safe usage of

drug, its benefits balanced by potential risks, which is possible if the curriculum includes various aspects of pharmacy practice along with pharmacovigilance.

Conclusion

Looking into aforementioned scenario, the authors resolve the following:

- There should be optional stream, made available at final year with the subject critically required to acquire pharmacy practice knowledge (incorporating pharmacovigilance aspects). The successfully candidates be given a B.Pharm (Honours) degree in Pharmacy Practice.
- The Pharmacy U.G. degree be segregated into two streams with two different approaches i.e. "Industrial oriented" pharmacy knowledge and "Clinically oriented" Pharmacy approach
- Diploma course may be supplemented to incorporate clinical pharmacy practice approaches relevant to pharma-cogivilance.

Note: Further Suggestions are Welcome.

DRUG - DRUG INTERACTION: A CHALLENGE FOR COMMUNITY PHARMACISTS

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INTRODUCTION :

Drug interaction and adverse drug effect have received much attentions since studies published in various scientific Articles and journals have shown that they results in upward of 100,000 citizens each year being hospitalized or remaining hospitalized longer then necessary, as well as leading to the death of number of patients. Use of multiple drugs is common in a number of therapeutic regimens. In addition to multiple drug therapy a patient may have access to several prescriber and may have predisposing illness or age as risk factors for the interactions.

The potential of drug - drug interaction to precipitate adverse effect is well documented and the majority should be recognized by the vigilant pharmacist. A drug - drug interaction may take the form of a pharmaceutical, pharmacokinetic, or pharmacodynamic interaction which may either increase the toxicity or reduce the therapeutic efficiency of a drug. Pharmaceutical interaction are related to the physicochemical properties of a drug and may have involves a loss of potency, increase in toxicity as other adverse effect. Generally these interaction arise outside the body and results inactivation of drug, example include the inappropriate mixing of drug in syringes, e.g. Gentamycin and Carbenicillin which inactive one another. Combining of drugs may cause pharmacokinetic and or pharmacodynamic interaction. Pharmaco-kinetic mechanism of interaction includes alteration of absorption, distribution, biotransformation, or elimination. Drug interaction may occur between prescription drugs, but also between foods and drugs and chemical and drugs. Whereas some may be adverse Interaction may also be sought to decrease side effect or to improve therapeutic efficacy.

Besides of these factor foods also have the potential to interact with drug interaction. Certain foods and beverages can interact with medicines potentially making them less effective or causing side effects. Changes in a medicines effect due to an interaction can be significant; however there are many individual factors that influence the potential for variations, such as dosage, age, weight, sex and overall health. Calcium - rich dairy products (such as milk, iron, cheese, and ice-cream), antacids, and vitamins containing iron can all losses the effectiveness of antibiotics particularly tetracycline. Grapefruits juice should not be taken with certain blood pressure lowering medication the antihistamines terfenadine and cyclosporine, a drug taken to prevent organ transplant rejection.

Commonly Reported Interactions :

Herbal supplements, which have grown significantly in availability and popularity to recent years, can add to the risk of drug-drug interactions for example Ginkgo - which inhibit blood clotting may cause trouble if it is taken with anticoagulant or blood - thinner, such as

Warfarin. Kava - Kava a popular herbal taken to reduce stress -may have additive effect if taken with muscle relaxants, sedative or antidepressants.

Vitamins and minerals like Ca, Fe, Zn also have the potential to interact with medications for example Ferrous Sulfate an essential iron can negate the effect of Tetracycline a commonly used antibiotic.

Paracetamol or Acetaminophen an oldest and widely used drug as analgesics and antipyretics is well recognized drug for pain and fever . Paracetamol undergo interaction with Chloroquines, antacids, anticonvulsants etc.

Aspirin an another analgesic, anti-inflammatory and antipyretic agent show augmented effect with H2 Receptor leading to increased adverse effect or toxicity. Aspirin shows a remarkable declined effect (Minor et. Al. 1986) due to increased metabolism when taken with Oral Contraceptives.

NSAID's is also widely used OTC drugs worldwide. Patients are not aware about the toxicity of these drugs. NSAID's taken concurrently with Warfarin may results in increased risk for bleeding. They inhibits platelet function and have the potential to cause the gastric erosions. NSAID's. other drug interaction are those with Loop diuretics, and Antihypertensive agent which lead to decreased efficacy of the said agents.

Role of Pharmacist in Drug-Drug Interaction : A Challenge

Practicing community pharmacists should be trained in such a manner that he /she can efficiently perform following functions

- Identify the patients risk factors
- Take a through drug history
- Understand the different mechanisms through which drugs can interact by being knowledgeable about actions of drugs
- Know how to screen for potential interactions and be able to manage drug interactions
- Educate patient
- Monitor therapy and drug-drug interactions
- Individualize therapy so as to prevent drug-drug interactions and prevent ADRs.

The prevailing system of education and training during undergraduate studies or Diploma in Pharmacy studies requires more inclination towards clinical pharmacy approach so as to make pharmacists vigilant about identification, evaluation, monitoring and managing drug reactions. The practicing pharmacist require a meaningful and pharmacovigilant training at medical hospitals (< 300 beds) in collaboration with medical and paramedical staff so that the trainee pharmacist become vigilant in identifying and reporting ADRs or Drug-drug interactions precipitating in patients.

As the list of established drug-drug interactions has enormous examples & it is not so easy for the practicing pharmacist to retain all examples in memory due to which many interacting prescription remain unidentified. For easy detection of drug-drug interaction in prescriptions a database of interactions can be prepared as following;

"Prescribing trends of various diseases like diabetes mellitus, CVS disorders, GIT disorders, Viral infections, etc can be identified and a database of prescribing alternatives/ trends can be prepared, from which the interacting combinations can be pointed out.

Whenever a pharmacist dispenses a prescription, simple entry of prescribed drug in the software can be made and processed for the presence of any drug-drug interactions which is likely to occur due to misprescribing. Such types of softwares should be made available to the pharmacists for safe dispensing of drugs". Thus the challenge of identification of drug-drug interaction can be resolved effectively so as to reduce the incidence of occurrence of ADRs and Drug-drug interaction.

Evaluation, monitoring and management of drug-drug interaction is another challenging task of pharmacist especially, hospital pharmacist. The role of hospital pharmacist in Indian context is limited upto distribution of formulations to patients and his assigned workplace is mainly drug store. Hospital pharmacists must be trained such that they are able to evaluate, monitor and manage drug-drug interactions & ADRs so as to minimize the hazards of drug interactions. An opportunity to play an active role in evaluating, monitoring and managing drug-drug interactions and/or ADR be provided to trained Hospital pharmacists.

Thus it may be concluded that clinical pharmacy practice approach training be imparted to pharmacist so that they effectively detect, evaluate, monitor and manage drug-drug interactions. For easy detection of drug-drug interaction pharmacies providing on up to date and accurate information on ADRs and drug-drug interactions.

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YOU MUST KNOW IT, WHEN YOU PRACTICE PHARMACOVIGILANCE

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Pharmacovigilance is the science dealing with the activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Its concerns include:

- herbals
- traditional and complementary medicines
- blood products
- biologicals
- medical devices
- vaccines.

Many other issues are also of relevance to the science:

- substandard medicines
- medication errors
- lack of efficacy reports
- use of medicines for indications that are not approved and for which there is inadequate scientific basis
- case reports of acute and chronic poisoning
- assessment of drug-related mortality
- abuse and misuse of medicines
- adverse interactions of medicines with chemicals, other medicines, and food.

Specific Aims of Pharmacovigilance are to :

- improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions,
- improve public health and safety in relation to the use of medicines,
- contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use, and
- promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

To accomplish all these important objectives, an understanding of the terms used during communication and practice is necessary. The following given list of defined terms may be of help to you develop your practice of pharmacovigilance.

Adverse Event/Adverse Experience - Any untoward medical occurrence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment.

Adverse Reaction - A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Active surveillance system - The collection of case safety information as a continuous pre-organized process.

Bayesian confidence propagation neural network (BCPNN) - A computer architecture that mimics the network of cerebral neurones (neural network) and that uses a logic that determines the disproportionality of relationships between any of the items in the database including complexes of items compared with the background of the remaining or selected items. Changes in the disproportionality can be monitored, as new data are added or different patterns of items selected.

Benefit - An estimated gain for an individual or a population. See also: Effectiveness/risk; benefit/harm.

Biologicals - A medical product prepared from biologic material of human, animal or microbiologic origin (such as blood products, vaccines, insulin).

Benefit /harm - Benefit and harm are the positive and negative subjective qualitative experiences of individual patients. These are not usually assessed except in modern quality of life studies or in case reports. Benefit and harm at a societal level may also be considered, but then must include relative effectiveness and risk, the impact of all the outcomes on society and include cost analysis.

Case control study - Study that identifies a group of persons with the unintended drug effect of interest and a suitable comparison group of people without the unintended effect. The relationship of a drug to the drug event is examined by comparing the groups exhibiting and not exhibiting the drug event with regard to how frequently the drug is present.

Clinical trial - A systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the objective of ascertaining their efficacy and safety. Clinical trials are generally classified into Phases I to IV. Phase IV trials are studies performed after marketing of the pharmaceutical product. They are carried out on the basis of the product characteristics for which the marketing authorization was granted and are normally in the form of postmarketing surveillance.

Cohort study - A study that identifies defined populations and follows them forward in time, examining their rates of disease. A cohort study generally identifies and compares exposed patients to unexposed patients or to patients who receive a different exposure.

Complementary/Alternative Medicine - These terms are used interchangeably with traditional medicine in some countries. They refer to a broad set of healthcare practices that are not part of that country's own tradition and are not integrated into the dominant health care system. They have not usually been tested in specified clinical indications by an objective scientific discipline.

Counterfeit Medicine - A medicine that is deliberately and fraudulently mislabelled with respect to identity and/or content and/or source.

Drug/medicine - Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient. The term drug/medicinal product is

used in a wider sense to include the whole formulated and registered product, including the presentation and packaging, and the accompanying information.

Drug Alerts - The action of notifying a wider audience than the initial information holder(s) of a suspected association between a drug and an adverse reaction. Note that the term is used in different contexts that can be confusing, for example, an alert may be from a manufacturer to a regulator or from a regulator to the public.

Effectiveness/risk - The balance between the rate of effectiveness of a medicine versus the risk of harm is a quantitative assessment of the merit of a medicine used in routine clinical practice. Comparative information between therapies is most useful. This is more useful than the efficacy and hazard predictions from pre-marketing information that is limited and based on selected subjects.

Ethics committee - An independent body (a review board or an institutional, regional or national committee), constituted of medical professionals and non-medical members whose responsibility is to verify that the safety, integrity and human rights of the subjects participating in a particular clinical trial are protected and to consider the general ethics of the trial, thereby providing public reassurance. Ethics committees should be constituted and operated so that their tasks can be executed free from bias and

from any influence of those who are conducting the trial.

Generic (multisource pharmaceutical product) - The term 'generic product' has somewhat different meanings in different jurisdictions. Generic products may be marketed either under the non-proprietary approved name or under a new brand (proprietary) name. They are usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company

and marketed after the expiry of patent or other exclusivity rights.

Herbal medicine - Includes herbs, herbal materials, herbal preparations and finished herbal products.

International Conference on Harmonization (ICH) - The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

Lack of efficacy - Unexpected failure of a drug to produce the intended effect as determined by previous scientific investigation.

National pharmacovigilance centre - A single, governmentally recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety.

Pharmacoepidemiology - The study of the use and effects of drugs in large numbers of people.

Pharmacovigilance - The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Prescription event monitoring - System created to monitor adverse drug events in a population. Prescribers are requested to report all events, regardless of whether they are

suspected adverse events, for identified patients receiving a specified drug.

Product stewardship - The demonstrable process by which a business can identify and manage its safety, health and environmental performance as applied to the development, manufacture, marketing, use and disposal of its products (including packaging).

Record linkage - Method of assembling information contained in two or more records, e.g., in different sets of medical charts, and in vital records such as birth and death certificates. This makes it possible to relate significant health events that are remote from one another in time and place.

Risk evaluation - Risk evaluation is the complex process of determining the significance or value of the identified hazards and estimated risks to those concerned with or affected by the process.

Risk management - The making of decisions concerning risks, or action to reduce the consequences or probability of occurrence.

Side effect - Any unintended effect of a pharmaceutical product occurring at a dose normally used in man, which is related to the pharmacological properties of the drug.

Signal - Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

Spontaneous reporting - System whereby case reports of adverse drug events are voluntarily submitted from health professionals and pharmaceutical manufacturers to the national regulatory authority.

Traditional Medicine - Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. The terms 'complementary medicine' / 'alternative medicine' / 'non-conventional medicine' are used inter-changeably with traditional medicine in some countries.

Unexpected Adverse Reaction - An adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorization, or expected from characteristics of the drug.

PREVENTING MEDICATION MISADVENTURES - TIME TO INTRODUCE PHARMACY PRACTICE COURSE AND SERVICES IN INDIAN INSTITUTIONS/HOSPITALS

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Introduction

As necessity leads to invention, significant number of medication misadventures must lead to setting up of a separate department of Clinical Pharmacy Practice in Indian Hospitals. To give this department a proper shape, introduction of courses in Clinical Pharmacy Practice would obviously be essential. The department is to be manned by persons specializing in Clinical Pharmacy Practice at postgraduate level with a basic degree in medical or pharmaceutical sciences.

If we look back to 1960s, even developed countries did not recognize pharmacy as a profession, the reason being all duties of pharmacy qualified personnel could be handled by persons not holding pharmacy degree. As the time passed, introduction of courses like Hospital Pharmacy, Community Pharmacy and Clinical Pharmacy and strengthening of courses like Pharmacology, Toxicology, Pharmacokinetics and Pharmacotherapeutics gave separate identity to pharmacy professionals. Besides his role in Pharmaceutical industry and academic institutions, a pharmacist became important element of health care team.

Need For Clinical Pharmacy Services:

Many of the activities performed by physicians can be performed by a clinical pharmacist thus relieving physicians to perform his specialized functions. Thus the services that are expected from a clinical pharmacist would be as follows:

(i) Patient interviews at admission and determining eligibility.
(ii) Counseling on drug therapy and identifying drug related problems.
(iii) Participation in patient care rounds.
(iv) ADR reporting .
(v) Therapeutic drug monitoring.
(vi) Answering drug information requests from patients or doctors.
(vii) Patient counseling at discharge after assessing patient outcomes.

Need For Pharmacy Practice Program For Clinical Pharmacy Consultants :

To perform functions mentioned in above paragraph, a person with basic degree in medicine or pharmacy requires to go through postgraduate program in Clinical Pharmacy Practice or Pharmacy Practice. He must acquire knowledge in the following relevant areas :

(i) Pharmacotherapeutics
(ii) Clinical Pharmacokinetics
(iii) Hospital Pharmacy
(iv) Drug Information Service
(v) Health Education
(vi) Community Pharmacy
(vii) Regulatory Affairs

Skills Expected To Be Acquired By a Clinical Pharmacist :

Thorough understanding of pathophysiology of important diseases and their rational treatment.

Knowledge of clinical Pharmacokinetics, therapeutic drug monitoring, methods and techniques of bioavailability and bioequivalence studies.

Ability to prepare medication history; monitor, evaluate and comment upon drug therapy, adverse drug reactions and drug interactions; provide drug and poison information.

Ability to evaluate statistical data available in clinical and pharmacological literature.

Ability to manage medical emergencies, drug over dosage, burns etc.

Specializing in managing one of the major disease, like cardiovascular, psychotic, renal, hepatic, respiratory, gastro-intestinal, oncologic, or severe infections.

Understanding of following vital areas of Clinical Pharmacy Practice:

- ❒ Clinical laboratory investigations
- ❒ Clinical trials
- ❒ Handling of cytotoxic drugs and radiopharmaceuticals
- ❒ Total parenteral nutrition
- ❒ Intravenous admixture
- ❒ Drug utilization reviews
- ❒ Patient counseling
- ❒ Quality control
- ❒ Research in hospital settings
- ❒ Concept of essential drugs and rational drug usage.

Adequate knowledge about the principles of the management of hospital pharmacy.

Ability to apply computer technology in the areas of clinical pharmacokinetics, drug information and drug interaction.

Ability to participate in the teaching of students of medicine, pharmacy and nursing in patient care areas.

Excellence in communication skills for interaction with the physicians, nurses and patients.

Who should conduct the program?

Medical institutions in their department of pharmacology or clinical medicine and pharmacy institutions can conduct the program. Medical institutions have an edge over pharmacy institutions due to natural association with hospitals. Pharmacy institutions have to search for such an association. However, medical institutions have to hire services of faculty from pharmacy and other disciplines due to interdisciplinary nature of the program. They will require faculty who can use software and visit websites and also have special interest in pharmacokinetics and drug delivery systems. The department/division of pharmacy practice must have a good digital library and an independent wing in the hospital.

Benefits

Besides reduced discomfort to the patient through reduction in number of drugs and pricks, the Clinical Pharmacy Practices shall have significant impact on cost of therapy. Due to psychological reasons, advertisements on drugs tend to increase the cost of therapy of a particular disease. A clinical pharmacist shall be able to offset this effect of advertisements through his knowledge in pharmacovigilance, pharmaco-economics, pharmacotherapeutics, adverse drug reaction monitoring and other relevant skills. Although no clear data are available in our country on cost-reduction by Clinical Pharmacy Services, following paragraphs give the importance of such services in developed countries. Even

developed countries have become conscious of the rising cost of therapy. Therefore a poor/ developing country like ours should become even more serious and concerned about the cost of medication and other relevant factors.

Cost-Containment

Borgdorf et al (1994) collected and analyzed data on U.S. patients receiving a pharmacist-conducted medication review. They observed significant reduction in unscheduled physician, urgent care and emergency visits. Benefit to cost ratio in first year of progress was found to be 3.2 due to average saving of $644 per patient. In another study of Maryland Medicaid patients (Lai & Sorkin, 1998), the pharmacist intervention group saved $824 per patient per year by determining patients' eligibility, identifying potential drug related problems, making recommendations to the physicians, providing consultation to the patients, and assessing patient outcomes. This shows that pharmacists' professional expertise is the key to optimizing use of medications to improve patients' health and clinical outcome. Several other reports show positive economic impact of Clinical Pharmacy Services (Boyko et al., 1997; Gerber et al., 1998; Schumock et at,2003). Hospitals had fewer deaths per year by employing four Clinical Pharmacy Services viz. clinical research, drug information, drug admission histories and participation in a cardiopulmonary resuscitation team (Bond et al., 1999). Significant reduction in number of medical errors has been observed by availing services of Clinical Pharmacists (Bond et al., 2002).

The clinical pharmacists are making a major impact to reduce drug misadventures in U.S. Most patients appropriately recall pharmacists recommendation for altering medication use and also improvement in compliance as well as minimization of adverse events have been reported (Opdyke et al., 1992).

Geriatric Population

As medical advances prolong life, chronic illness becomes a greater problem. Pharmacists are targeting this population to optimize pharmacotherapy and avoid many potential drug misadventures. Besides being very cost-effective (Bond et al., 1999; Gattis et al., 1999; Leaks et al., 1999; McMuliin et al., 1999; Renville, 1999; Schumock et al.,1999), clinical program improves quality of patient care by reducing patient drug related problems (Schumock et al.,1996).

Influencing Physician Prescribing:

In U.S., the collaboration between prescribers and pharmacists has significantly improved patient care in recent years. The process for understanding and predicting prescribing decisions follow two steps. The initial step includes generation of a small set of possible treatment options and the other step entails specific therapy for an individual patient (Segal & Stepler, 1982). The pharmacists play a crucial role in influencing quality of prescribing. Their knowledge is the key in designing interventions to influence prescribing. Wilson (1963) and Stolly (1972) found that relatively young, recent graduates from medical school, and additional post-graduates training are characteristics of better prescriber.

Current Status In India

Nearly nine pharmacy colleges in this country (two in North India, rest in South) have introduced Clinical Pharmacy Practice programs. All India Council for Technical Education has also granted permission to Department of Pharmaceutical Technology, Jadavpur University, Kolkata. Why all these years pharmacy education couldn't keep pace with the developments around the world? It is high time we think ahead.

How to begin and develop the services?

The pharmacist can follow the successful model practiced in the U.S. From the beginning, emphasis should be placed on documentation of all clinical interventions based on pharmacists' evaluation of the patierventions and associated outcomes.

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A COMPARATIVE STUDY OF THE INDIAN SYSTEM OF MEDICINE (AYURVEDA) AND THE WESTERN SYSTEM OF MEDICINE (ALLOPATHY) FOR THE EFFECTIVE CURE OF DIABETES

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AIM AND OBJECTIVES

The primary aim of the study was to evaluate and to find the merits and demerits of 2 systems of medicine for the treatment of Diabetics, using clinical reports, medication reports, doctor's feedback; patients feed back, studying the patient's record of private hospitals in Chennai, Tamilnadu.

The specific objective includes:

1. To increase the awareness of the nature of various available medicines systems.
2. To find out complications associated with the Ayurvedic and Alopathic systems of medicine.
3. To achieve the control of blood glucose effectively, by choosing one of the systems.
4. To bring about economic benefits.
5. To improve patient-compliance.
6. To find out weather there was any drug interactions from the drugs prescribed.
7. To project the present study as a model study, so that patients could follow.
8. To actively involve in ensuring the better treatment given to the patients in various medicine systems and then raising g the dignity of the profession of pharmacy.

METHODOLOGY

For the present study, case reports from a private hospital in Chennai have been selected for detailed analysis. From the patients case reports a total number of 120 patients profile were taken for the study. From the 120 patients profiles 60 from each system was selected. The case records were collected in the presence of a physician. A specially designed form was used for collecting information. Those consist of:

1. Patient Details (Form I)
2. Complication after onset of diabetes (Form II)
3. Lab investigation (Form III)

Medication Chart (Form VI)

1. Systems of medicine selected: Ayurvedic systems and Allopathy systems.
2. Selection of patients according to their age, sex, location, social status, type of disease for each system of medicine.
3. Collection of clinical records with periodic monitoring, essential clinical test reports taken.
4. Feed back from patients.
5. Feed back from doctors.
6. Survey carried out.

RESULTS AND DISCUSSIONS

Demography

In this study, 120 patients' data were collected. 60 patients data were studied under Allopathic and 60 under Ayurveda systems medicine.

Out of this, 55% were males 45% were females in the Ayurveda system.Out of this, 52% were males and 48% were females in the Allopathy system.

From the results, it was found that the male population has the higher incidence of diabetes.

The locality of the patients in the study were almost 47% patients from urban, 13% patients from semi-urban and 40% patients from rural population under Ayurveda system.

The localities of the patients in the study were almost 72% patients from urban, 20% patients from semi-urban and 80% patients from rural population under Allopathy system.

In the two systems the businessmen and housewives were more common

In this study middle age group people were more common. Age groups between 40-55 years were more in number for the 2 systems.

The study indicates about 80% of the patients had any one of the complications. This study shows that higher number of patients had heart complications followed by eye, neurological, kidney problems.

In the Ayurveda systems of medicine the hospitalization periods were 2-5 weeks.

In Allopathy systems of medicine the hospitalization periods were 3-15 days.

CONCLUSION

From the study, it is found out that the systems of medicine -Allopathy and Ayurveda had their own merits and demerits. Ayurvedic patients, hospitalization periods are when compared to that of patients treated under Allopathy systems of medicine.

a. In Ayurveda, diagnosis, method of treatment and action of the drug is over prolonged period. Cure of the disease is in stepwise manner. Ayurveda treatments have strict diets (pathiyams) medication which may be bitter, which the patient might discontinue if they are sent back home. Laboratory reports are taken once in 10 or 20 days and not everyday. Ayurveda treatment mainly comprises of powders, tablets, decoctions, medicated oils, etc. prepared from natural herbs, plant and minerals.

b. In Allopathy diets are very easy to follow (ie) not very strict diabetic diet when compared to Ayurveda. The patient on their own can follow the diets at home. Pharmacological activities of the drugs are very rapid, immediate, and there is a considerable reduction of sugar levels; when these drugs are taken at the correct time with the correct diets. This the patients can manage at home, as it is not difficult to follow. Allopathic treatments mainly comprise of tablets, capsules (insulin). In this way it differs from Ayurveda.

Mostly type-1 classes of the disease were seen both the systems of medicine.

Medications: This is one area where Ayurveda and Allopathy differ markedly in the use of medications. According to Ayurvedic thought, by using the combined herbal preparation,

which sometimes includes whole plant products, the various rather than isolated chemicals that we consider the active ingredients, the various chemical constituents work synergistically, mitigating many harmful side effects.

Treatment: Ayurvedic practitioners use written questionnaires to establish the person's tricdosha, which include questions about the body, metabolism, habits, sleep, self-image, interest, preferences, emotional and psychological attributes.

Allopathic practioners generally questions the patients verbally. This includes the patient's initial symptoms, social habits, family history, past medication, etc.

From this study it is clear that the patients blood glucose levels were in a controlled state after hospitalisation for both the systems of medicine.

This comparative of the two systems of medicine for the effective treatment of diabetes have their own positives and negatives.

Ayurveda is a good system of medicines for the treatment of diabetes, but it having long duration (hospitalization stay), strict diets, and their tasteness drugs. Research should be carried out in this area where Ayurvedic drugs show rapid cure.

Allopathy is also an equally good system of medicine in the effective treatment of diabetes, with their hospitalisation stays less, but treatment should be continued for life. They have a comparable less strict diet. Injections are also a pain when compared to the tasteless drugs in Ayurveda. Research work should also be carried out in this area, were instead of administrating insulin induce the secretion from glands for permanent cure, side effects should be reduced by necessarily altering the drug delivery system, on using noval drug delivery devices - carriers like liposome noisome, monoclonal antibodies.

This study can be helpful to analyse the effective treatment of diabetics using these two systems of medicines and also to fine out the requirements for the future research in these medicinal systems.

DRUG USE EVALUATION OF ANTIBIOTICS IN UPPER RESPIRATORY TRACT INFECTIONS

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Aim and Objective

The prime objective of the study was to ensure that the evaluation of the use of Antibiotics for upper respiratory tract infections (URTI'S) by an analysis of the prescription by 10 doctors in Trichy District., Tamil nadu.

The specific objectives include:

1. To reduce the improper use of antibiotics by doctors for URTI'S
2. To rationalize the use of drugs for URTI'S
3. To promote cost effective drug therapy
4. To reduce drug interaction in commonly prescribed drugs
5. To bring economic benefits by reducing unnecessary use of drugs
6. To reduce communicable diseases like AIDS, Hepatitis by the usage of safe injections
7. To improve the drug therapy
8. To reduce the antibiotic resistance.

Method

For the present study, the patients' case records from 10 hospitals have been subjected to detail analysis. From the patients case reports a total number of 500 patients profile were drawn for this study.

The case records are collected in the presence of doctors, from their diagnosis and treatment pattern for URTI'S. A specially designed form was prepared. The form consists of three parts.

1. Details of patient (Appendix-1)
2. Interviews with patient (Appendix-2)
3. Review of medicine chat (Appendix-3)
4. Data were collected by interviews with the patient and doctors and by observing them during diagnosis

The relevant data were transferred to the form. Drug data from the form were further analyzed by the patient approach.

1. Improper use of antibiotics.
2. Irrational drug therapy
3. Drug interactions
4. Unnecessary drug use
5. Non-compliance
6. Wrong dosage form
7. Wrong dose

Results

Demography

500 patients were interviewed - of whom 62% were females and 38% males.

Of the included patients, 60% lived in cities and 40% in the countryside in Southern India.

The maximum number of people affected belongs to age group 56-60years.

The income of the patients shows that the majority of the study subjects had an income range of Rs 500-1000, followed by the patients whose earnings were even less than Rs .500/- per month.

Reasons for consultation shows 68% of the patients consulted the doctors for fever, cough with sputum, 26% for common cold, 1.2% for sinusitis, 4% for pharyngitis and 0.8% for epiglottis.

Antibiotics prescribed by the doctors

The prescription by 10 doctors was analyzed. 6 doctors prescribed the antibiotics for viral infection, even though such viral infections do not respond for antibiotics. These studies examine improper use of antibiotics by the doctors.

There has been irrational use of drugs for URTI'S. Almost all the doctors prescribed a large number of drugs (maximum 5 drugs) which include vitamins, minerals, anti-anxiety tablets, tonics etc. This type of treatment deviates from therapeutic objective. This in turn will increase the expenses for the patient.

Drug-drug interactions and Drug-food interactions are two important aspects of medical science. But some doctors neglect this. For instance if ciprofloxacin is given together with antacids, it results in poor bioavailability of the former. If the patient takes coffee while using ciprofloxacin, it leads to theophyline toxicity, which is the case of drug food interaction. Now a few doctors are care less in prescribing drugs are some times fail to instruct the patients properly.

Out of 10 doctors, 4 gave symptomatic treatment to the patients. Others administered unnessocery drugs. (Anlagen, Paracetmol, Chloromphenicol, Diclofinac etc) in the form of multiple injection.

The study shows that the main reasons for the non-compliance is, patient's illiteracy, lack of knowledge and want of money.

The dose calculations were not based on exact age or body weight the doctors guessed the weight according to age, and gave an erratic dose.

This study shows that the doctors prescribed tablets and capsules for children, but the result was patient compliance. Children cannot swallow these drugs. They should have been given syrups.

From the studies it has been found that 56.8% of the patients received over the counter drug before admission to hospital.

It has been found that some doctors are re-using the disposable syringes and needles.

Some doctors prescribed drugs only for one day or two days and asked the patients to come for a re-view. But the patients seldom follow this and to that refill drugs. Only 20% of the patients are refilling the drugs. The above reasons may increase the antibiotic resistance.

CONCLUSION

Several drug utilization Evaluation studies (DUEs) have been conducted all over the world mostly in advanced countries to assess antibiotic usage and most of these studies point to words the improper usage of antibiotics.

Antibiotic guidelines in a hospital setup can improve anti microbial prescribing both as empiric therapy as well as definitive therapy. Continued education, periodic reviewing of use of antibiotics and giving feed back of such

reviews to the prescriber will definitely improve the quality of prescribing and lead to rational anti-microbial therapy.

Doctors, not the pharmacists are completely reasonable for the clinical atmosphere in the country. Pharmacists do not have any effective role in counseling and dispensing. This kind of atmosphere does not permit the doctors to satisfy every patient with the most exclusive consultation. When patients are backing home they are not able to all the contents of the doctors guidelines. So the advice given by the doctors needed to be penned on the prescription paper or told to the person advising to the patient in to the clinic. Mass media like T.V., Radio should play an active role in awareness program to public about the importance of the fallowing guidelines given by the doctors. People should be aware about the details of the banned drugs in India.

INTERNATIONAL WORKSHOP ON
ADVERSE DRUG REACTION MONITORING
&
4th Annual Conference of Pharmacovigilance Society of India

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HERBAL DRUG IN ALCOHOL-INDUCED HEPATOTOXICITY

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Drug abuse has reached an alarming proportion in recent years. The non-medical use of alcohol has become a matter of serious concern is many countries. Over the past 30-40 years, alcohol consumption has increased in quantity and frequency. The age at which people start drinking has also been declined.

Alcoholic liver diseases (ALD) is a common consequence of prolonged and heavy alcohol intake and it is a leading health problem after heart disease, cancer and AIDS. Since alcoholism ranks as the world's biggest health problem today. Hence, investigators from a number of disciplines have been attracted to study the effect of ethanol on hepatic metabolism and the mechanism of ethanol induced liver injury. A drug that protects the liver cells from toxic substances could diminish hepatocellular necrosis and could thereby delay or prevent the occurrence of hepatic failure. Internationally, there are more than 600 commercial preparations with claims of liver protective activity. The inability of the modern synthetic approach to provide a satisfactory answer has led to shift in focus to alternative forms of therapy based on drugs derived from plants. In India, several combinations of about 100 Indian medicinal plants are available as hepatoprotective formulations. The present paper discusses few plant drugs and/or formulations used in treatment of alcohol induced hepatotoxicity viz Silymarin (Silybum mariamum), green tea (Camellia sinensis), ginger (Zingiber officinale), Liv 52, Livotone, Livomyn.

ROLE OF HOSPITAL AND COMMUNITY PHARMACIST IN PHARMACOVIGILANCE

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The study was undertaken to underline the impact of pharmacovigilance on patient welfare and public health. It is fully realized that reliable system of pharmacovigilance is necessary for public health and rational, safe and cost effective use of medicines. Drug safety monitoring is key to public health protection plight.

In principle, when two or more drugs are used simultaneously, there is possibility that these drugs may interact with each other in our body and can do a lot of harm. Therefore, physicians and pharmacists must be trained to anticipate such interaction and prevent them from happening. Role of hospital and community pharmacist has been explored in the present study to meet future challenges in pharmacovigilance. Out of over 5 lakh registered Pharmacists in India, thee are a Community and Hospital Pharmacy practice. Although there are 269332 retail outlets in India, hardly any may have infrastructure, competent manpower and commitment to secure safe, effective and economic medication. The Community Pharmacy simply undertakes trading of medicines almost without any professional touch/ service. The situation is alarming for public health and effective measures need to be taken so that patients get most of the benefits of modern medicines at minimum cost and are not at all exposed to untowards effects/Adverse Drug Reactions through efficient patient counseling mechanism and tracking feed back. The huge network of Communicty and Hospital Pharmacy has all potential to be utilized if professional training of Pharmacist is tuned properly.

THE ANTIBACTERIAL STUDY OF TODDALIA ASIATICALINN

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Objective : To study the Anitbacterial properties of the bark of plant Toddalia asiatica Linn.

Material and method : The plant *T. asiatica* is a prickly shrub collected from hilly region of Mayurbhanj Dist and was identified by the Taxonomist. The plant material was washed properly and was dried under shade less than 4 °C. The dired material was made in to course powder and the extract was prepared using soxhlet apparatus with Petroleum ether, chloroform, acetone, ethanol and aqueous solvent. The testing was done using cylinder-plate method. (Cup-plate method). The microorganism was used for the test was (a) Staphylococcus aureus (b) Ehcherichia coli. The zone of inhibition of different extract of *T. asiatica* was determined by using cup-plate and agar diffusion method. The extract was solubilised in DMSO. The nutrient agar media was prepared and inoculated with different test organisms such as S. aureus and *E. coli*. The size of the micorwells was filled with the test solution 100 micro liter of petroleum extract, chloroform extract, acetone extract, ethanol and aqueous extract. For comparison the standard drug Ampicillin was used in a dose of 100 micro grams per ml.

Result & Discussion : The zone of inhibition was found to be in petroleum ether extract for *S. aureus* 29 mm and for *E. coli* 27mm. In chloroform extract the zone of inhibition for *S. aureus* 19 mm and for *E. coli* 16 mm. In acetone extract the zone of inhibition was for *S. aureus* 21 mm and *E. Coli* 15 mm. In ethanol extract the zone of inhibition for *S. aureus* 09 mm and for *E.coli* 05 mm. In case of aqueous extract the zone of inhibition for *S. aures* 06 mm and E.coli was found to be 04 mm. where as the standard drug Ampicillin showd the zone of inhibition 42 mm for S. aueus and 41 mm for *E. coli* in 100 micro gram per ml concentration.

Conclusion : The Antibacterial studies of the plant *Toddalia asiatica* Linn showed significant antibacterial activity in petroleum ether extract, chloroform extract and acetone extracxt in comparison with the standard drug aginst *S. aureus* and *E.coli*.

HERBAL DRUG IN ALCOHOL-INDUCED HEPATOTOXICITY

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PHARMACOGNOSY IN COMMUNITY PHARMACY

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On February 6, 2004 FDA issued the final rule stating that supplements containing ephedra present an unreasonable risk of illness to those taking them. This rule puts ban on manufacture and distribution of ephedra containing dietary supplement with effect from April, 12, 2004. This is the first time that a supplement has been removed from the market under DSHEA (Dietary Supplement Health and Education Act).

This is an early warning to the pharmacognosists world over. It is generally believed that the herbal medicines are safe and posses practically no side effect. But in recent times pharmacognosists have become aware of the fact that much safety data is required for these complementary and alternative medicines.

WHO has taken up the issue of standardization and reulatory control of herbal products. Today the world market of herbal medicine and medicinal plants is estimated worth more than US$ 60 billion. By the year 2050 it is estimated to grow to the tune of US$ 5 tillion. In some industrial countries like Germany, HMP have a long tradition in professional therapy and in self-medication. In 1988 a survey of the complementary and althernative medicine (CAM) among more than 5000 adults in England reported that almost 20% of the sample had purchased over the counter (OTC) herbal medicinal product (HMP) in the previous year. In addition, almost 1% had consulted a herbal practitioner. Similar studies in USA have indicated that the proportion of adults who had self-treated with herbal medicine and those who had consulted an herbalist had increased significantly during the period 1990-1997.

Herbal Medicines are used as OTC products and there are little or no regulations regarding their use as compared to allopathic medicine. However these medicines are taken by men, women and children alike.

It is now being realized that a data bank on the safety profile of these herbal medicine must be available. An attempt is being made to understand the gravity of situation and work out the role of community pharmacist in the safe use of herbal medicine.

CANNABIS SATIVA L.-A GOOD PHYSICIAN OR A BAD FRIEND

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Cannabis sativa L.the hemp plant, grows wild, throughout most of the tropic and temperate regions of the world. Prior to the advent of synthetic fibers, the cannabis plant was cultivated for the tough fiber of its stem. Marijuana is a product of the hemp plant. The main active chemical constituent is THC (delta-9-tetrahydrocannabinol), which is one among connabis. Marijuana is the flowering tops and leaves of cannabis plant. Its constituents have been claimed in anecdotal reports to relieve symptoms associated with medical conditions like nausea and vomiting, wasting syndrome, multiple sclerosis, epilepsy and glaucoma. The treatment of AIDS-related anorexia use of dranabinol (synthetic THC). On the other hand effect from ingestion appear more gradually and last longer than smoking. The person may feel dull and sluggish impaired memory, enhanced sensory perception, appetite increase, fearfulness, anxiety, depression, hallucination, rapid heartbeat, red eyes, dry mouth are some common short term effects. But long-term effects are decreased motivation, difficulties with memory, respiratory system damage. This study tries to bring forth an eternal truth-Cannabis sativa L.is a good Physician but may prove to be a bad friend.

ABSRACT

MONITORING OF MEDICINE IN MARKET

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To Err is Human, medical errors and the risk of Pharmaceuticals have been in the news lately. The Institute of Medicine's (IOM's) report on medical errors released late last year, drew public attention to the economic and human costs of medical errors, which the report says are responsible for an estimated 44,000 to 98,000 deaths anjually. Nimesulide a relatively new anti-inflammatory analgesic drug is recently withdrawn from markets due to cases of fatal hepatitis and renal failure during course of its treatment. The diabetes drug troglitazone was withdrawn following reports of 63 deaths and 90 cases of liver failure linked to the drug. Cisapride, which has been used to severe heartburn and gastro esophageal reflex disease, is being voluntarily withdrawn by Janssen Pharmaceuticals, following 341 reports of arrhythmia and 80 deaths. Late in 1999, the rotavirus vaccine Rotashield was withdrawn after 99 reports of bowel obstruction (Intussusceptions) and the deaths of two infants. Among proposals to preven medical errors the IOM report called for the creation of a national patient safety center, with an initial budget of $30-35 million and expanding to $100 million that would develop the tools and system necessary to preven medical errors.

AMAROLI : A KEY TO GOOD HEALTH

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Amaroli, also called urine therapy is the use of one's own urine as food, medicine, restorative, gransforming agent and immune ystem booster. It is also known as Shivambhu or Auto Urine Therapy. According to Hindu philosophy and religious practice "urine therapy" invvolves any method of inegestion or injection of a pers's own urine for the purpose of health improvement or as a way to promote or maintain health. Amaroli comes from the root word 'Amar' wich means immortal, undying and imperishable. Aamaroli is thefore a techinique dsigned to bring about immortality. Urine therapy has been in practice since the time immemorial and its use is mentioned in many scriptures and ancient texts including Bible. Urine has been mentioned as 'Amrita' in Vedas.

Urine is not a dirty or toxic substance rejected by body. Medicinally it referred as 'plasma ultrafiltrate' wihi contains excess water, salts, vitamins, mineral, enzymes, antibodies and urine. Unine therapy has bee use extensively in many ill health conditions like jaundice, mental illness, beginning stage of dropsy, skin diseases, immuno-therapy for cancer patients.

Despite of numerous benefits and advantages urine therapy deserves some special attention. Monitoring is required and Amaroli should not be used if patient is under some sort of medical treatment or in patients with liver, kidney or heart disease, problem in protein metabolism and salt imbalance or pus filled urine. Consumption of white sugar, refined flour tinned food, spicy food, milk, intake of alcohol and tobacco should be avoided during this therapy.

So, it is concluded that Amaroli is a key to good health and will prove to be a boon to improve health care if practiced with proper monitoring.

NEWPATENT LAW AND PAHRMACEUTICAL EDUCATION

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Now that the GATT is a reality and will co0me into force within agreed time-frame, the Indian companies are visualizing the bes possible means to encounter the situation. The more forward looking and internationally minded among them have evoloved a two-fold strategy:

- To strentghten R & D capabilities during the 10 year transitional period.
- To enter into strategic alliance with research-based companies abroad for setting up joint ventures in India or licensing in patented new Drugs.

Pharma education will keep the industry growing in the globalised era because the coming era is going to be a time for thorough professionals and competitiveness will be the buzzword in the entire industry, Similarly, the theory of perform or perish is very much applicable to educational field as well. Taking the future into context, our basic policy should be to think ahead, which means anticipation and preparedness for the future requirements it is obvious. Even the present Indian scenario shows that the pharmacists will continue to play very critical role in the industry. In pharmacy education, with the philosophy of core competence coming in, this is the time for super specialization.

Topics:

- Impact of patent regime on pharmaceutical industy
- Impact on research & development
- Future strategies to face new challenges
- Educational awareness about gatt and ipr

DRUG INTERACTIONS

Smriti Sharma

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A drug interactions occurs when two or more drug interacts in such a way that the effectiveness or toxicity of one or more of the drugs is altered.

Objective

It is not known exactly how common drug interactions are. Up to 11.1percent of partients actually experienced symptoms that maym have been attributed to the effect of an interactions.

Drug interactilns may cause serious problems like alleragy, sometimes hospital admisson etc. To avoid this situation drug combination should be given in such a way so that serious effcts can be prevented.

Methods

Drug interaction often occur by more than one mechanism at the same time. They are not always easy top predict. Types of interaction-pharmocodynamic interaction, pharmco-kinetics interaction

PATIENTS likely to be affected-elderly patients, gentic characteristics of the patient.

DRUGS likely to be involved in clinically interaction : Warfarin, digoxin, rifampicin, cimetidine etc.

Result

Most absorption interaction are not clinically significant and can be managed by separating the administration the drugs.

Drug displacement interactions resuts in an increase in the concentration of free (active drug) but is usally colmpensated for by an increase in exreation.

Conclusion

With the knowledge of drug interaction, maximum benifts can be obtained from drugs.

CONTINUING EDUCATION PROGRAM FORM MEDICAL STORE OWNERS AND EXPECTATIONS OF PHYSICIANS AND MEDICAL STORE OWNERS REGARDING THE SAME

Akanksha Tripathi and Manisha Pandey

Faculty of Pharmacy, Department of Pharmaceutics, B.B.D.N.I.T. & M., Lucknow.

1. Views of medical store owners and physicaians regarding the same.
2. Desing of curriculum so that students can organize the same.
3. The fields of interest of owners and whom they want as organizer.
4. The field in which emphasis should be given during studies.

CHILDREN AND HERBAL REMEDIES: WHAT TO ADVISE FOR A VIGILANT DRUG USE?

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The practice and consumption of complementary medicine isn't a new phenomenon. Amongst a variety of medicine system, herbal medicine is the most accepted system of medicine. parents are considering the use of herbal remedies to maintain their children's good health and treat their illnesses.

Pediatricians, other primary care clinicians and Pharmacists are generally looked for advice concerning the safety and efficacy of herbal products for children. In this review, among a variety of modalities in CAM, only one - pnly one - the use of herbal products to treat children's health conditions-is addressed. The text reviews principles to keep in mind while addreesing the use of herbal medicines in children with parents.

OP1 AUTOMATION IN SIGNAL GENERATION

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One of the most important aspects of pharmacovigilance is the early detection of serious, unknown, and unexpected signals of Adverse Drug Reactions (ADRs). Signal generation is a method of highlighting potential safety issues in a drug that need to be investigated further. The process of generating signals from enormous number of case reports has been likened to looking for a needle in a haystack. In earlier days, the analysis was carried out by a systemic manual review of every report sent by the physician(s) to pharmacovigilance experts. It was a time consuming process. In the recent years, automated signal generation methods have been introduced to supplement qualitative clinical methods in order to speed up the procedure of screening large number of drug-event combinations in databases for potential signals. The Uppsala Monitoring Center and Food & Drug Administration (US) use automated detection algorithm based on Bayesian statistics and the use of neural network computer program for signal generation. Other automation methods used for signal generation include Proportional ADR Reporting Ratios (PRRs) and Incidence Rate Ratios (IRRs), which are based on proportionate and comparative approach. These methods are reproductive & generate promising results. However, to date these methods have not been prospectively evaluated and there is no gold standard for signal detection. The performances of these quantitative methods are limited by the fact that they are non-clinical and do not take into account the semantic information existing in controlled vocabularies used to code ADRs in case reports. However, the researchers are attempting to improve the performance of current signal detection methods using knowledge-based approach that will take ADR terminology in account. Automation does save the time but cannot replace expert clinical reviewers. More research work and head-to-head comparison between methods is required to quantify the utility of these methods.

OP2 GINGER, NOT SO INNOCENT

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Ginger (Zingiber officinale, Zingiberaceae) has been used throughout history as both a culinary herb and a medicinal agent. It is taken as capsules or the powdered plant, as a ginger tea or candied ginger. It is best known for its antiemetic (carminative or digestive aid) and antimotion sickness cure. It has been reported anti-inflammatory, antihyperlipidemic and antihyperglycemic properties. It is usually not considered harmful, although same people experience burning sensation when they eat it. It contains volatile oils and an oleoresin (sesquiterpene hydrocarbons-zingiberene and bisabolene) which may cause oral and GI irritation. It has a cholagogue effect so is contraindicated in gallstones. Another important adverse effect is on cardiovascular system i.e. platelet dysfunction. It inhibits platelets aggregation. It is thus contraindicated in patients on anticoagulant therapy or have a bleeding disorder. Animals studies of specified purified ginger compounds demonstrate pressor effects. Symptoms of overdose may include sleepiness, confusion, dizziness & irregular heartbeats. There is no information available regarding the use of ginger by children. Hence, the ginger though generally considered as safe and harmful, yet is not so innocent.

OP3 GENERIC MEDICINES: BOON OR BANE?

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As per WHO, drug use is described as rational when the patients are prescribed appropriate medication in required doses for an adequate period of time at the lowest cost to the them. Generic products are cheaper than the branded ones because they have not gone through the costly process of R&D, sales and marketing. Percentage of drugs prescribed by the generic name is one of the core-prescribing indicators, which is used to evaluate drug use in a health care setting. India is a developing country with a large number of poor people who cannot afford costly drugs. It is expected that prescribing of drugs by generic names will reduce the cost of treatment and improve the health outcomes. To find out the cost effectiveness of the generic prescribing, a survey of retail pharma market was undertaken. It was found that most of the generic medicines are priced at the same rate as the branded ones and in some cases even more than the branded ones. However, the retail chemist gets the generics at much cheaper rates. Apart from the government healthcare facilities where drugs are distributed free, a sizeable population of patients visiting private hospitals and nursing homes are given ride for their money, as the retail chemist trades at MRP. Not only is this but due to higher margins rampant generic substitution is prevalent. The other area of concern is bioequivalence of generic medicines to the branded ones. It is suggested that a mechanism of rating of generics with regard to there bioequivalence should be evolved as it is done by other countries.. It is high time that regulatory authorities should intervene so that Indians give fair price for their medicine.

OP4 A 4- MONTH PHARMACOVIGILANCE STUDY IN THE DEPARTMENT OF MEDICINE OF A 150 BEDDED TEACHING HOSPITAL

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A prospective evaluation of the ADRs attributed to drugs reported in the Department of Medicine at Majeedia hospital (a 150 bedded teaching hospital) over a period of 4-months was carried out. In the present study, evaluation of these reports with respect to various parameters such as drugs implicated, time of ADRs, outcome, causality assessment, severity and predictability was done. Out of 122 ADRs, 97 (79.50%) were observed in OPD where as 25 (20.5%) were detected in wards. The incidences of ADR per thousand patients in OPD were 12.18 and IPD were 46.73. The percentage of ADRs leading to the hospitalisation of patients was 3.1%. Out of 122 reports that were identified, a high % of ADRs in males (52.45%) as compared to females (47.55%) was observed. Of the 122 ADRs, 50 were found to be mild (41%) 49 moderate (40.2%) and 23 severe (18.2%). As expected polypharmacy had a major influence on the occurrence of ADR with a total of 71 (58.02%) ADR observed in-patients receiving medication concurrently. Conversely 46 (37.70%) ADRs were detected in patients using three or less medicines. In only 5 cases (4.1%) number of medicines was not specified. The largest number of reports was associated with antihypertensive therapy (40.16%) followed by antidiabetic (25.41%) and antitubercular drugs (20.49%). Amongst the organ system affected GI ADRs constituted a major component (24.7%) followed by adverse skin or cutaneous reaction (22.2%). On causality assessment, nearly 29.51% ADRs were considered probable, 33.61% were assumed as possible and 6.56% could not be categorised and were placed under unassessable.

OP5 The Ancient System of Medicine: Reorientation of Modern Scientific Parameters

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The origin of the ancient system of medicine known as Ayurveda was lost in cosmic antiquity. Ayurveda means "Science of life" prevention and longevity is the oldest and most holistic medical system available on the planet today. It believes and it is essentially because of people growing disillusionment with western medicine. It has failed to deal with chronic problems as well as new antibiotic resistant bacteria. While, Ayurveda has an excellent record of curing the sort of chronic problems that do not respond well to western medicine. People in the west are becoming disgruntled with the detrimental effects of drug therapy. There has been a growing awareness that in modern medicine, the treatments are palliative rather than curative.

The globalization of Ayurveda, however, is not solely because of the perceived failing of western medicine, it is also a result of shifting social patterns in the west. On the medical front, Homeopathy, Chinese herbal medicine, Aromatherapy, Acupuncture, Yoga, Meditation and other fringe or complementary therapies found in vogue. Ayurveda continues to grow rapidly as one of the most important system of mind-body medicine, natural healing and traditional medicine as the need for natural therapies, disease prevention and a more spiritual approach to life becomes ever more important in this ecological age. From remedies for cold or viral hepatitis to antimalarial or antineoplastc drugs, Ayurvedic preparation has taken new avatars. But sugarcoating is not all. Traditional knowledge will serve as a powerful search engine and most importantly, will greatly facilitate International focus and safe natural product research and rediscover the drug discovery process. The ancient system of medicine or Ayurveda has reoriented itself to modern scientific parameters and industrial trends and started getting the stamp of approval from across the seas.

OP6 SPONTANEOUS REPORTING OF ADVERSE DRUG REACTIONS IN A TERTIARY CARE HOSPITAL IN NEPAL: A SURVEY

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Introduction : Adverse Drug Reactions (ADRs) cause hospitalizations significantly; upto half of ADRs can be preventable. New drugs enter the market after phase III trials, but rare ADRs may go undetected. Pharmacovigilance studies aim to attain safe and rational use of medicines that are released into the market and identify uncommon and unusual ADRs.

Objective : To categorize reported ADRs and perform causality and preventability assessment.

Methods : This study was conducted in Manipal Teaching Hospital, Pokhara, Nepal. Doctors and pharmacists reported ADRs to pharmacovigilance cell through ADR reporting forms; following which relevant case details were obtained. The causality and severity assessments were performed based on Naranjo algorithm and Modified Hartwig and Siegel scale, respectively.

Results : Totally, 29 ADRs were reported from 71 drug exposures. Oral drugs accounted for nearly 2/3rd of ADRs. Antimicrobials constituted more than 1/3rd of reactions. More than half of the reports were from dermatology department and dermatological reactions accounted 69%. The causality assessment revealed equal proportions (44.8%) of the reactions could be possibly and probably attributed to the reported drugs. The severity assessment showed 41.45% of the reactions were attributable to Moderate (Level 3), and 6.9% to be Moderate [Level 4(b)].

Conclusion : Majority of ADRs were from oral dosage forms and antimicrobials. Dermatologists reported more ADRs and dermatological reactions constitute majority of it. More awareness program is essential to improve spontaneous reporting from other specialties too. Although no drug is free from side effects, a systematic approach can definitely reduce the incidence of their occurrences in future.

OP7 CASE STUDIES OF HOSPITALISED PATIENTS DUE TO DRUG RELATED COMPLICATIONS

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Introduction: More than one million hospitalized patients have been suffered and approximately 1,80,000 die each year due to Drugs Related Complications (DRCs) with an estimated economic burden of more than US$136 billion. Dose dependent DRCs are very common and are predictable and preventable by exercising a high degree of suspicion and close attention.

Objectives: To evaluate the occurrence of drug related complications leading to hospital admissions.

Methods: A cross-sectional survey, involving five major hospitals in Nepal covering Kathmandu, Bharatpur and Palpa, was conducted during February to May 2003. Pharmacists and doctors collected the data from file of those in-patients who were admitted due to DRCs and entered the details in the study-encounter form. The study excluded outpatients and patients experiencing DRCs in the hospital.

Results : Among 15,624 hospital admissions, 63 (0.4%) were attributed to DRCs. Hypersensitivity and gastrointestinal (GI) bleeding accounted for nearly 1/5th of the complications each. Adverse drug reactions (ADRs) caused 51 (80.96%) of the complications followed by overdose (17.46%). Higher incidence of ADRs was due to analgesics (23.82%) followed by antibacterials (17.46%), antitubercular agents (15.87%), centrally acting drugs (11.12%) and steroids (4.76%).

Conclusion : Analgesics were the main therapeutic category causing DRCs. Hypersensitivity and GI bleeding were the major complications and ADRs to be the major cause with higher incidence attributable to analgesics and antibacterials. More in-depth and broader scale studies addressing the pharmacoeconomic impact of the DRCs are needed.

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OP8 SAFETY AND ACCEPTABILITY OF DEPO-PROVERA (MEDROXY PROGESTERONE ACETATE) INJECTION AS A CONTRACEPTIVE IN INDIAN WOMEN

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The study was designed as an open level prospective survey to assess the safety and acceptability of Depo-Provera (Medroxy progesterone acetate) 150mg injection as a contraceptive in 100 women attending Family Planning Clinic of Mool Chand K.R. Hospital, New Delhi. These patients were evaluated every three months till four injections and reviewed after three months of the last injection. Injection of Depo-Provera 150mg was given either from first to fifth day of menses or in post partum period or with Medical Termination of Pregnancy (MTP) or after removal of cut. Depo-Provera 150mg proved hundred percent effective with a continuation rate of 93% while drop out rate was only 7 percent. After four injections amenorrhoea was observed in 47% cases, while spotting was seen in 44% cases. Three percent patients had headache and bloating of abdomen. A significant increase in weight was noticed in only 3% cases while there was a non-significant change in blood pressure. Thus, Depo-Provera (150mg) advocated intramuscularly every three months is well tolerated and an effective method of contraception. The details will be presented.

OP9 STUDY OF ADVERSE REACTION TO COMMONLY PRESCRIBED DRUGS IN S.N.MEDICAL COLLEGE AND ASSOCIATED HOSPITAL, AGRA

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Aim of the study was to monitor the information of adverse drug effect (ADR's) of commonly prescribed drugs in different departments of S.N.Medocal College, Agra. Prescription were randomly collected from the indoor & outdoor departments of medicine, cardiology, paediatrics, orthopedics etc. for a period of one month . P.G. students of pharmacology department record the information in a predesigned & tested proforma (ADR forms).Any new symptom, sign or discrepancy with the drug administered as reported by the patients was recorded. Questionnaire had details of reaction, treatment of reaction, & sequalae. Majority of these patient were treated with more than one drug simultaneously & a repeat challenge with a probable offending drug was not attemped. Out of 2567 prescription collected total 395 patients were having adverse effects(15.4%). Because repeat challenge with the probable offending drug was not attemped, therefore it was difficult to say with certainty which drug was responsible for observed ADRs. Following drugs seems to be responsible for observed ADRs. Cefaclor (diarrhoea), Ceftrioxone (hypoprothrombenemia), metronidazole (metallic taste, nausea, vomiting), Ferrous sulfate (diarrhoea), Phenytoin(drowsiness, ataxia), Zental (abdominal cramps), Erythromycin(jaundice, fever, hepatic failure), Amytriptyline(urinary retention), Quinine(arrythmia, hypoglycemia), Iron dextran(anaphylactic reaction, arthralgia), Streptomycin(Tingling sensation in ear), Hydrocortisone (gastritis, skin infections), Diclofenac (Pain in abdomen), Glibenclamide (Phototoxicity). Incidence of ADR's were higher with antimicrobials, NSAID's, antiepileptics and steroids and were more commonly seen in elderly. Most of the ADR's produced by these drugs subsided by themselves after withdrawing the causative agent while the other required treatment according to effect.

OP10 TO EVALUATE THE COST EFFECTIVENESS OF DIFFERENT ANTI MICROBIAL AGENTS OF DIFFERENT PHARMACEUTICAL COMPANIES IN PAEDIATRIC DEPT. OF S.N.MEDICAL COLLEGE AGRA

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We know that in poor countries most people have to pay for their medicines out of their own pocket, while in richer countries there are often mechanisms such as insurance schemes/government provision, has been developed to get medicines. This compels people living in poor countries frequently face a choice between buying medicines or buying food or other necessities. Therefore medicine prices do matter. These are the people who know that medicine prices are a problem. This study was conducted to evaluate the cost effectiveness of different antimicrobials of different pharmaceutical companies prescribed in paediatric dept. of S.N.Medical College, Agra and was analysed in the department of pharmacology. Various prescriptions of anti microbial- agents prescribed in OPD patients were collected , analysed & their cost effectiveness was compared on the basis of information obtained from MIMS & from local pharmacies. The above study shows, that there is difference between costs of products from different pharmaceutical companies and also between generic products and branded products of pharmaceutical companies. The study provides clear evidence that mean number of antimicrobial agents must be kept low because it causes increased cost of treatment. This study also gives an idea of difference between cost effectiveness of products of different pharmaceutical companies.

OP11 RACECADOTRIL Vs. LOPERAMIDE: THE CHOICE IS CLEAR

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Racecadotril is a novel antihypersecretory agent indicated in the treatment of acute watery diarrhea. It reduces degradation of endogenous enkephalins and thereby reduces hypersecretion of water and electrolytes into the intestinal lumen. The aim of this study was to evaluate the adverse effects of Racecadotril as compared to another antisecretory drug Loperamide commonly used in acute watery diarrhea. This study was conducted on patients attending the OPD in the Department of Medicine at S. N. Medical College, Agra and Allied Hospitals, Agra. 30 patients were enrolled between the age group of 15 - 45 years, who presented with complains of acute watery diarrhea. These patients were divided into two groups: Group I (n=14) and Group II (n= 16). While Group I was given a commonly used antisecretory drug Loperamide (0.45 mg/kg/day), Group II was given Racecadotril (1.5 mg/kg/Tds). The ORS therapy was continued in both groups. Only 9% of the patients in Group II reported secondary constipation as compared to 39% in Group I. Racecadotril was also found to be significantly superior to Loperamide in relieving associated symptoms of diarrhea such as abdominal pain and distension. It can therefore be concluded that the use of this novel antisecretory drug to treat acute watery diarrhea in adults should be encouraged as it was found to be significantly superior to the other commonly used drug Loperamide in both adverse effect profile and symptomatic benefits.

OP12 EVALUATION OF PRESCRIBING PATTERN FOR RATIONAL DRUG THERAPY AT MEDICAL COLLEGE & ASSOCIATED HOSPITAL, AGRA

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Prescription order is an important transaction between the physician and the patient. Now-a-days it looks that at hospitals, pattern of drug prescribing is changing and has become just an indication of only giving medicine with some instructions, regarding mode and frequency of therapy without considering its rationality. Irrational drug use practices with a significant medical, economic and psychosocial impact and involving both pharmacists as well as the patients, increasingly become a serious public health hazard in many developing countries. Common irrational prescribing practices are emerging in the form of overuse of antibiotics (dose and duration), overuse of parentral therapy, polypharmacy, misuse of multivitamin and minerals preparations etc. Keeping all these facts in consideration, this study was undertaken to analyse the prescribing habits of physicians for rational drug therapy. Prescriptions prescribed by the doctors were collected from OPD & indoors of different faculties at S.N.Medical college; Agra & analysed retrospectively. Total 175 prescriptions were prescribed in one month were analysed to assess whether the prescriptions are in conformity with the standard prescription pattern, average number of drugs per prescription, drugs prescribed by generic name, prescription containing antibiotics, prescriptions containing parentral therapy drugs prescribed from essential drug list and were subjected to screening for rational therapy. Study revealed that 92% of prescriptions did not adhere with the standard pattern of the prescription writing.

P1 CURRENT TRENDS IN THE TREATMENT OF DIABETES MELLITUS IN HISAR

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In the present study an attempt was made to observe the number of patients suffering from diabetes mellitus and therapy recommended by the general physicians. A survey was undertaken to determine the trends in treatment of diabetes mellitus and patients who were suffering from diabetes as well as hypertension and glaucoma. Considering the economic status of the patient and geographical localities 100 physicians were recruited for the survey. A questionnaire was prepared on the line of treatment and choice of drugs used for treating diabetes as well as hypertension and glaucoma. The study revealed that all the patients who were approaching physicians to seek the medical help, were of the age more than 40 years. Of these patients 20% were suffering from IDDM , around 65% were suffering from NIDDM, 10% were suffering from both hypertension as well as diabetes and remaining 5% were suffering from glaucoma and diabetes. As soon as these patients approached physicians different tests were prescribed: Blood sugar (fasting and non- fasting) and urine sugar. If the person suffering from diabetes was an obese person physicians prescribed biguanides (Phenformin, Metformin) as first line treatment while second line treatment included sulfonylureas (Gliclazide, Tolbutabmide). The patients who were suffering from both diabetes as well as hypertension received both (Gliclazide, Captopril or Methyldopa). The patient who were suffering from glaucoma as well as diabetes receive both (Phenformin, Physostigmine, Dipiveferine). The patients who come to the physicians were mainly the persons who don't work quite often and were mainly chair seaters. Physicians asked the patients to do some exercise and go for morning walk. Physicians recommended the patients to increase the daily work load. Also the diet control was recommended by physicians. The diet which was prescribed mainly included - porridge, bitters, curd, citrus fruits and green leafy vegetables. After 6- 9 month when all the therapies recommended by the physicians get failed then the physicians switched over to the insulin therapy and this therapy was lifelong.

P2 PRESCRIBING PATTERN IN HARYANA STATE

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A prescription analysis study was conducted in some selected Private Hospitals and Government Hospitals of Hisar, Tohana and Sirsa of Haryana state over a period of 3-4 months with an objective to check prescribing pattern of medicines in Haryana state. The study revealed that in the antibiotics class, the percentile of prescription of Ofloxacin which is a fluoroquinolone derivative is 15.56 while percentile of other derivatives such as Norfloxacin, Levofloxacin and Ciprofloxacin was 3.12. In case of, Doxycycline that is group III Tetracycline derivative, percentile was found to be 9.37 and in Aminoglycoside class e.g. Streptomycin and Gentamycin it was 3.12. The percentile of Ampicillin which is an aminopenicillin is 3.12 and in the class of newer macrolides viz. Azithromycin and Erythromycin it was 9.37 and in case of Roxithromycin it was found to be 3.12. The percentile of sulbactam which is a ß-lactamase inhibitor was found to be only 3.12. The Cephalosporin derivatives such as Cephalexin and Cefixime showed prescrib-

ing percentile of 3.12. The various NSAIDs such as Paracetamol exhibit percentile of total prescriptions as 12.5, Ibuprofen and Mefenamic Acid 6.24, Diclofenac Sodium, Nimesulide and Aspirin in 3.12 percentile. In the class of Steroids, maximum percentile calculated with Prednisolone was 9.37, then Betamethasone (6.24) and minimum in case of Mometasone and Simethicone (3.12). H_2- Antagonist such as Ranitidine showed the percentile of 12.5 while in case of 1st generation H_1- Antagonist, Cetirizine it was observed to be in the percentile of 3.12. Benzodiazepine derivative e.g. Alprazolam and class of Anthelmintics such as Albendazole and Mebendazole had prescribing pattern of 12.5 and 3.12 percentile respectively. In other antihistamines such as Chlorpheniramine was found to be 12.5 and Dicyclomine in the class of Anticholinergic had 9.37 percentile. Sulfadiazine, Sulfomoxole, Clotrimazole and Trimethoprim all were found to be with the percentile of 3.12 and Domperidone in the category of Antiemetics possessed 12.5 percentile. Theophylline, a Bronchodilator had prescribing pattern with percentile of 12.5. Other than all these, nutrient supplements on survey showed the prescribing pattern with a maximum percentile i.e. 21.85.

P3 CONTRIBUTION OF THE REGIONAL DRUG INFORMATION CENTER TOWARDS DRUG SAFETY - AN EXPERIENCE FROM WESTERN NEPAL

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Introduction : Drug Related Complications (DRCs), one of the major causes of hospitalizations, leads to huge economic burden. Improper knowledge regarding drugs and medication errors largely contributes to DRCs. Drug information center is an essential means of providing authentic and unbiased information to the healthcare professional and patients and ensuring safe use of drugs.

Objectives : To analyze the drug information services provided by the drug information center in relation to drug safety in Western Nepal.

Methods : The drug information queries pertaining to drug safety received by the center during November19th 2003 to November 30th 2004 were analyzed for results.

Results : The center received 127 queries concerning drug safety. Medicine department submitted 29.1 % of the queries. Medical doctors asked 3/4th of queries and patient care was the purpose behind nearly 2/3rd of queries. 50% of the enquirers either visited the center or personally approached the drug information center staff to submit their queries. One third of the enquirers received oral as well as printed information. Nearly half the queries were related to the causality of particular drug towards adverse drug reactions and 1/10th regarding drugs use in pregnancy and lactation. Centrally acting drugs accounted for 21% of the queries and 22% of the queries required an immediate answer. Tertiary sources were consulted to answer 52% of the queries.

Conclusion : Drug Information Centers by providing unbiased and objective information can reduce the occurrences of drug related complications. Constant awareness programs emphasizing the usefulness of drug information centers towards drug safety are needed.

P4 EFFECT OF CIPROFLOXACIN AND CHLOROQUINE ON HUMORAL IMMUNE RESPONSE ELICITED BY BOVINE SERUM ALBUMIN BEARING NIOSOMES

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Chemotherapeutic agents affect the immune system in several ways. These agents act mainly on phagocytic activity, interleukin level and antigen binding sites. Present investigation was done to evaluate the effect of ciprofloxacin and chloroquine on humoral immune response elicited by bovine serum albumin (BSA) bearing niosomes. Niosomes were prepared by reverse phase evaporation method and characterization was done by considering different parameters like optimum surfactant:cholesterol ratio, particle size and entrapment efficiency to optimize the formulations. ELISA method was used to measure the anti-BSA antibody titre. Further investigation on rats with chemotherapeutic agents according to dose dosage regimen, followed by immunization with optimized formulation of niosomes encapsulating bovine serum albumin suggested that Ciprofloxacin significantly reduced antibody titre induced by bovine serum albumin. It was proposed that Ciprofloxacin reduced the biological activity of IL-1a and IL-ß, led to reduction in antibody titre. On the other hand, chloroquine exhibited almost negligible effect. Earlier studies indicated that chloroquine potentially interfere with antibody response by interfering with replication of virus and raises pH within lysosomes and thus may interfere with fusion of viral and lysosomal membrane necessary to release viral nucleocapsid. But with bovine serum albumin (model antigen), it did not interfere, thus not suppressed the humoral immune response. Thus, it concluded that new vaccine candidates should be employed to study immunomodulatory activity of chemotherapeutic agents.

P5 STUDIES ON IMMUNE RESPONSE AS A RESULT OF INTERACTION BETWEEN SOLUBLE PROTEIN EMBEDDED IN NOVEL VACCINE DELIVERY SYSTEM AND CHEMOTHERAPEUTIC AGENTS

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Reports indicated that antimalarial drugs in regular treatment have immunomodulatory activity. It was investigated that chloroquine prophylaxis in children actually enhanced the antibody response to meningococcal group A and C vaccine, whereas chloroquine administered at the time of immunization had no effect on antibody production to tetanus toxoid. However, to investigate other common antimalarial drugs for immunomodulatory activity, proguanil was selected as an antimalarial drug in present study. Moreover, chloramphenicol, generally given to children, was also selected in the present investigation. The experimental animals (rats) were pre-medicated with selected candidate drugs and subsequently immunized with soluble protein (bovine serum albumin) entrapped in novel vaccine delivery system like liposomes. Liposomes are reported to be better immunoadjuvant in novel vaccine delivery systems. Particle size analysis and entrapment efficiency were the different parameters to characterize the immunoadjuvant. ELISA method was used to measure the antibody titre developed against bovine serum albumin. It was investigated that Proguanil and Chloramphenicol did not reduce the antibody titre signifi-

cantly in experimental animals, induced by bovine serum albumin. Therefore, present study indicated that Proguanil did not interfere with the antibody production when the candidate antigen is bovine serum albumin. Moreover, Chloramphenicol has also not exhibited any kind of immunosuppressive effect when humoral immune response was evaluated in terms of antibody titre. This indicated that further investigation should be carried out with new vaccine candidates for the selected drugs.

P6 ADVRSE EFFECTS OF ANTIMALARIAL DRUGS

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Malaria is one of the major problems in all over the world. Globally at least 300,000,000 people are suffered from malaria. Malaria is also one of the major public health problems in the Bundelkhand region. Antimalarial drug resistance is widespread and an important cause of recent resurgence of Plasmodium falciparum in this region. Antimalarial drugs are used sequentially one after another in many areas of the region, when therapeutic failure is observed with a drug. In view of this, the present study was undertaken to assess the therapeutic efficacy and adverse drug reaction of common antimalarials such as Chloroquine, Sulfadoxine + Pyrimethamine and Prymaquine at Jhansi district of Bundelkhand region. Fifty malarial patients (28 male and 22 female) have been surveyed for the adverse effects of mentioned antimalarials in Jhansi. It major adverse effects were abdominal discomfort (50%), headache (43%), dizziness (25%), nausea & vomiting (20%), skin rashes (15%), weakness and body pain (20%), and drug induced diseases were also observed in our survey aenamia 18%, jaundice 12%, peptic ulcer 13%, diarrhea 10%, edema 6%, typhoid 4%, depression 2%. These finding raises the question against the therapeutic efficacy of the commonly used antimalarial drug by government agencies. Resistance against the antimalarial drugs is continuously increasing in the Bundelkhand region therefore a systematic study need to be done to review the situation as well as to develop an alternative medicine (Herbal) for effective antimalarial chemotherapy.

P7 TO STUDY THE DRUG UTILIZATION OF ANTI MICROBIALS IN S. N. MEDICAL COLLEGE & ASSOCIATED HOSPITALS AGRA

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The prescription order offers a means of communication between doctor , pharmacist , and patients. Assessment of drug utilization is important for clinical, educational and pharmaco- economic purposes. Drug utilization studies are powerful exploratory tool to ascertain the role of drug in society. Auditing of prescriptions, forms a part of drug utilization studies. Periodical auditing of prescribing pattern is vital for promotion of rational use of drug It is necessary to define prescribing pattern and identify the irrational prescribing habit to derive a remedial message. This study was undertaken to determine the pattern of drug utilization of Anti microbial agents in OPD of different faculties of S.N.Medical College &Associated Hospitals, Agra. The study was conducted in the department of pharmacology and different medical faculties of S.N.Medical College and Associated hospitals, Agra. During the study period total 438 prescriptions collected from different faculties of S.N.Medical College & Associated Hospitals, Agra. The analysis was done for the number of anti microbial agents in each prescription, prescribed frequency of individual group of drug with age and sex.

The frequency of prescribing cephalosporins was highest among different groups (31.34%) followed by penicillins (22.00%), Aminoglycosides (13.68%) fluroquinolones (11.26%). The least frequently prescribed groups are antimalarials, antifungals, antihelmenthics, sulfonamides and chloramphenicol. The study shows a high incidence of polypharmacy, use by brand name, use of injectables. Proper interventional measure can improve the quality of prescribing behaviour and to improve the rational use of antimicrobial- agents in hospitals.

P8 Communicating the Adverse Effects : A Model of Community Persual

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Adverse effects remain the mainstay of a medical treatment. Any type of reporting system is based on self care. To facilitate the communication of an investigator and subject, we are to inform the community about the physiological status of any substance they have ingested. Patients should not be afraid to ask their doctors or pharmacists any questions they may have about their medications, such as side effects, food interactions, drug interactions, and how and when to take their medications. The open communication will decrease the likelihood of a potential drug interaction and, hopefully, encourage medication compliance, which can lead to overall improved patient care and satisfaction. A trial on community perusal and community information was carried out to study the existing level of awareness and willingness for selfcare. The interventions were designed to study the effect of questionnaire based direct communication approach on the need of health information and create a social demand for pharmaceutical care in an unaware and unwilling community setting. The trial shown an increase in drug related queries and served to enhance consumer's expectation towards health care services.

P9 PROBLEM OF COUNTERFEIT DRUGS IN INDIA

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Counterfeiting of medicines is a huge global problem, which poses public health and safety concerns, and affects both the developed and developing countries. The WHO has estimated that 5-8% of drugs worldwide are counterfeit; and India is responsible for about 35% of the world's counterfeit medicines amounting to illicit business worth USD200 million. The use of ineffective and poor quality of drugs places thousands of individuals at risk; endanger therapeutic treatment, and results in huge profit for criminals. According to the sec. 17B of the Drugs and Cosmetic Act (1940), counterfeit drugs are termed as "spurious drugs" in India. Drugs, which are targeted for counterfeiting, include: high cost and speciality drugs (HIV/Cancer), widely prescribed medicines (drugs for Tuberculosis, Malaria, antibiotics), and fast moving brands like Amritanjan, Crocin, etc. The magnitude of counterfeit drugs' problem in India is so alarming that the Indian parliament is contemplating a bill authorizing the death penalty for drug counterfeiters. The major factors that contribute to the counterfeiting of medicines include:

1. High profit margin on the products selected for counterfeiting; **2.** Difficult to detect and track the counterfeit; **3.** Lack of the implementation of the regulations; **4.** Inadequacy of the supply chain; **5.** Inadequate number of drug testing facilities

The attempts in order to overcome this problem can be made at two different levels. **I.** Pharmaceutical companies, on their part, should encourage the use of high-tech packaging and holograms in order to distinguish the original from the counterfeit. The supply chain loopholes are also under the domain of the manufacturer. **II.** Government may **a.** Provide effective co-ordination between the state and central drug control authorities; **b.** Consider the recruitment of additional staff and strengthening of the drug testing facilities **c.** Impose stiffer penalties; **d.** Enhance the investigative efforts by making a specialized force for this purpose; **e.** Restrict excessive concentration of retail/wholesale outlets; **f.** Finally, awareness amongst health practitioners and the pharmacists will go a long way to combat this problem.

P10 BIO-ORGANIC FORMULATION FOR TREATING DERMAL INFESTATION IN DOGS

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Chemical miticides have been in use for the last few decades. Because of the projected toxicities and high cost of allopathic drugs along with health risk to humans exposed to such drugs, it is high time to access and evaluate bio-organic formulations in the treatment of mite infestations (mange). Further, these days, already the use of some ectoparasiticidal chemicals has been highly reduced or not recommended because of the risk of human exposure. In animals, the use of bio-organic formulations in therapy of mange is in its various stages of development but still the possibility for development of a highly effective herbal preparation is to be explored. Olinall lotion, a bio-organic formulation was tried against Sarcoptes scabiei var canis (a microscopic ectoparasite i.e, mite) on dogs and its efficacy was compared with that of cypermethrin. Skin scrapings examined at scheduled intervals after the topical application of Olinall lotion caused complete recovery after 12 to 15 days in severe infestation and 6 to 9 days in mild to moderate infestations with regrowth of hair on Day 30 post-treatment. No adverse reactions were observed except mild irritation and restlessness, which persisted for a few hours soon after application.

P11 HERB- DRUG INTERACTIONS

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Medicinal herbs generally refer to plant parts, sometimes ground, extracted, or otherwise prepared, used for health benefits. People are buying herbal remedies for every-thing from migraines to memory preservation to depression. Herbal products now are widely available on drugstore shelves and in health food stores, making the ability to self-medicate greater than ever. But with that opportunity comes a warning: mixing herbal remedies and prescription drugs could be harmful to our health. Just like drug-drug and drug-food interactions, herb drug interactions are very common. Some herbal medicines may cancel the effect of a prescription drug; others may reduce it, or even exaggerate it. Herb-drug interactions may occur more frequently due to the many pharmacologically active compounds present in most herbal products. The herb-drug interaction of Ginseng anticoagulant such as warferin, asperin and other NSAIDS interaction result in increase in the risk of bleeding. Dietary supplements are becoming increasingly popular, physicians need to ask questions about the use of herbal products as many people have the

mistaken notion that, being natural, and all herbs are safe. This is not so. Very often, herbs may interact with medications. We normally take that result in serious side reactions. It is always a good practice to tell our doctor or health practitioners what we are taking so that they can advise us of possible complications, if there is any. We should also keep an eye for unusual symptoms. Very often, this may foretell the symptoms of a drug interaction part of the medication history. Even though herbal products are available without a prescription, medical guidance is necessary because of the adverse effects of these products and the potential for drug interactions. Before taking supplements, as herb, we people should consult their doctor, so that such interactions can be avoided. Although few well-designed studies have been conducted to investigate herb-drug interactions, so most information about these interactions comes from sporadic individual reports of interactions.

P12 MANAGEMENT OF DRUG INTERACTION IN HIV POSITIVE PATIENTS

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The HIV infected patient is typically taking a number of medications for prophylaxis as well as therapy of opportunistic infections, and for controlling HIV replication. This significantly increases the likelihood of drug interactions in these patients. Drug interactions usually occur when one drug affects the manner in which another drug is absorbed, metabolized, distributed or excreted in the system. Thus a drug could either decrease or increase the blood levels of another drug, leading to suboptimal efficacy and development of drug resistant virus. Drug interactions may occur immediately or take weeks to develop. The objective of this study is that, concomitant use of certain drugs is to be avoided or carefully monitored to avoid complications. This can help the physician treating HIV/AIDS to be familiar with commonly occurring interactions in their patients. The clinical management of the HIV infected patient certainly posses a challenge, due to it's wide spectrum of opportunistic infections which are encountered. Multiple drug therapy with antiretroviral is considered the most optimum approach to inhibiting viral replication. Superimposed on this regimen are drugs used to treat opportunistic infections. Drug interactions between these various classes are complex, and need to be born in mind for ensuring therapeutic success.

P13 NEED OF MONITORING OF HERBAL MEDICINE

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According to the World health organization (WHO), as much as 80% of worlds population relies on traditional medicine system. The use of herbal medicines refers to the long historical use. Its use is well established and widely acknowledged to be safe and effective. Ayurvedic (Herbal) medicine particularly in the last two decades, have come to be widely and increasingly used in both developing and developed countries despite limited evidence of efficacy. One reason to used by majority is that citizens are being persuaded that herbal medicine is based on its low or even absent toxicology. However the number of reports on unwanted side effects of phytomedicines increased in the last few years. Behind this side effects lack of pharmaceutical quality, unqualified recommendation of herbal medicines, unproven efficacy, little

or no federal regulation are found. Drug-drug interaction between prescription medication and herbal medication, and the fact that certain groups of individuals often experience a higher incidence of adverse drug effects, which could have dire consequences. For example ephedra (mahuang) are included in doses of popular herbal remedies, which are chemically related to stimulants and have been linked to many deaths and adverse events. These drugs, like other stimulants, can provoke insomnia, heart attacks, strokes, tremors, and seizures etc. Though ayurvedic medicines generally considered as safe but most of the herbal remedies are technically unapproved drugs, however these may have been used centuries but substantial data on the effectiveness and safety of long term use are often lacking. So it is need of hour that ayurvedic medicines must be monitored for their long term use and reviewing the potential side effects with contraindication prior to take.

P14 CLINICAL STATUS OF PLASMA EXPANDERS IN JHANSI

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Plasma expanders are natural, colloidal and crystalloidal substances. The human albumin plasma is sterile, non-pyrogenic preparation of serum albumin obtained by fractionating the blood plasma. They are used as life saving agents in the conditions like hypovolemic shock, severe hemorrhage, severe trauma, acute hypo proteinemia, acute liver failure, cardiac pulmonary bypass, dialysis, endotoxin shock, severe damage etc. We found in our survey that various plasma expanders like dextran-70, dextran-110, human albumin plasma and whole human blood plasma are well described theoretically in books but clinically are of no use due to their severe adverse drug reactions and clinical complications. They may also interfere with crossmatching of blood group. Gelatin and hydroxyethylstarch (HETA starch) are most widely used plasma expander (90-95%) as preloading solution in spinal anesthesia, in priming heart lung machine (major heart surgeries), acute hemorrhage, excessive plasma loss and in prevention of cellular death. Dextran- 40 second in use (5-10%) in-patients of hypovolemic shock, septic shock, orthopedic surgery, polytrauma, severe burns and prophylaxis of multiple organ failure syndrome (MOFS). Because of narrow range of choice in plasma expanders they are used at the cost of severe adverse drug reactions like hypersensitivity reactions (60-65%), urticaria, chills (32-35%), fever, pruritis, blood grouping and cross matching, rouleaux formation, coagulation disorder etc. as plasma expanders are used in life saving processes, so it is a demand of time that new plasma expander free from such severe adverse drug reactions should be introduced.

P15 POSSIBLE IMPACTS OF OVER THE COUNTER MEDICATION AND HERBAL REMEDIES IN PREGNANCY

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Over-the-counter and herbal products are available and consumed frequently in population of pregnant women. As limited information exists on the effects of many of these agents during pregnancy; it is not safe to assume that because these products are available without a prescription so they are without

danger to the pregnant woman and her fetus. The basic principles that are utilized in deciding prescription medications (such as dose, embryological timing and potential toxic fetal effects) also apply to herbal medications and over-the-counter agents. The discussions in the literature indicates that maternal exposure to poorly studied medications should be limited; therefore, many of these agents should be used sparingly or not at all by pregnant women. This paper includes a review of selected herbal and over-the-counter agents, including those which are considered to be acceptable for use in pregnancy.

P16 β- BLOCKERS AND CALCIUM CHANNEL BLOCKERS AS FIRST LINE AGENTS FOR HYPERTENSION

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Hypertension is the most potent force for the development of multiple atherosclrotic diseases that are leading causes of morbidity and mortality. In present life style, tension and anxiety are the main cause of hypertension. A survey was done on the personal attitude between the Physician and patient, towards the hypertensive condition and problem/adverse effects of common drug therapy in Jhansi city of Uttar Pradesh, through an open and closed study patterns. About 250 patients' cases were studied over a 4-month period between Augusts to November 2004, in Jhansi. We concluded from our survey that the common drug therapies in this region were b1-blockers (45.6%), Ca++ channel blockers (41.2%), diuretics (24.4%), benzodiazepine (11.14%), and ACE inhibitors (6.36%). It has been found that the adverse effect of drug reaction of b1-blockers were sinus bradycardia (91%), tiredness (87.8%), fatigue (86.2%), insomnia (85%), nightmare (80%), lethargy (73.9%), bronchospasm (72%), impotence (55.7%), glucose intolerance (48.3%), hyperlipidaemia (30.2%). And the adverse effects associated with calcium channel blockers were ankle edema (94.1%) constipation (90.0%), flushing (89.9%), dizziness (86.8%), headache (80.2%), weakness (78%), gastrointestinal problems (76.9%), and palpitation (74.8%). Fourth generation of β–1-blockers are awaited in India. Therefore, a lot of work is still required in this direction.

P17 SAFETY PROFILE OF PHARMACIST IN PHARMACOVIGILANT WORLD

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Introduction: It is a matter of pride that over the decade, the pharmacy profession has gained the repute of its own to get the desired status in India, because of the constant effort of our government. The good pharmaceutical interest has been generated so that the team of general medical unit reduce adverse drug events (ADEs) by proper control over the drug therapy and drug administration. The report published in the journal of internal medicines, it was observed that almost 20% of people die because of improper or drug abuse. A short-term survey was carried out in various govt. and semi govt. hospital pharmacy and medical dispensaries, to assess the role of various health care practioners.

Method: One of the four elements of good pharmacy practice addressed in the document covers activities associated with self-care, including advice about , where appropriate, the supply of a medicine or other treatment for self-care and self-medication. The methodology involves the questionair : a. Raising the issue of the responsibility of consumers and patients to ensure that the care or medication they select is appropriate to their needs, safe and effective. b. How are patients and consumers advised regarding the technical and ethical issues associated with self-care and self-medication?

A report was gathered from the patients (of different ailments) and was assessed for the role of pharmacist and the nurses for promt and timely medications.

Result : It was observed that reducing the cost, there was a significant decrease in the death rate of patients due to better control over the excessive use of drugs. Moreover, the study explored, that the pharmacist contributions leads to a significant help in prevention of adverse drug interaction. Thereby, leading not only to cost reduction for the benefit of patients that can not

afford the high medical cost and other requirements. The result may be well understood through the flowcharts and diagrams.

Conclusions: While individual needs may vary, determination of optimal ranges for effective amounts of the compounds and/or compositions is within the skill of the art and varies depending on the age, health, physical condition, sex, diet and medical condition of the patient, the severity of the cardiovascular disease, the route of administration, pharmacological considerations such as the activity, efficacy, pharmacokinetic and toxicology profiles of the particular compound used, whether a drug delivery system is used, and whether the compound is administered as part of a drug combination. Further from the study, it has now been unexpectedly discovered that the mortality of black patients is significantly reduced, and that their oxygen consumption, quality of life and/or exercise tolerance are improved by the administration of at least one hydrolyzing compound or a pharmaceutically acceptable salt.

P18 ROLE OF SERUM COPPER, ZINC AND COPPER/ZINC RATIO IN CHILDREN HAVING PRIMARY COMPLEX IN DIAGNOSIS AND TREATMENT

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Primary complex is the most common form of childhood tuberculosis and no single clinical as well as laboratory parameter can confirm the diagnosis. Trace elements especially zinc and copper have gained popularity in the recent time not only making the diagnosis easy but also to cure the disease by supplementation of these nutrients in the diet. The aim of this study was to estimate serum copper, serum zinc and Cu/Zn ratio in children having primary complex before and after 2 months of antitubercular therapy. This study was conducted in Department of Pharmacology in collaboration with the Department of Pediatrics on children attending Pediatric OPD in the S. N. Medical College, Agra. 120 patients chosen between the age group of 1-15 years, who presented with varied complaints of fever, repeated chest infections, loss of appetite and growth failure and chest X ray suggested the diagnosis. Serum copper, zinc levels and Cu/Zn ratio of these patients estimated by atomic absorption spectrophotometer before and after giving ATT (Rifampicin, INH, Pyrazinamide, Ethambutol) for 2 months. The average plasma copper and zinc concentration is 129.96 $\pm$ 3.18 mg/dl and 61.89 $\pm$ 3.21 mg/dl respectively and Cu/Zn ratio 2.11 $\pm$ 0.12 before starting treatment which changes to 124.91 $\pm$ 3.48 mg/dl and 65.24 $\pm$ 3.60 mg/dl and

Cu/Zn ratio 1.92±0.12 after treatment. It is therefore concluded that copper and zinc play a very important role in children with primary complex and their estimation and supplementation can be a very important tool for diagnosis as well as for treatment of childhood tuberculosis.

P19 Self-Medication in Sirsa, Haryana : A Questionnaire-Based Study

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Background : Self-medication and non-doctor prescribing of drugs is common in developing countries. Complementary and alternative medications, especially herbs, are also commonly used. Along with increasing use of these "safe" medicines, basic information about adverse effects is lacking. There are near negligible studies on trends of drug use especially self medication medications in Sirsa district, Haryana. To plan any intervention, a baseline data on drug use is required to be collected.

Method : Previously briefed third year pharmacy students, using a questionnaire, carried out the study on 600 respondents of age group 20 - 50 years of either sex. Demographic information on drugs consumption habits, self-medication and information regarding adverse effect of medications was collected.

Results : 81% of the respondents had taken self-medication. The ailments for which self-medication was practiced ranged from mild illness to disorders like hypertension; attributed to previous experience of treating a similar illness through self medication or because of repeated prescriptions. For self medication, the sources of medicines were pharmacy, one' home, office, hand bags and on advise from family and friends. 60% of them were taking herbal remedies for their discomfirt. Only 5% of the sample population did know about adverse effects and showed concern about cautions.

Conclusions : Self-medication and non-doctor prescription is common in the Sirsa district. In addition to allopathic medicines, herbal remedies were also commonly used for self-medication. Medication, especially antimicrobials, were not taken for the required duration. There was no awareness or information regarding adverse drug events of prescription as well as nonprescription medicines. An education and community involvement exercises may help.

P20 SILICOSIS: A SURVEY OF BUNDELKHAND REGION

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Silicosis, a rare disease, it is a form of pneumoconiosis, caused by excessive inhalation and accumulation of fine free silicon di-oxide (silica) dust. Silica is a very fibrogenic dust causes the development of hard nodules of scar tissue. Silicosis may be entirely benign, with no evidence of immediate or long-term ill effects from the dust deposition in the lungs. Therefore, the most common form of silicosis, called chronic silicosis develop over many years (> 10-20yrs) of exposure, while acute silicosis, the rare form develop quickly (< 2-5 yrs) within short period of exposure to high level of silica dust. Bundelkhand is a rich treasure of minerals, rock, stones, sand, granite and man made thermal power station & steel industries are also located in this region. Therefore, a number of foundries, poultry making, sandstone cutting,

granite cutting take place at all the corners of Bundelkhand region. Muller operaters and other employees and resident in the "dusty" trades may have potential exposure to silica sand. Due to unavailability of specific treatment, there is increased susceptibility to lung infection and tuberculosis. It's essential that the person with silicosis remove themselves from the risks of further silica exposure and that they stop smoking. The present endeavor has been designed on the survey of occupational disease silicosis at the Bundelkhand region. A larger population of workers/population suffered with this disease. Therefore, we would like to draw the kind attention of researchers, physician, NGO and social organization can go a long way in controlling this disease by developing a perfect diagnostic kit, vaccine and alternative medicines.

P21 Suspected Adverse Reactions To 'Safe' Traditional Medicines

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Interest in alternative remedies, including traditional herbal medicines is increasing world wide owing to their lower cost, easy availability and a common belief of less associated adverse effect. However, it is important to be aware that not all 'natural' medicines and therapies are necessarily safe. Literature supports several evidences of adverse reaction to a herbal remedy due to an effect of one of the intended constituents of the herbal remedy; contamination or substitution with herbs known to be toxic (such as Aristolochia); use of heavy metals; illegal inclusion of a medicine (e.g.corticosteroids).Monitoring the safety of herbal remedies, reporting of suspected adverse reactions to unlicensed herbal remedies is necessary in present scenario. In the present work some adverse effects, interaction and warnings of most commonly used traditional herbal medicines is reported.

P22 Tuberculosis in Jhansi (Parichha): Problems And Prospects of Treatment and Control

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Tuberculosis is a chronic granulomatous disease. It continues to be the major concern all over the world, despite all the advances in medical science. It is the major cause of morbidity and mortality. As per WHO one patient of TB dies every minute in India. Realizing its seriousness, the Indian government has launched the National Tuberculosis Programme. The recommended treatment for tuberculosis was a combination of four (4) drugs. As the man-made thermal power station is located in Parichha region of Jhansi, therefore a survey was conducted .It was found that due to increased amount of dust (coal, stone crushing) in the atmosphere, where the mycobacterium tuberculii gets trapped and becomes the major cause of infection through the inhaled air. Our studies showed that the treatment was obscured by the improper diagnosis between the tuberculosis and silicosis. It was observed that in a population of 5000 about 75 patients were tuberculosis carriers, 80% of these were pulmonary tuberculosis. Jaundice was noticed as the major adverse reaction in 40% of the population of tuberculosis.

P23 DRUG UTILIZATION STUDY RESEARCH

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Objectives: Prescribing errors encountered among the outdoor patients of C.R.Gardi Hospital, Surasa, Ujjain, M.P. and methods to prevent them.

Methodology: All the prescriptions of different outdoor patient departments were audited in toto along with relevent clinical information. Following areas were put under scrutity to detect common prescription errors. **1.** Completeness of Prescription; **2.** Possible incompatable drug Interactions; **3.** Appropriateness of dose, route, frequency and duration as compared to standard treatment guidelines; **4.** Selection of drugs based on National Essential Drug List; **5.** Polypharmacy

The concerned physicians were given a questionaire as to which error was most dangerous, preventable and asked sugestions to prevent them.

Results: Out of 628 Prescriptions evaluated, 82% (514) prescriptions were erroneously/incompletely formulated. 28% (176) prescription contained two or more incompatable drugs altogether. 19%(119) prescription were inappropriate regarding any of dose, route, frequency and duration. 7% (44) drugs were not listed in National Essential Drug List.(1992).The average number of drugs were 3.9% prescription 0.5 %(31) prescription contained 8 or more drugs while prescriptions contained as many as maximum of 15 drugs at a time. 90% of the physicians considered that the most serious error was prescription of incompatable drugs while 8% answered that missapropriate dose, route, frequency and duration was most dangerous, 2% opted multiple choices. 100% opined that the error most easily preventable nad is due to wrong spells.

Conclusion: The most common form of error was incompleteness of prescription while the error, which is poteltially most dangerous, is drug drug incompatabilaty, which needs to be prevented. According to the suggestions the most suitable method for improvement is continuing medical education.

P24 BIO-ORGANIC FORMULATION FOR TREATING DERMAL INFESTATION IN DOGS

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Chemical miticides have been in use for the last few decades. Because of the projected toxicities and high cost of allopathic drugs along with health risk to humans exposed to such drugs, it is high time to access and evaluate bio-organic formulations in the treatment of mite infestations (mange). Further, these days, already the use of some ectoparasiticidal chemicals has been highly reduced or not recommended because of the risk of human exposure. In animals, the use of bio-organic formulations in therapy of management is in its various stages of development but still the possibility for development of a highly effective herbal preparation is to be explored. Olinall lotion, a bio-organic formulation was tried against Sarcoptes scabiei var canis (a microscopic ectoparasite i.e, mite) on dogs and its efficacy was compared with that of cypermethrin. Skin scrapings examined at scheduled intervals after the topical application of Olinall lotion caused complete recovery after 12 to 15 days in severe infestation and 6 to 9 days in mild to moderate infestations with regrowth of hair on Day 30 post-treatment. No adverse reactions were observed except mild irritation and restlessness, which persisted for a few hours soon after application.

PL02 DRUG UTILISATION IN DIABETES MELLITUS

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Physicians prescribing pattern vary from patient to patient. A drug is selected by considering both the patient related and drug related factors. Superiority of a drug over the others is decided by equally considering all the factors like cost of therapy, efficacy, and safety of a drug, co-existing disease conditions and suitability for a patient. Both qualifications and practicing area has influenced prescribing habits in diabetes mellitus. Both the availability of drug in rural area and physicians inialility to retrience current information affect the delection of drug. There is a need of continuing medical education to make correct decision about the choice of drugs in treatment of diabetes mellitas.

PL04 NEED FOR PHARMACOVIGILANCE OF COSMETICS

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Pharmacovigilance is the science and activities relating to the detector, assessment, understanding and prevention of adverse or any other drug related problem (as defined by WHO, "Adverse Drug Reaction" or Adverse Reaction is a response to a medicine in Pharmacovigilance is changing and growing into a clinical, scientific, regulatory discipline, WHO programme for international drug monitoring started as a small research project. Now the programme has grown to embrace 60 countries. The Upasaia Monitoring Center technologies to support this large internation endeavor. This public health programme is or the increase, concernt use of many OTC and herbal preparations. Cosmetics suggested by several beauticians/dermatologists without knowing each others prescriptions/suggestions recommendations. Lack of regulation, use of many cosmetics ingredients banned by FDA, but still in use due to the trade secret plea (menthylene chloride). Cosmetics are not subjected to pre-market approval by regulating agercies. Safety/effiency testing or good manufacturing practices by the FDS. The statutory warming "excessive use is injurious to skin" is missing on luning packages. No mentioning of storage condition on the cosmetics package, leading to early expiry. Lack of information and training: Incidence of cosmetics injury due to bad prescribing, dispensing and poor practices. It's not easy to be an informed consumer. Consumers can read the labels but their chemistry to decipher is difficult for the ordinary consumer. Exaggerated claims by manufactures of cosmetics-such as whitening of skin, anti-pigmentation anti-acne, anti-aging. An FDA analysis (1968-1972) of 138 compound used in cosmetics that most frequently involve in adverse reaction, identify it 5 chemical (alpha-terpineol, benzyl acetate, benzyle alcohol limonene and linalool) that are among the 20 most commonly used fragrance products tested by EPA in 1991. 95% of the chemicals used in frangrances are synthetic compounds derived from pteroleum. They include benzene dentives aldehydes and many toxic sensitizers-capable of causing cancer, both defects, CNS Disorders and allergie reactions, (Report by the committee of sciences and technology, 1986). More than 105 ingredients available for use in cosmetics are suspected to cause cancer (like stains, dyes and lead etc.). Cosmetics may cause adverse effects on the nervous system, including convulsions. Some ingredients cause adverse effects on the nervous system, including convulsions. Some ingredient cause teratogenic defects and injury. Many ingredients banned by FDA still are in use are as no enforcement possible due to trade secret lawas protecting chemical fragrance industries. A 13-month-old girl was treated died of cyanide poisoning after awallowing a liquid used to remove artificial nails. A two-year-old boy was rushed to emergency room for rigonous intensive care unit after his parents found him bed vomiting, moaning and unresponsive, after have prevented these causalities. This can be lackled by the introduction of expirty date on the lable, storage condition of the product and it's shelf on the label, quality control and quality assurance of cosmetics, preventing polypharmacy and introduction of cGMP in cosmetic industries. The detailed ADF reported so far will be presented.

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