

Pharma Insight

Newsletter



A Biannual Newsletter from Department of Pharmacy Practice, KLE College of Pharmacy, Bengaluru

About College

KLE College of Pharmacy is the constituent unit of KLE Academy of Higher Education & Research (Deemed to be University), Belagavi, which is Re-Accredited by NAAC "A Plus" grade by UGC. We are running D.Pharm, B.Pharm, M.Pharm, Pharm.D and PhD courses in a spacious well-equipped building of its own with hostel, library and sports facilities. The pharmacy curriculum is approved by Pharmacy Council of India (PCI) and All India Council for Technical Education (AICTE). The UG programme is accredited by the NBA (National Board of Accreditation).

Department of Pharmacy Practice

KLE Academy of Higher Education and Research (KAHER), Belagavi has started Doctor of Pharmacy course in its constituent college, KLE College of Pharmacy, Bengaluru in the year 2014. To impart education, the pharmacy practice department is having adequate infrastructure and facilities as per the requirement of statutory bodies for the students from Doctor of Pharmacy course and PhD programme. All the faculty members have rich experience to make the student excel in her/his studies and to suit the professional opportunities in the hospital, clinical research and pharmaceutical industries.

Our department is associated with Aster RV Hospital, JP Nagar, Bengaluru, which is located 12 kilometres away from the college premises. In addition, it is associated with Prakriya Hospital, Nagasandra, Bengaluru, which is 10 kilometres away from the institution. Moreover, KLE bus facility is available from KLE Hostel, College and Hospital.

The department is keen to have collaboration with other hospitals, clinical research organizations and pharmaceutical industries towards the pharmacy practice related research projects and services.

KAHER CONDUCTS ITS 14TH CONVOCATION TO HONOUR SCHOLARS



The KLE Academy of Higher Education and Research (KAHER, Belagavi, Deemed-to-be-University) has conducted its 14th convocation ceremony on May 27, 2024 [Monday] at KLE Centenary Convention Centre, JNMC Campus, Belagavi, Karnataka. The ceremony was graced by the Chief Guest, Shri Jagdeep Dhankhar, Honorable Vice-President of India, Guests of Honour, Shri Thaawar Chand Gehlot, Honorable Governor of Karnataka, Honorable Chancellor Dr. Prabhakar Kore, KAHER, Dr. (Smt.) Sudesh Jagdeep Dhankar, Vice-Chancellor Dr. Nitin M. Gangane, Registrar Dr. M.S. Ganachari, Members of the Board of Management of the KLE Society and Academic Council Members, Deans of Faculties, Principals, Heads of various departments of KAHER and other distinguished members.

Chief Guest, Shri Jagdeep Dhankhar, delivered the convocation address. Exhorting the students to always keep the nation first, he urged them not to be guided by fiscal considerations while serving humanity at large. "Fiscal considerations have to take a back stage. Service has to be your primary motto". Referring to our millennia old civilization, he said that no other country can rival our civilization ethos. Urging the students to catalyze big change for a Viksit Bharat at 2047 as India regains its past glory and becomes the most developed Nation of the world by the year 2047. Further, he advised the students not to fear about failure and keep working for the betterment of the society. He reaffirmed Swami Vivekananda's quote 'Arise, Awake and Stop not till the goal is reached'. Further he underlined that, "Bharat is the fastest developing major economy on the globe. Our march is sustainable and for the welfare of the entire humanity". The Chief Guest and Dr. Smt. Sudesh Dhankhar planted a sapling in the JNMC campus to mark the occasion.

Dr. Nitin M. Gangane, Vice-Chancellor, KAHER welcomed all distinguished guests and outlined the achievements of the University for the year 2023-24. He informed that KAHER, has earned national and international recognition in the field of health sciences within a short span of 18 years. KAHER, for the first time, awarded Honorary Degree of Doctor of Science (D.Sc.) (Honoris Causa) to Dr. Richard Derman, Vice-Provost, Global Affairs, Director of Global Health Research & Professor of Obstetrics & Gynecology, Thomas Jefferson University, Philadelphia, USA in recognition and appreciation of his significant contribution for overall global health initiatives including collaborative research, educational exchanges on clinical initiation and for his long-standing research collaboration with KAHER, Belagavi, particularly on maternal and new-born health. In his acceptance speech, Dr. Richard Derman thanked faculty and researchers of KAHER who worked with him for 23 years. He said that many faculty and students are benefitting with mutual academic and research exchange program between KAHER and Thomas Jefferson University, Philadelphia, USA under the guidance of Chancellor and Vice-Chancellor, KAHER.

A total of 1739 Degrees were awarded in various disciplines of Health Science including 39 Gold Medals for their academic achievements in their respective courses / specialties by Chief Guest; the degrees included 30 PhDs, 13 Post-doctoral (DM/M.Ch.), 644 Post-Graduate, 1023 Under-Graduate, 9 Post-Graduate Diploma, 4 Diploma, 5 Fellowship and 11 Certificate courses.

KAHER CONSTITUENT, KLE COLLEGE OF PHARMACY, BENGALURU, RECEIVES AWARD IN THE AREA OF PHARMACEUTICAL CHEMISTRY

Dr Subhas S Karki, Professor and Head, Department of Pharmaceutical Chemistry has received an "Award of Outstanding Research Publications (AORP)" for the academic year 2023-24 on the basis of his quality of research scientific publications. This award was presented by the committee constituted under the Chairmanship of Prof. C. N. R. Rao, Bharat Ratna, the Vision Group on Science & Technology (VGST), Department of Science & Technology (DST), Government of Karnataka.

DEPARTMENT SERVICES

Adverse Drug Reactions Reported*

Generic name	Dosage form	Adverse Drug Reactions
Enoxaparin	Injection	Hematuria
Torsemide	Oral	Hypokalemia
Piperacillin and Tazobactam	Oral	Rashes
Furosemide	Injection	Hypokalemia
Cefoperazone and Sulbactam	Injection	Rashes and itching
*January to June 2024		

Case, Journal and New Drug/Medical Device Club Presentations*

Type of Presentation	College
Case Presentation	74
Journal Club Presentation	53
New Drug Presentation	65
*January to June 2024	

Department Publications*

Sl. No.	Type	Published	Accepted	Communicated
1	Research article	03	00	00
2	Review article	01	00	00
*January to June 2024				

Workshops and Short Term Courses Attended*

Type of workshop	Number
Webinar	26
Workshop	26
Guest talk	04
Short term program	27
Conference attended	26
*January to June 2024	

PhD Scholar Received Travel Grants

Dr. Feroze Fathima, Ph.D. scholar has received a travel grant of INR. 2,500 for having presented her research paper on the title “Cost estimation for treating children with adverse events following pentavalent vaccination in a rural area of Chikkaballapur district” under the guidance of Dr. Mahesh NM, Professor and Head, Department of Pharmacy Practice, during the National Conference on Health Economics and Outcomes Research (March 8-9, 2024), jointly organized by the NGSIM Institute of Pharmaceutical Sciences, Deralakatte, Mangalore, and ISPOR Nitte Student Chapter, Mangalore, Karnataka.

NEW DRUGS / DRUG FORMULATIONS APPROVED IN INDIA

GENERIC NAME	DOSAGE FORM	ROUTE AND STRENGTH	INDICATIONS	APPROVED DATE
Tirzepatide	Injection	SC 2.5mg/0.5ml 10mg/0.5ml	To improve glycemic control in adults with Type II diabetes mellitus	19-01-2024
Plazomicin	Injection	IV 500mg/10ml	Treatment of complicated urinary tract infections (cUTI), including pyelonephritis	02-02-2024
Etifoxine Hydrochloride	Capsule	Oral 50mg	Indicated for psychosomatic manifestations of anxiety	21-03-2024
Vonoprazan fumarate	Tablet	Oral 10mg 20mg	Prevention of recurrence of gastric ulcer or duodenal ulcer during low dose aspirin or NSAIDs administration	08-05-2024
rdESAT-6 and rCFP-10 (Cy-Tb)	Injection	ID	Detection of Latent - TB for population of age group 1 year and above.	16-05-2024
Selpercatinib	Capsule	Oral 40mg 80mg	Adult patients with metastatic RET fusion-positive non-small cell lung cancer(NSCLC)	16-05-2024
Nelarabine	Injection	IV 250mg/50ml	Treatment of patients with T- cell Lymphoblastic leukemia and T- cell Lymphoblastic lymphoma	31-05-2024
SC – Subcutaneous; IV- Intravenous; ID – Intra dermal				

- <https://cdsco.gov.in>

Mr. Nesar S
IV Pharm D.

Section editors: Dr. Mandara M.S.

NEW DRUGS APPROVED BY FDA

Brand Name	Generic Name	Route and Dose	Indications	Approval Date
Zelsuvmi	Berdazimer	Topical gel: 10.3%w/w	Molluscum contagiosum	Jan 05, 2024
Exblifep	Cefepime and Enmetazobactam	Intravenous Infusion 2g + 0.5g	Complicated urinary tract infections	Feb 22, 2024
Tevimbra	Tislelizumab-jsgr	Intravenous Infusion 200mg	Metastatic oesophageal squamous cell carcinoma	Mar 13, 2024
Tryvio	Aprocitentan	PO: 12.5mg	Hypertension	Mar 19, 2024
Duvyzat	Givinostat	PO: 8.86mg	Duchenne muscular dystrophy	Mar 21, 2024
Anktiva	Nogapendekin alfa inbakicept-pmln	Intravesical : 400mcg	Bladder cancer	Apr 22, 2024
Xolremdi	Mavorixafor	PO: 400mg	WHIM syndrome	Apr 26, 2024
Imdelltra	Tarlatamab-dlle	IV: 1mg,10mg	Extensive stage small cell lung cancer	May 16, 2024
Rytelo	Imetelstat	IV: 7.1mg/kg	Low to intermediate - 1 risk Myelodysplastic syndromes	Jun 06, 2024
Iqirvo	Elafibranor	PO: 80mg	Primary biliary cholangitis	Jun 10, 2024
Sofdra	Sofpironium	Topical gel: 12.45%w/w	Primary axillary hyperhidrosis	Jun 18, 2024

PO: Oral; IV: Intravenous injection;

- <https://www.fda.gov/drugs>

Ms. Neha B
V Pharm D

NEW MEDICAL DEVICES APPROVED BY FDA

DEVICE NAME	CATEGORY & APPLICATIONS	APPROVAL DATE
TZ Medical Adult and Pediatric Multi-Function Defibrillation Electrodes and Adaptors	Medical disposable electrodes are intended for use by trained professionals in hospitals, doctor's offices and emergency medical services for low-energy defibrillation, transcutaneous pacing, cardioversion and monitoring.	Jan 09, 2024
XACT Carotid stent system	A rapid exchange (RX) system designed to deliver the self-expanding stent to the carotid vasculature.	Feb 07, 2024
Xstim Spine Fusion Stimulator	Noninvasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels	Feb 09, 2024
AGENT Paclitaxel-coated balloon catheter	Catheter is intended to be used after appropriate vessel preparation in adult patients undergoing percutaneous coronary intervention for improving myocardial perfusion when treating in-stent restenosis.	Feb 29, 2024
LIAISON Biotrin Parvovirus B19 igG plus LIAISON Biotrin Control Parovirus B19 igG plus.	Laboratory used to detect human parvovirus igG antibodies against the parvovirus b19 antigen in blood	Mar 29, 2024
Triclip G4 system.	Triclip G4 system is used to treat tricuspid regurgitation. Often caused by an enlarged heart or damaged tricuspid.	Apr 01, 2024
Colosense	Laboratory test to detect colorectal neoplasia-associated RNA markers and for the presence of occult hemoglobin in human stool that is not visible to the eye.	May 03, 2024
Cobas HPV test for use on the cobas 4800 system	Laboratory test designed to detect human papilloma virus in cervical sample and self collected vaginal samples	May 14, 2024
BD onclarity HPV assay	Laboratory test for the detection of high-risk Human Papillomavirus	May 14, 2024
Abbott SCS system including prodigy, proclaim plus, proclaim XR, and eterna systems.	ANS Genesis Neurostimulation (IPG) System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs	May 30, 2024

- <https://www.fda.gov/drugs>

Mr. Vasanth P
V Pharm D

Section editors: Dr. Shilpashree B.M.

INVITED ARTICLES

ROLE OF ONCOLOGY CLINICAL PHARMACOLOGIST



The oncology clinical pharmacologist (CP) has a crucial role in cancer patient care through improving medication use including chemotherapy and other high alert medications. As part of multidisciplinary team, CP has major role in assuring safe, effective and cost-effective drug therapy. Role of CP is mainly to identify, prevent and manage any drug related problem including drug choice, dosage, interactions, administration and side effects. Oncology CP need to be very effective in optimizing medication use and has a promising role through providing clinically important interventions regarding medication use.

CP role is emerging as vital addition to the health care team resulting in improved patient care. Interacting with health care professionals on rounds, patient interview, medication reconciliation, and providing patient discharge counseling and follow-up all resulted in improved outcomes. In oncology setting, CP has a major role in the adjustment of medications and being part of multidisciplinary team is recommended to prevent and manage medications errors. CP should be expert in aseptic admixing of chemotherapy drugs.

All chemotherapy drugs are prepared and reconstituted by professional Clinical Pharmacologists or nurses who are well trained in the area of aseptic and cytotoxic drug reconstitution. Preparation takes place within an accredited Positive Isolator Cabinet (Biosafety cabinet) within which there is provision for the safe collection of cytotoxic wastematerials inadvertently generated during the process of chemotherapy drug reconstitution (toxic fumes or spills). Protective clothing must be worn by all personnel preparing chemotherapy drugs which include respiratory masks and double gloves. All chemotherapeutic medicines should be checked for light sensitivity, tendency of drug to cause extravasation, batch number and expiry date prior to reconstitution. Complete details of reconstitution which includes time of reconstitution, patient details, diagnosis, protocol, current cycle, drug details, batch number, expiry date, consultant name, signature of person who reconstituted the medicine must be documented for all patients receiving chemotherapy.

CP has to follow and evaluate the chemotherapy protocols regarding appropriate doses, potential drug interactions and side effects management to achieve safe and effective drug therapy and to prevent medication errors. CP has potential role in symptoms management and was effective in optimizing the use of antiemetic for chemotherapy induced nausea and vomiting. Pain management is another field where clinical pharmacist interventions were effective in improving safety, efficacy and patient satisfaction. Also, CP participation in patient care is important to improve patient compliance to the prescribed medications and avoidance of cost-ineffective drug therapy. Clinical Pharmacologist should reach the events and evaluate the reaction and documenting it in the suspected Adverse Reaction Reporting and documentation form and send the ADR FORM to Pharmacovigilance.

In nutshell, clinical pharmacist role in oncology area is diverse and involve interaction with many professionals from healthcare area.

Dr. Vandana A.M.

Associate Clinical Pharmacologist
Cytocare Hospital, Yelehanka. Bangalore

ALUMNI EXPERIENCE



Myself Arun Kumar, from outgoing batch of 2023 like to express my experience in KLE. As an alumnus of KLE College of Pharmacy, Bangalore, who studied Pharm. D course, had an incredibly transformative experience. The campus includes advanced laboratories and a well-stocked library which enhanced our learning experience. Beyond academics, the college organized numerous workshops, seminars, and conferences that broadened my perspective and kept me updated with the latest developments in pharmaceutical sciences. The foundation laid at KLE College of Pharmacy has been instrumental in shaping my career I am immensely proud to be a KLE College of Pharmacy alumnus.

Dr. Arun Kumar
Clinical Data Analyst
Concert AI, Bengaluru

I'm Janani JVS, and I had the privilege of studying at KLE College of Pharmacy in Bangalore, graduating with the outgoing batch of 2023. My time at KLE College of Pharmacy was nothing short of transformative, setting a strong foundation for my career.



One of the most valuable aspects of my education was the hands-on experience gained during my internship and reinforcing the theoretical knowledge I acquired in classrooms at KLE. Throughout my academic journey, they offered a nurturing environment supported by dedicated faculty members who guided and encouraged me. The laboratories and an extensive library enhanced my learning experience and facilitated comprehensive understanding of pharmaceutical sciences.

Beyond academics, KLE enriched my personal growth through various extracurricular activities and cultural events, fostering a well-rounded education. Engaging in these activities not only helped me to develop interpersonal skills but also allowed me to forge lifelong friendships with fellow students.

Dr. Janani JVS
Research coordinator
Paraxel, Bengaluru

TIRZEPATIDE: AN EFFECTIVE TREATMENT FOR WEIGHT LOSS

Several clinical guidelines recommend pharmacotherapy for obesity. Tirzepatide, a dual glucose dependent insulinotropic polypeptide and glucagon like peptide receptor-1 agonist recently approved in US for the treatment of type 2 diabetes, induced clinically relevant weight reduction in phase 2 studies of people with diabetes. Obesity is a chronic, progressive disease caused by disruptions in the mechanisms that control body weight, often leading to an increase in food intake and/or a decrease in energy expenditure. It often does not receive the same standard of care as other conditions, despite its impact on physical, psychological and metabolic health, which can include increased risk of hypertension, heart disease, cancer and decreased survival. Obesity impacts 650 million people worldwide that results in substantial global morbidity and mortality.

Tirzepatide is the first dual GIP/GLP-1 receptor co-agonist approved for the treatment of type 2 diabetes. It is an acylated peptide engineered to activate the GIP and GLP-1 receptors, key mediators of insulin secretion that are also expressed in regions of the brain that regulate food intake. The drug integrates the actions of both incretins (GIP & GLP-1) into a single novel molecule. In preclinical models, GIP has been shown to decrease food intake and increase energy expenditure therefore resulting in weight reduction, and when combined with GLP-1 receptor agonism, may result in greater effects on markers of metabolic deregulation such as body weight, glucose and lipids.

In a trial, participants experienced substantial and sustained weight loss with a weekly injection of Tirzepatide. Other studies showed that sizable proportion of patients (23.0 to 62.4%) reached an HbA1c of <5.7% and 20.7 to 68.4% lost more than 10% of their baseline body weight. Tirzepatide was significantly more effective in reducing HbA1c and body weight than the selective GLP-1 RA semaglutide (1.0 mg per week), and titrated basal insulin. In the phase 3 trial of Tirzepatide, the overall average weight reduction for the highest dose of tirzepatide (15 mg) was about 52 pounds. Substantial weight loss was also achieved on lower doses of tirzepatide: 35 pounds for the 5 mg dose and 49 pounds for the 10 mg dose. The trial observed change in body weight from baseline and greater percentage of participants achieving body weight reductions of at least 5% compared to placebo.

The overall safety and tolerability profile of tirzepatide was similar to other incretin-based therapies approved for the treatment of obesity. The most commonly reported adverse events were gastrointestinal-related and generally mild to moderate in severity, usually occurring during the dose escalation period. Nausea, diarrhea, and constipation were the most frequent adverse events. Major Adverse Cardiac Events tend to be reduced over up to a two year-period. As an anti-diabetic drug, Tirzepatide was found to improve insulin sensitivity and insulin secretory responses to a greater extent than semaglutide, and this was associated with lower prandial insulin and glucagon concentrations as well.

CONCLUSION:

Obesity is a chronic disease that results in substantial global morbidity and mortality. Tirzepatide is in phase III development for adults with obesity or overweight with weight-related comorbidity and is currently approved as a treatment for adults with type II diabetes mellitus.

- <https://www.nejm.org/doi/full/10.1056/NEJMoa2206038>

Mr. Jatin A
Pharm D Intern

STUDENTS DESK

New Advancements in Cancer Treatment

Recent advancements in cancer treatments have marked significant progress in improving outcomes and quality of life for patients. These advancements encompass various approaches, including targeted therapies, immunotherapy and advancements in surgical techniques. Targeted therapies have revolutionized cancer treatment by targeting specific molecules or pathways involved in the growth and survival of cancer cells. These therapies are designed to interfere with specific abnormalities present within the cancer cells, thereby blocking their growth while minimizing damage to normal cells. Examples include drugs that target HER2 in breast cancer or BRAF mutations in melanoma, leading to more effective and personalized treatment strategies.

Immunotherapy has emerged as a promising approach by harnessing the body's immune system to recognize and attack cancer cells. Checkpoint inhibitors such as PD-1 /PD-L1 inhibitors have shown remarkable success in various cancers by releasing the brakes that cancer cells use to evade immune detection. CAR-T cell therapy, another form of immunotherapy, involves genetically modifying a patient's own T-cells to recognize and destroy cancer cells, offering new hope especially in hematologic malignancies like leukemia and lymphoma.

Advancements in surgical techniques have also contributed significantly to improved cancer outcomes. Minimally invasive surgeries such as laparoscopic or robotic - assisted procedures have reduced recovery times and post-operative complications compared to traditional open surgeries. These techniques enable surgeons to remove tumors more precisely while preserving healthy surrounding tissue, critical for improving patient recovery and reducing long-term side effects. Additionally, advancements in radiation therapy have enhanced precision and effectiveness in targeting tumors while sparing nearby healthy tissues.

Furthermore, genomic and molecular profiling have enabled oncologists to better understand the genetic makeup of tumors, guiding treatment of decisions towards more effective therapies. Liquid biopsies, which analyze DNA circulating in the blood, offer a non-invasive method to monitor treatment in cancer. In conclusion, these advancements represent a transformative era in cancer treatment, shifting cancer patients worldwide.

- <https://www.fda.gov/consumers/consumer-updates-gene-therapy-can-cure-or-treat-diseases>

Ms. Harini
I Pharm D.

Implementation of Artificial Intelligence in Healthcare System

Artificial intelligence (AI) has emerged as a transformative force in healthcare system worldwide, revolutionizing various facets of patient care, clinical decision-making and operational efficiency. One of the most impactful areas of AI implementation is in medical imaging and diagnostics. AI algorithms can analyze vast amounts of medical imaging data, including X-rays, MRIs, and CT scans, with remarkable accuracy. This capability aids radiologists in detecting subtle abnormalities and making faster, precise diagnosis. AI also plays a crucial role in personalized treatment plans. By leveraging machine learning techniques, AI can sift through extensive patient records, genetic information, and clinical trial data to identify patterns and correlations that inform personalized treatment strategies.

In drug discovery and development, AI accelerates the identification of potential drug candidates by predicting molecular interactions and optimizing clinical trial design. This computational prowess expedites the traditionally lengthy and costly drug development process, potentially bringing new treatments to market faster and at lower costs. Virtual health assistants and chat box powered by AI are transforming patient engagement and care delivery. These systems can provide preliminary diagnoses, offer medical advice, schedule appointments. AI-driven predictive analytic enables healthcare organization to forecast disease outbreaks, predicts patient readmissions, and identifies individuals at risk of developing specific conditions. By analyzing vast datasets in real-time, AI helps in proactive intervention and resource allocation, thereby improving population health management. In the realm of surgical interventions, AI-enabled robotic systems support surgeons with enhanced precision and efficiency, particularly in complex and minimally invasive procedures. These technologies improve surgical outcomes, shorten recovery times, and expand access to specialized surgical expertise. Administratively, AI automates workflow tasks such as billing, scheduling, and medical coding, reducing administrative burden and allowing healthcare providers to focus more on patient care. Additionally, AI facilitates remote monitoring through wearable devices.

In conclusion, while AI holds immense promise in transforming healthcare delivery by enhancing efficiency, improving outcomes, and personalizing patient care requires collaboration among healthcare providers, researches, policymakers. AI has the potential to reshape the future of healthcare, making it more accessible, effective, and patient-centered.

- <https://www.fda.gov/drugs/news-events-human-drugs/role-artificial-intelligence-clinical-trial-design-and-research-dr-elzarrad>

Ms. Annie
I Pharm D.

Section editors: Ms. Aishwarya C.H.

DEPARTMENTS PROFESSIONAL ACTIVITY

Date	Topic	Type & Speaker Name
18/01/2024	Financial Management	Guest Talk Mr. Kiran Kumar NL
23/01/2024	Innovative Technologies in Drug Delivery	Guest Talk Prof. Dimitrios Lamprou
29/01/2024	Youth Day Celebration	Guest Talk Sri Pradeep Natraj
14/02/2024	Ayurvedic Approach for Treatment of Psychiatric Disorders	Guest Talk Dr. Kishore Kumar
02/02/2024	Study Abroad Options for Pharmacy students”	Guest Talk Mr. Hiren Rathod
12/02/2024	Pharmacy beyond boundaries: A Guide to International Careers with Academic Support	Guest Talk Mr Mushin Ahamed & Sivakumar
17/02/2024	Career Counselling in Herbal Industry: Scope and Opportunities	Guest Talk Dr. Prakash NS
24/02/2024	Preclinical research: Importance in Drug Discovery and development	Guest Talk Dr. Srinivas Seekallu
24/02/2024	Awareness on Cervical cancer: The Fourth most common Cancer in Women Globally	Guest Talk Dr. Abhilasha Narayan
29/02/2024	Prescience in Silico Solution Suite PR in S3 AI/HPC Driven Solutions Suite for Drug Design and Discovery	Guest Talk Ms. Mahima Kori
01/03/2024	Overview of Pharmaceutical Industry	Guest Talk Dr. Sunil Chiplunkar
09/03/2024	Women’s Rights are Human Rights	Guest Talk Dr. Vahini
14/03/2024	Supportive Medicines Used in Chemotherapy	Guest Talk Dr. Sumi L
23/03/24	Roadmap to Research	UDHEP Workshop Dr Vatsala PG, Dr Vandana Patravale Dr Srikumar BN, Dr Srinivas Seekallu Dr Pratima Narayan, Dr S P Muthkumar
05/04/2024	Effective Presentation Skills	Guest Talk Dr Anasuya Patil
20/04/2024	Chromatography in Herbal Industry: Scope and Opportunities	Guest Talk Dr. Prakash N S
23/04/2024	Design of Experiments	Workshop Mr. Zaheer Abbas
27/04/2024	Intellectual Property Right	Guest Talk Mr. Praveen Kumar TN
07/05/2024	Orientation of Clinical Key platform from Elsevier (Science direct).	Guest Talk Dr. Subash S Karki
16/5/2024	Overview of Pharmaceutical Industry	Guest Talk Dr. Phani Kumar Kundra

EDITORIAL DESK

MATERIOVIGILANCE: ENSURING MEDICAL DEVICE SAFETY

Materiovigilance is the coordinated system for identifying, collecting, reporting, and analysing untoward occurrences associated with the use of medical devices. Primary goal is to protect patient health and safety by preventing the recurrence of adverse events related to medical devices. Materiovigilance importance are: Essential for ensuring benefits outweigh potential risks, Monitor and report adverse events in medical devices, Allow regulatory authorities and manufacturers to identify issues and Involve issuing safety alerts, device recalls, and design changes.

The Materiovigilance Program of India (MvPI) was launched in 2015 by the Ministry of Health and Family Welfare. It promotes and facilitates reporting of adverse events related to medical devices and in-vitro diagnostics. MvPI is led by the Indian Pharmacopoeia Commission as the National Coordination Centre. Establishes Medical Device Adverse Event Monitoring Centres (MDMCs) for adverse event collection and reporting.

Benefits of materiovigilance are as follows: Offers several benefits to patients, healthcare providers, and the medical device industry, Improves patient safety by reducing device use risks, Informs regulatory decisions, enhances device design, influences healthcare policies, and promotes quality medical devices, Builds trust in medical devices by fostering safety and reliability among patients and healthcare providers, Ensures compliance with regulations by ensuring monitoring and reporting of adverse events. Pharmacists can play a crucial role in strengthening the medical device vigilance (Materiovigilance) system in the following ways such as Reporting adverse events, Patient education and collaboration with monitoring centers and give feedback to manufacturers. By leveraging their expertise and accessibility, pharmacists can significantly enhance the effectiveness of the Materiovigilance program and improve the overall safety of medical devices used in healthcare.

Reporting Adverse Events:

Who can report?

- Healthcare professionals like clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses, and technicians.
- Patients and consumers.
- Manufacturers, importers, and distributors of medical devices.

Why to report?

Medical devices have been associated with several adverse effects and, at times, fatally harmful effects on patients.

What to Report?

- The reporting form collects details like the type of reporter, device information, adverse event details, patient outcomes, and root cause analysis.
- Reports can be initial, follow-up, final, or trend reports.
- All types of adverse events related to medical devices, irrespective of whether they are known or unknown, serious, or non-serious, frequent, or rare.
- This includes issues such as device malfunctions, user errors, product quality problems, and therapeutic failures.

How do I report?

- The Medical Device Adverse Event (MDAE) Reporting Form is available at www.ipc.gov.in.
- NCC-PvPI helpline: 1800-180-3024 (toll-free).
- ipcindia@gmail.com

Whom to Report?

To the nearest Medical Device Adverse Event Monitoring Centre (MDMC).

In conclusion, materiovigilance is a crucial component of medical device safety and regulation. By actively monitoring and reporting adverse events, the Materiovigilance Program of India (MvPI) plays a vital role in protecting the health and safety of the Indian population. Healthcare professionals, patients, and the public are encouraged to participate in this important program to ensure the continued safe and effective use of medical devices.

Reference:

- https://ipc.gov.in/images/Guidance_Document_MvPI.pdf
- <https://www.ipc.gov.in/mandates/materiovigilance-programme-of-india-mvpi.html?id=597:medical-devices-adverse-event-reporting-tools&catid=2>
- <chrome-extension://efaidnbmnnnibpcajpcgclcfndmkaj/https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadNewsFiles/MDAEform.pdf>
- <https://abudhabi2019.fip.org/programme-session/pharmacists-role-in-medical-devices-from-diagnosis-to-monitoring-of-therapy-a2/>

Dr. Feroze Fathima
PhD Scholar

Section editors: Dr. Feroze F.

Model Community Pharmacy



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Feedback Link: <https://forms.gle/sy6fkH2oAs1tx6F66>



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