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Chief Research Officer <chief.researchofficer@sumandeepuniversity.co.in> Tue, Aug 22, 2017 at 9:55 AM
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RESEARCH NEWSLETTER

May - July, 2017

4th Issue

Research Cell

2nd Floor, Pharmacy Building,
Sumandeep Vidyapeeth
Vadodara - 391760.

It is our pleasure to release 4th issue of Research Newsletter. This Newsletter reflects activities of Research Cell of last quarter. The theme of the present issue is on ADR and its research prospects considering its socioeconomic and clinical importance.

Adverse Drug Reaction (ADRs) is the 4th leading cause of death, when compared to AIDS, pulmonary disease, motor car death and accidents. A huge amount of money worth $136 billion is poured to cover ADR globally including ADRs of ambulatory and nursing home patients. Medical Professionals are expected to report ADRs which may significantly turn down the frequency of hospitalization and mortality *(Development and regulation of drugs. In: Katzung BG. Ed. 10th edn. McGraw-Hill,*

senior faculty, Dr. (Mrs.) B.M. Sattegiri, Professor & Head, Department of Pharmacology, SBKSMI & RC, on ADR and its management at our institute. The experience and expertise of Dr. (Mrs.) B.M. Sattegiri will be the guiding force for our faculty and the students to avoid the negligence of reporting ADRs.

Research Cell believes that sufficient numbers of hypothesis based research proposal will be received from our Clinicians, Pharmacologists, Clinical Pharmacists, Nursing faculty, Dentists, Physiotherapists and healthcare management professionals.

Research Cell feels that this issue of Newsletter will update our faculty and researchers. Suggestions are

2007).

Research Cell is sincerely thankful for an exclusive interview of our

always welcome to make this communication more meaningful.

- Director Research

CONTENTS

RESEARCH RELATED UPDATES

1. Budget allocation for each institute for the academic year of 2017-18

Research Budget has been allocated to each institute for the year of 2017-18 and the information of the same has been circulated to each institute. We are expecting evidence/ hypothesis based high-end research proposals from the faculty for utilization of the research budget.

2. Collaboration with Institutes/Government Agencies at State level

Last quarter, SBKSMI & RC has established two collaborations, one was with **Health & Family Welfare Department, Government of Gujarat** for functioning of Rural Health Training Center, Urban Primary Health Center, Primary health Center and Public Health Center by Interns as per MCI guidelines. Another one was with **Vaman Trust, Bhadalpur** to provide quality medical and health care to the needy rural/ tribal people. Department of Prosthodontics, KMSDCH has established collaboration with **Department of Prosthodontics, AMC Dental College, Ahmedabad** to facilitate promotion of academic and research co-operation under mutual benefit.

3. Winners of University Research Awards for the academic year-2016-17

Sr. No.	Name & Designation	Department & Institute
1	Dr. Chirag Kapoor, Assistant Professor	Orthopaedics, SBKSMI&RC
2	Dr. Chandramani More, Professor & Head	Oral Medicine & Maxillofacial Radiology, KMSDCH
3	Dr. Nirmal Shah, Associate Professor	Department of Pharmacy
4	Prof. Dr. Lata Parmar, Professor & Principal	College of Physiotherapy
5	Anjali Kukreja, UG Student	SBKSMI&RC
6	Mr. Pandya Kartik, PG Student	Department of Pharmacy

Apart from above Research Awards, one special Award has been conferred upon Dr. R. Balaraman, Professor, Department of Pharmacy, for publishing research article in high impact factor journal (J. of Diabetes; Thomson Reuters IF- 3.039). (i.e. Highest among all publications for the year 2016-17).

4. Distribution of Research Award for the academic year 2014-16

For the outstanding contribution under various research activities, winners were conferred upon 'University Research Award' for the academic year 2014-16.

5. Achievement by our faculties

i. Research done by Dr. Steffi Dhillon under the guidance of Dr. Anshula Deshpande, Professor, Dept. of Paediatric & Preventive Dentistry, KMSDCH was selected by Public Health Agency of Canada under the heading of *Best and Promising Practices*. This research has been appraised and being reflected on the Canadian Government Web Portal. It's an achievement in terms of recognition of research work at international government agency.

Congratulations Dr. Anshula and her team...!!!

(http://cbpp-pcpe.phac-aspc.gc.ca/ppractice/perinatal-oral-health-care-education-program-for-gynaecologists/)

ii. Dr. A. K. Seth, Professor & Head, Department of Pharmacy, has published two books in the field of Pharmaceutical Science. The title of the books are "A Textbook of Pharmaceutics" and "Pharmaceutical Microbiology".

Congratulations Dr. A.K. Seth...!!!

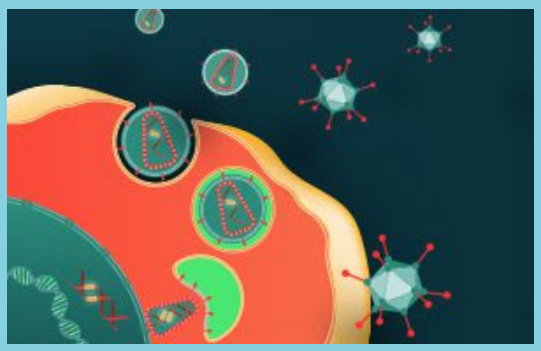
FOLLOW UP NEWS OF PREVIOUS RESEARCH THEME

(i.e. Antibiotic Resistance and Stem Cell Research)

IIT Delhi team develops a new antibacterial drug-delivery system

A new antibiotic drug-delivery system has been tested by researchers at the Indian Institute of Technology (IIT) Delhi that improves the efficacy of drugs thereby reducing the dosage used for treating bacterial infections. A peptide has bound to gold nanoparticles was able to kill *E. coli* and *Salmonella typhi* more efficiently at lower dosages.

Dr. Neetu Singh from the Centre for Biomedical Engineering, IIT Delhi, and one of the corresponding authors of the paper published in the journal Scientific



Gene Therapy in a Patient with Sickle Cell Disease

Sickle cell disease results from a homozygous missense mutation in the β-globin gene that causes polymerization of hemoglobin S. Gene therapy for patients with this disorder is complicated by the complex cellular abnormalities and challenges in achieving effective, persistent inhibition of polymerization of hemoglobin S. Scientists of collaborative institutes of more than 3 countries treated first patient with lentiviral vector-mediated addition of an antisickling β-globin gene into autologous hematopoietic stem cells.

Reports said that “Drug delivery becomes better and the bioavailability improves when the drug is conjugated [bound] to gold nanoparticles. So reduced dosage is sufficient to kill the bacteria. Reducing the dosage of antibiotics used is one of the strategies to reduce the possibility of drug resistance setting in".

(http://www.thehindu.com/sci-tech/science/iit-delhi-team-develops-a-new-antibacterial-drug-delivery-system/article19435706.ece)

Adverse events were consistent with busulfan conditioning. Fifteen months after treatment, the level of therapeutic antisickling β-globin remained high (approximately 50% of β-like-globin chains) without recurrence of sickle crises and with correction of the biologic hallmarks of the disease.

(http://sci-hub.bz/10.1056/NEJMoa1609677)

Research Theme

ADVERSE DRUG REACTIONS (ADR)

In simplest words, ADR can be expressed as “Unwanted Effects”.

According to the World Health Organization (WHO) and definitions by Karch and Lasagna, an adverse drug reaction (ADR) is “any reaction to a drug that is noxious and unintended, and occurs at doses used for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended response.”

ADRs are major cause of morbidity and place a substantial burden on limited healthcare resources. In addition to human costs, ADRs have a major impact on public health by imposing a considerable economic burden on the society and the already stretched healthcare systems.

In India, around 84,870 Individual Case Safety Reports (ICSRs) were reported under PvPI till May 2014 and 43,161 ICSRs were reported during 1st June, 2014 to 31st May, 2015. Incidence of ADR is between 5.9% to 22.3% while deaths due to ADRs account for 1.8% (Sivsankaran *et. al.*, 2015).

Evaluation of ADRs requires understanding of drug mechanisms and interactions, and of disease diagnostics. Not only the expertise as a pharmacologist, pharmaceutical scientist and a clinician, each healthcare professional can participate in resolving the ADR related issues by being aware and report to the authorized agency of the institute.

ADR BUZZ AROUND THE WORLD

Doctors need awareness of adverse drug reactions

Around 3.7% of all patients visiting the outpatient department (OPD) of hospitals across the country complain of drug reactions while 0.7% even require hospital admission, revealed a study by the Pharmaco-epidemiology and drug safety journal. The reports says that due to lack of adequate awareness among pharmacologists, patients fall victim to adverse drug reactions (ADR) and they mostly go unreported.

(http://timesofindia.indiatimes.com/city/visakhapatnam/docs-need-awareness-of-adverse-drug-reactions/articleshow/59241710.cms)

CDSCO releases revised draft guidelines on post marketing surveillance of pharmaceutical products

The guidelines direct marketing authorisation holders (MAHs) of pharmaceutical products comprising importers and manufacturers to establish a pharmacovigilance (PV) system with a medical officer or a pharmacist who will act as a pharmacovigilance officer in-charge (PvOI) for collection and analysis of adverse drug reaction reports related to pharmaceutical products marketed by them in India.

(http://www.pharmabiz.com/NewsDetails.aspx?aid=102670&sid=1)

Cancer Patients' Drug to Drug Interactions Have Consequences

Drug combinations have the potential to interact, sometimes with deleterious effects, and patients with cancer face a real risk for such drug interactions that have clinical consequences.

(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4843587/)

PvPI of India leads ahead of 149 countries in drug quality as per ICSR submitted to WHO-UMC centre

Pharmacovigilance Programme of India (PvPI) leads ahead with 0.82 points as per quality completeness score of Individual Case Safety Reports (ICSR) as against the global average of 0.55 accounted on a quarterly basis for a total of 150 countries including India which contribute to the global PvP database.

(http://www.pharmabiz.com/NewsDetails.aspx?aid=101369&sid=1)

Antibiotics responsible for 20% Adverse Drug Events

Between September 2013 to June 2014, researchers reviewed medical records of patients admitted to the general medicine services at The Johns Hopkins Hospital. Patients were followed for 30 days after hospital discharge to determine the likelihood of an adverse reaction to antibiotics

and to identify how many adverse reactions could be prevented by eliminating unnecessary antibiotic use. They were observed for up to 90 days for the development of *Clostridium difficile* infection and for development of new multidrug-resistant infections.

In addition to finding that 20% of patients experienced one or more antibiotic adverse effect, researchers also found that antibiotic side effects increased by 3% for each additional 10 days of antibiotic therapy. The most common side effects experienced were gastrointestinal, kidney, and blood abnormalities. A total of 4% and 6% of patients developed *C. difficile* infections and potential multidrug-resistant organism infections. No deaths were attributed to any antibiotic side effects in this study.

The researchers say 24% of patients had prolonged hospital stays; 3% percent experienced additional hospital admissions; 9% required additional ED or clinic visits; and 61% needed additional diagnostic tests due to adverse drug effects.

(http://www.healthleadersmedia.com/quality/study-antibiotics-responsible-20-adverse-drug-events)

Ophthalmic incidents due to Avastin: A cancer drug in need of guidelines

Avastin is a cancer drug of the multinational pharmaceutical company Roche. The molecule name of this drug is Bevacizumab. Opthalmologists across the world have been using Avastin to treat eyes diseases such as age-related macular degeneration (AMD) because it has been extremely cheap compared to other eye medicines in the market, especially Lucentis. In the first week of April this year, over 20 eye patients, who were being treated at Guru TegBahadur (GTB) hospital in Delhi, reported breathlessness, blurred vision, redness, etc after they were injected with a

drug called 'Avastin'. The doctors stated that the incidents happened due to "contamination" of Avastin. This contamination has been happening across the country for three reasons. First, Avastin is a cancer drug that does not contain any preservatives and it needs to be compounded — which means it has to be divided into small doses as per each patient's need —through a "proper aseptic technique" before any ophthalmic usage. Second, it is impossible to divide this drug manually into small doses, which usually come to the value of 0.05 ml and therefore, precision instruments need to be used. Third, there are no guidelines of the Drug Controller General of India (DCGI) or of the health ministry for the safe and effective use of Avastin on eye diseases. The DCGI heads the Central Drugs Standard Control Organisation (CDSCO).

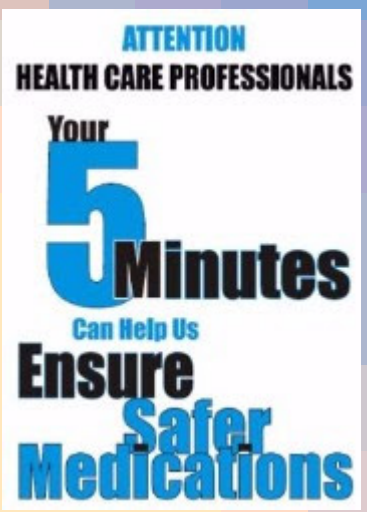
(http://indianexpress.com/article/india/opthalmic-incidents-due-to-avastin-a-cancer-drug-in-need-of-guidelines-4712366/)

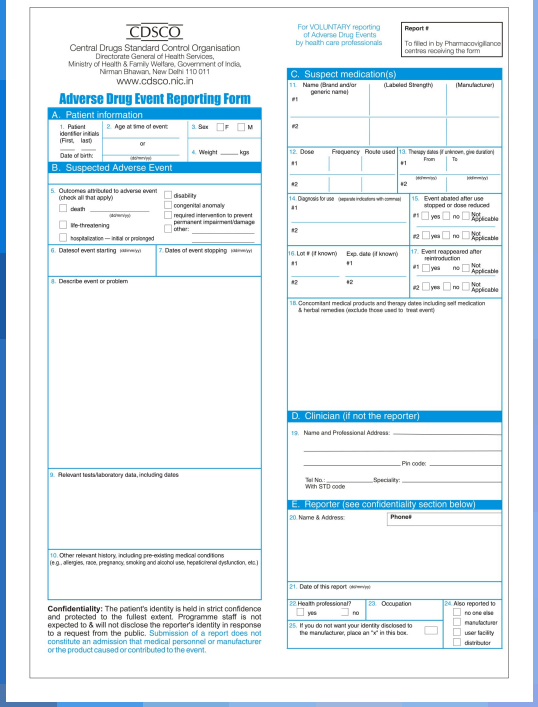
ADR Reporting System in India

In India, ADR reporting is done by filling ADR reporting form, available online on PvPI website, as shown below. One can also report through helpline no. 1800-180-3024 (All working days from 9 AM to 5.30 PM) and through android mobile application of ADR.

ADR Reporting Form

(http://www.ipc.gov.in/PvPI/adr/ADR%20Reporting%20Form.pdf)




CDSCO
Central Drugs Standard Control Organisation
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
Nirman Bhawan, New Delhi 110 011
www.cdsco.nic.in

Adverse Drug Event Reporting Form

For VOLUNTARY reporting of Adverse Drug Events by health care professionals

Report #
To filled in by Pharmacovigilance centres receiving the form

A. Patient information

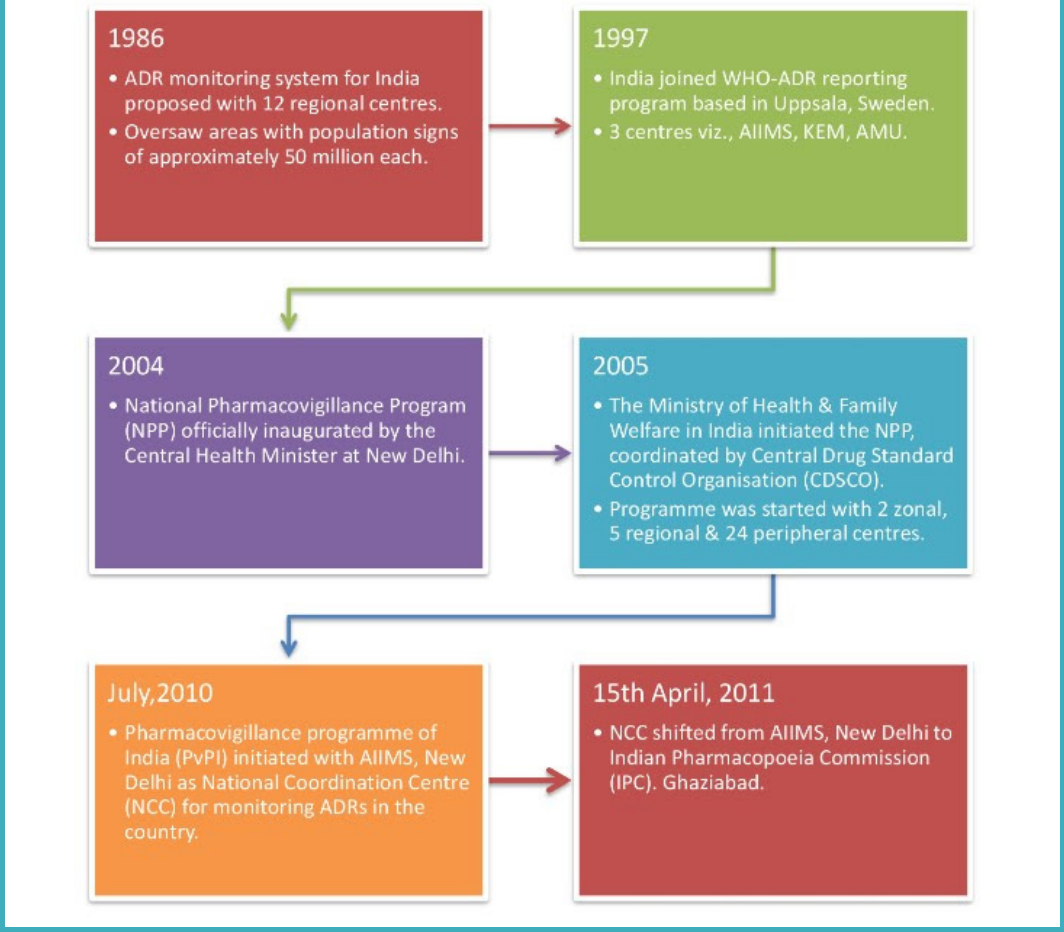
B. Suspected Adverse Event

C. Suspect medication(s)

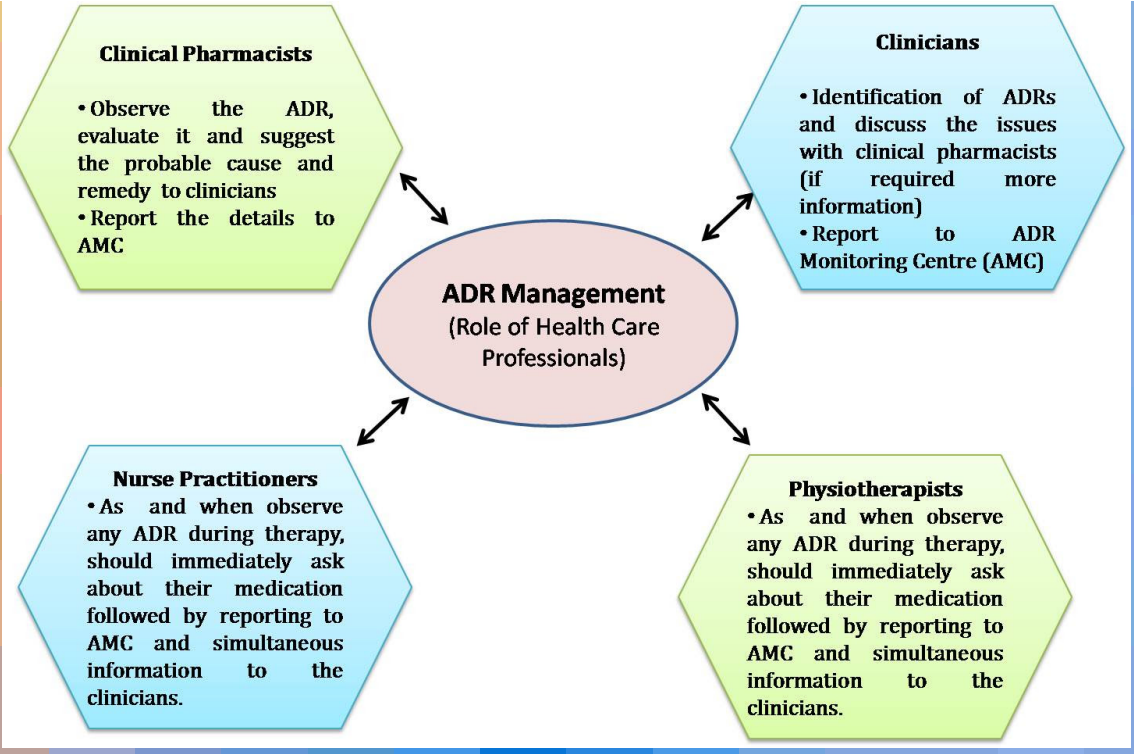
D. Clinician (if not the reporter)

E. Reporter (see confidentiality section below)

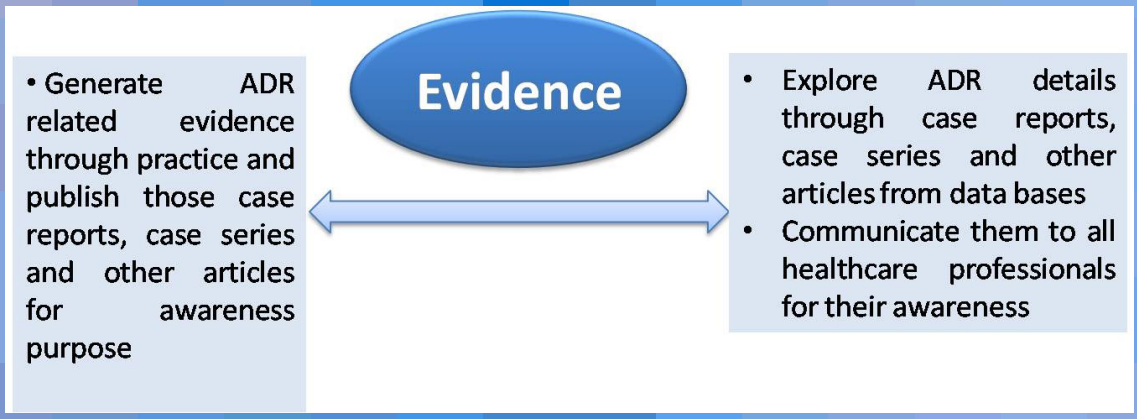
Pharmacovigilance Development in India



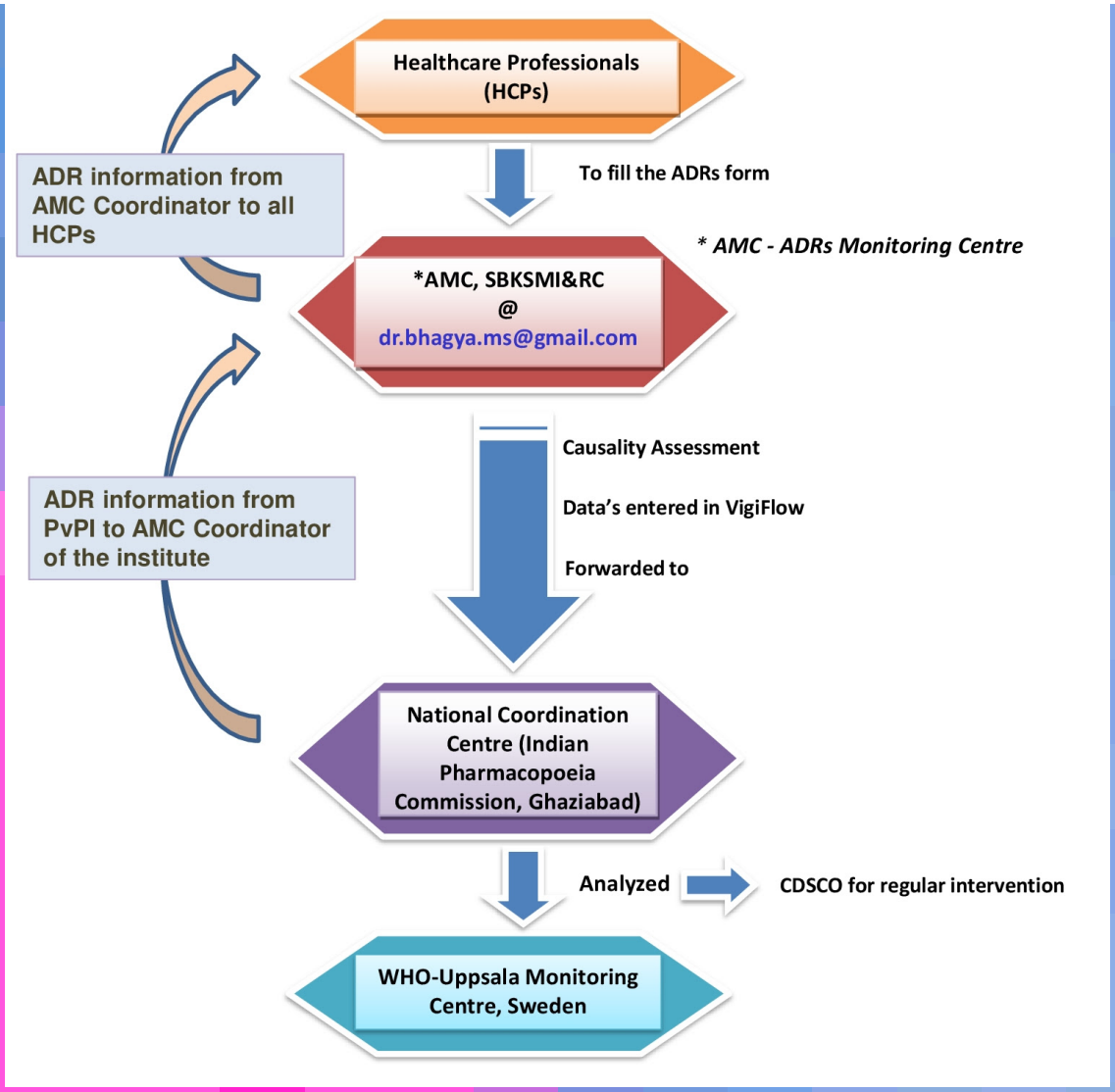
Role of Healthcare Professionals in ADR Management



Evidence Based Education System (EBES) and ADR management



Collation, Analysis & Evaluation of ADR



Guidelines for Managing ADR

The American Society of Health Systems Pharmacists (ASHP) provides guidelines and emphasizes the role of pharmacists in comprehensive ADR management. Here are some tips:

(http://www.pharmacytimes.com/future-of-pharmacy/tips-for-managing-adverse-drug-reactions)

Risk Minimization

- Understand patient views about medication therapy.
- Educate about the benefits of treatment.
- Inform patients about potential ADRs and management strategies should any occur.
- Ensure an updated and accurate medication list.
- Utilize decision support software to help prevent ADRs.
- Start with low doses and frequencies and slowly titrate as tolerated.

- Initiate less potent agents, agents with direct mechanisms of action, or alternatives with lower adverse event incidence.
- Avoid or reduce the use of interacting medications.
- Prescribe dosage forms with minimal systemic exposure (e.g. creams, patches).

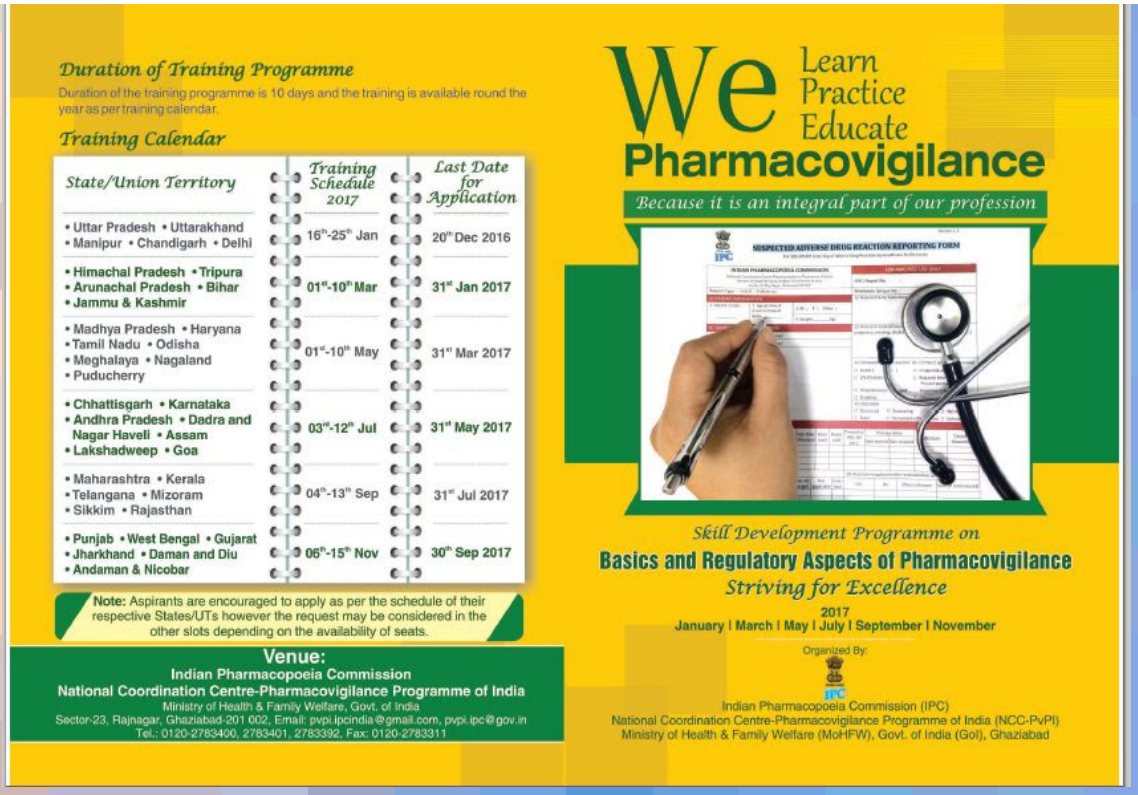
Recognition, Detection

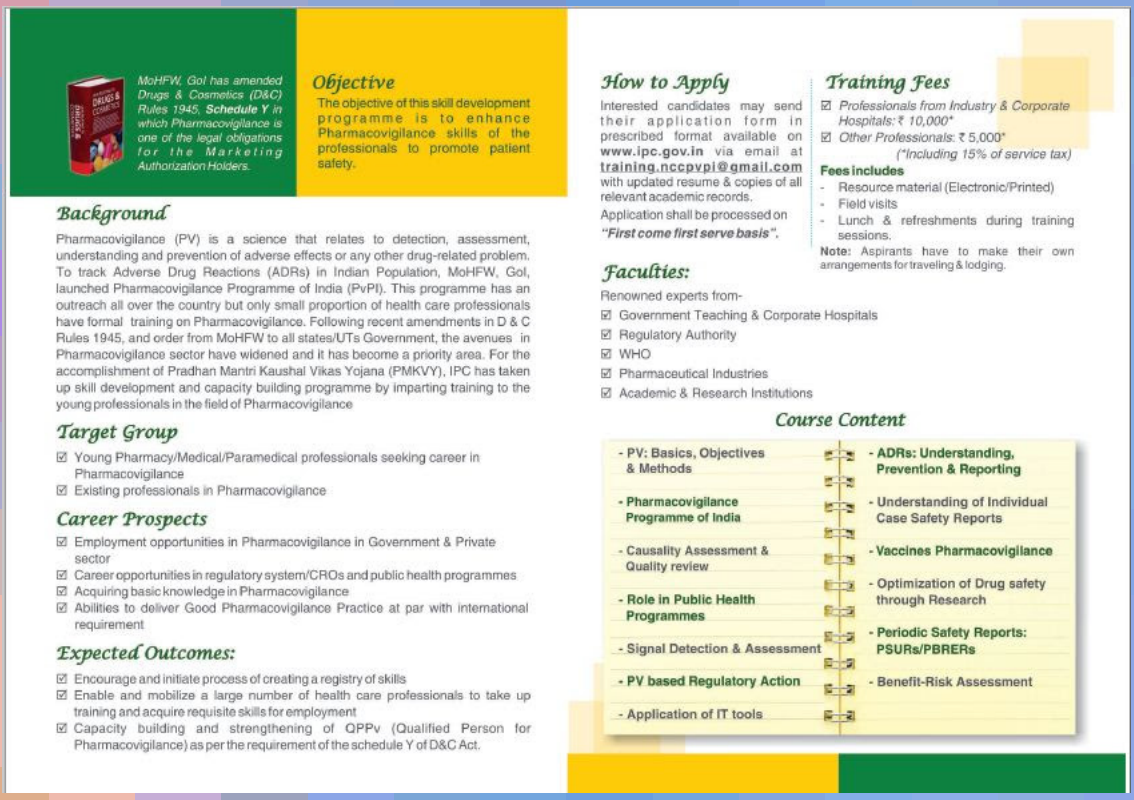
- Be familiar with known ADRs of the medication as well as the patient's preexisting symptoms.
- Evaluate new symptoms as possible ADRs, looking into health conditions, labs, or other factors which may explain the symptoms.
- Consider the temporal relationship between medication initiation and symptom onset.
- Challenge concepts like stopping the medication to see if the symptom subsides in absence of the medication, and restarting to see if symptoms return.
- Utilize lab tests for more evidence to identify an ADR.
- Apply probability tools such as the Naranjo Adverse Drug Reaction Probability Scale or 4Ts for heparin induced thrombocytopenia.
- Express empathy and maintain a trusting relationship with the patient.
- Reduce dosing or discontinue the offending medication.
- Switch to another agent or dosage form less likely to cause ADRs.
- Treat side effects when necessary (beware of prescribing cascades).
- Document the ADR in the patient's medical record.
- If working from a care setting separate from pharmacy, notify the patient's pharmacy to document the ADR in the pharmacy records.
- Report ADRs through appropriate channels such as your organization's reporting system, the drug manufacturer, FDA MedWatch or Vaccine Adverse Event Reporting System.
- Track and trend ADRs for ongoing process improvement.

Upcoming Training Programme on Pharamcovigilance

Indian Pharmacopoeia Commission (IPC) will organise skill development programme on Basics and Regulatory Aspects of Pharmacovigilance in the November 2017. Detail is given in brochure as below:

(http://ipc.nic.in/showfile.asp?lid=641&EncHid=)





From the View Point of Our Faculty

PERSONAL DETAILS	
Name	Dr. B.M. Sattigeri
Qualifications	MBBS, MD Pharmacology

Designation	Prof. & Head, AMC Coordinator
Institute	Dept. of Pharmacology, SBKSMI & RC, SVDU
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Email id	dr.bhagya.ms@gmail.com

Que.1: "Monitoring of Adverse Drug Reaction (ADR) is vital to patient safety and is also leading cause of death in many countries." Kindly express your views on this statement.

Ans.1: Patient safety is a major concern in health care management. Global data reflects that the ADRs significantly decrease the quality of life, increase hospitalization, prolong the hospital stay & increase mortality.

Historical evidence that reflect the damage caused by the administered drug to the human beings like Thalidomide,Sulphanilamide, Clioquinol tragedies and many more have proven beyond that ADRs have been the leading cause of death& disability in many countries.

It is known that every drug has an adverse effect, some of them are known at the time of clinical trial while some remain unknown even when the drug is in clinical use. Vast genetic & ethnic variations, different disease patterns, practice of different system of medicine shows that country like ours needs a chesty program like Pharmacovigilance to monitor the adverse drug reactions.

Que.2: How can we improve awareness of ADR in healthcare professionals of SVDU?

Ans.2: Under the flagship of Sumandeep Vidyapeeth, at SBKS MI&RC we are proud to have a Pharmacovigilance committee that has been established and been functioning actively since 2011.

In April 2016, with the team efforts from the Department of Pharmacology, the Department was recognized as an Adverse Drug Reaction Monitoring Center (AMC) by the National Coordination Centre (NCC), Pharmacovigilance Program of India (PvPI), Ghaziabad and it started to function effectively from June 2016.

Pharmacovigilance committee have organized sensitization programs for all the Health Care Professionals by conducting series of workshops with hands on training to fill the ADR form with GMC accreditation,for all the residents of all institutions at Sumandeep Vidyapeeth. We have been organizing CMEs with GMC accreditation and Guest Lectures (for the undergraduate, post graduates and clinicians of all institutions of the university).

We have also been forwarding the signals received from the PvPI to all the HCPs of our University.

More efforts in the form of competition on poster/ Paper presentations, Quiz, Essay writing competitions help us to create the awareness among all HCPs.

Que.3: Role of Clinicians, Clinical Pharmacists, Nursing and Physiotherapist in the area of Pharmacovigilance.

Ans.3: Clinicians,Clinical Pharmacists, Nursing and Physiotherapists are routinely involved in patient care. They can monitor the drugs in use for the occurrence of the ADRs. Spontaneous reporting system is one of the ways by which they can report the suspected adverse effect.

Clinicians are the better judge to decide whether the reaction occurred is due to drug interaction, an adverse event or an adverse drug reaction. Similarly, the clinical Pharmacists can avoid the practice of OTC medications by insisting on the medical prescriptions, thus contributing to the Pharmacovigilance program.

However, there is poor understanding with the HCPs about the ADR reporting for which there occurs under reporting. Therefore, it is important that every HCP understands that ADR report is meant to improve our understanding about the medicines and to improve the safety measures in the Health Care management.

Que.4: SVDU is EBES specialized institute. How this unique practice has a positive impact in ADR management?

Ans.4: The practice of EBES is unique to our university. All the academic programs and the training programs (FDPs) are core to EBES. The materials used in the training programs are substantially evidence based.

This has been reflected with the active interactions of HCPs that occur during the training programs and is also evident with the improvement in the reporting system of ADRs.

The rigorous training programs conducted by the Department of Pharmacology, SBKSMI&RC have influenced all the HCPs across the university.

Que.5: What is your opinion on the role of synchronized/systematic data registry of patients at each medical/dental/paramedical department for ADR management?

Ans.5: Maintenance of the patient records is of great importance. At our university, there is a good practice of documentation and maintenance the records.

Proper recording of the suspected ADRs at all levels of hospital records (OPD Cards, IPD case files) and reporting the same to the AMC will be of great help, so that adequate care is administered by the treating physician/any HCP, to the patient who suffered with the ADR.

The record would be a caution for the use of the same drug in future.

The data registry and data mining can be of great help in retrospective studies and would be guide for case management as they serve as rich source of information

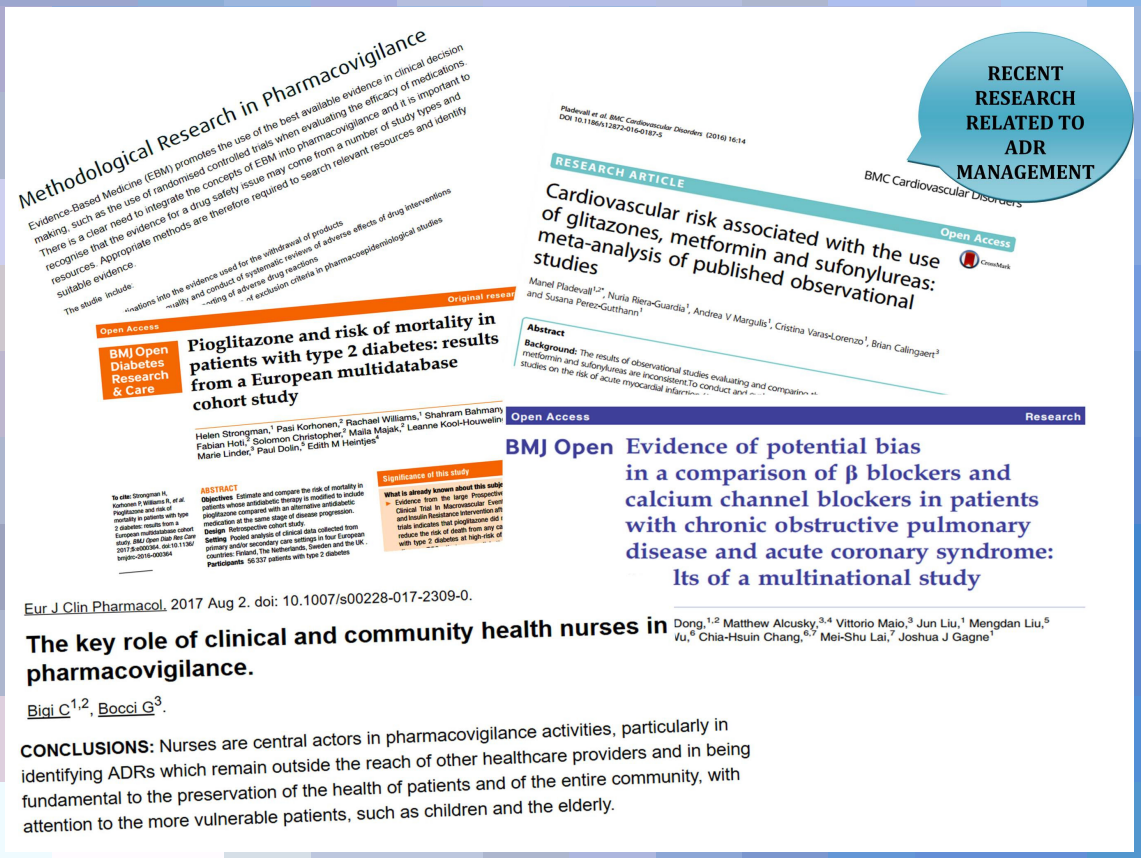
about the medicine safety. They are also useful for the research in the field of Pharmacovigilance and Pharmacoepidemiologic studies, which are the emerging fields of research.

Que.6: How our clinical/ paraclinical faculty and researchers can design hypothesis based/ evidence based/ innovative research proposals under this subject with a broader objective?

Ans.6: Field of Medicine is very vast. The descriptive studies will enable to generate hypothesis which can be either in the form of spontaneous reporting or intensive monitoring, while the analytical studies can be in the form of case control studies, cohort studies & clinical trials which can be rigorously conducted by our faculty and researcher for either a newly marketed drug or the old drug.

The integration of the Pharmacovigilance program of India with some of the National control programs like Tuberculosis, Vector borne diseases, Helminthic infestations &Vaccines, also with the introduction of special branches like Hemovigilance and Materiovigilance. It opens a wide area for research to benefit the mankind.

Recent Research articles related to ADR management



FEATURE NEWS

Doctors Without Frontiers

Virtual medicine is coming, but India must stand ready to seize the manifold opportunities

Devi Shetty

Online retail is a lot more complicated to deliver than online healthcare. If Mr Ghosh, who makes the best rasagulla in Kolkata, wants to send his fresh product to Bengaluru, he will confront a nightmare in terms of the cold chain logistics of transportation. Instead, if Mr Ghosh wants to consult a doctor in Bengaluru for acute chest pain from Kolkata, the doctor can converse with him on a video call and ask for some tests.

With a map app, the doctor can then direct him to the nearest diagnostic lab. When the tests are done, before Mr Ghosh puts on his clothes the doctor can see the test reports online, reassure him that his heart is fine and prescribe a pain killer.

Online retail needs to move products from point A to point B through complex logistics. Online healthcare just needs images and data to reach from point A to point B, which can be done from anywhere in the world virtually free. All it needs is an expert doctor with an internet connection and a payment gateway.

When you hear that someone is unwell, 99% of the time a sick person doesn't need an operation. Technically, 99% of illnesses can be treated online. The treatment decision depends on history which video conferencing will provide, and interpretation of lab and organ image reports which can easily be done virtually.

Today hand held devices can check

Uday Deb

The rest of the time, such things as seasonal cold and cough can easily be managed online, which is convenient for both child and mother.

The big advantage of online healthcare is that it is at one's fingertip, convenient for both patient and doctor since the patient can be in his bedroom and doctor may be stuck in a traffic jam. Patients from rural India can consult city experts at the click of a button. Because of the conveni-

Through a digital sharing economy, India can become the first country in the world to dissociate healthcare and other essentials of life from affluence

matter of time before doctors from Bangladesh or Pakistan will fill the vacuum.

Some changes are, therefore, urgently necessary. The Medical Council of India should adopt regulations permitting doctors to offer virtual consultation and legalise virtual prescriptions. According to Indian law a doctor's advice to patients even on telephone – a common practice today – is illegal unless it is a medical emergency.

Second, the government should define the standards for EMR development – respecting data privacy but not following the expensive HIPPA compliance so that start-ups can create mind-blowing doctor-friendly EMR on a dynamic cloud platform, unlike the billion dollar US EMR which doctors hate.

To develop doctor-friendly EMR, a technologist should work with doctors with free access to patients' data. In the US – a country where patients' data is more sacred than patients' lives – this can't happen. This is a billion dollar opportunity awaiting Indian technologists.

Through a digital sharing economy, India can become the first country in the world to dissociate healthcare and other essentials of life from affluence. India will prove to the world that the wealth of a nation has nothing to do with the quality of healthcare its citizens enjoy by offering high-tech care to the common man on a digital platform.

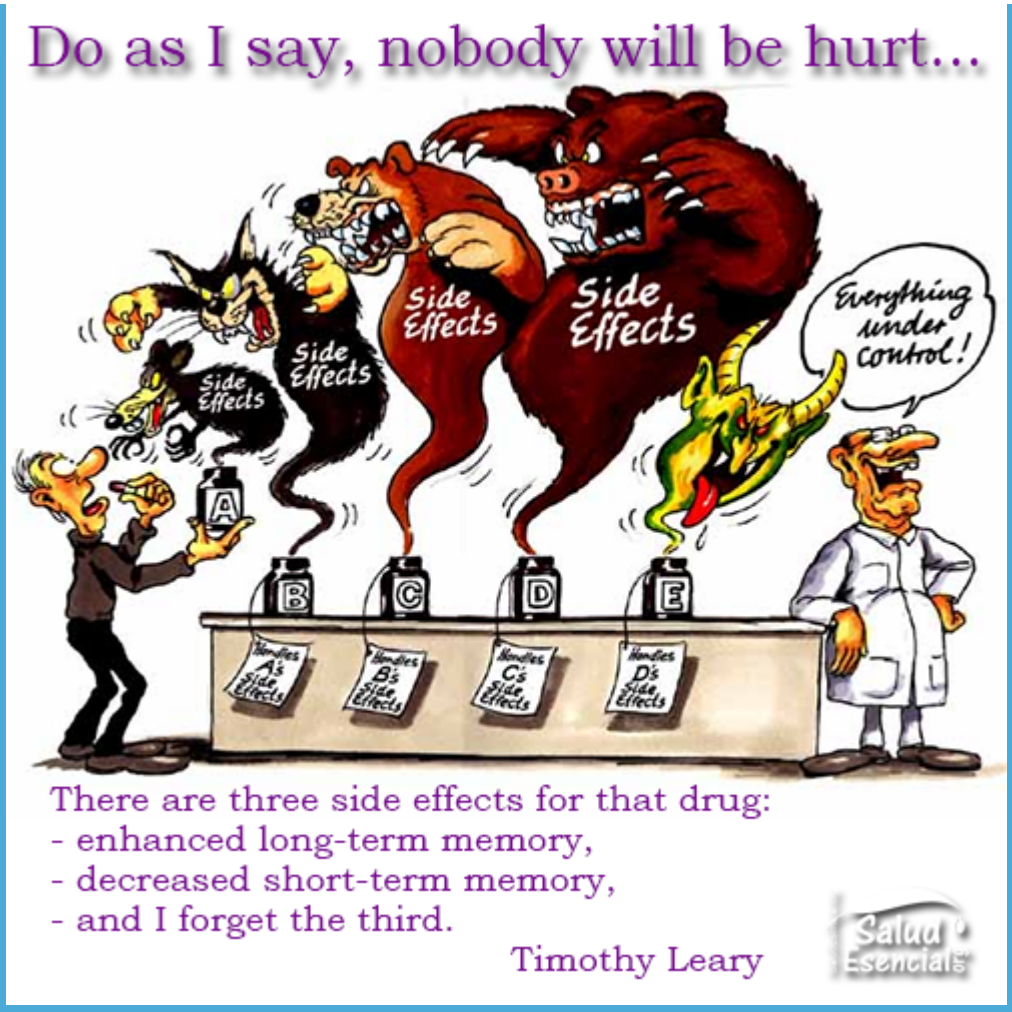
However, this will only happen if IT solution providers don't get carried away with billion dollar valuations and offer services for a tiny amount of money

5th May 2017, Times of India

(http://blogs.timesofindia.indiatimes.com/toi-edit-page/doctors-without-frontiers-virtual-medicine-is-coming-but-india-must-stand-ready-to-seize-the-manifold-opportunities/)

New Appointment in Research Cell

Ms. Nirali Chokshi is newly appointed as Research Associate in Research Cell with additional duty as an Assistant Professor in Department of Pharmacy.



For your suggestions, mail us on

chief.researchofficer@sumandeepuniversity.co.in