



R_x FACTOR

News letter by

NATIONAL ASSOCIATION OF PHARMACOLOGY AND THERAPEUTICS

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Highlights

1) Academic Corner

Current Therapeutics, New Drugs, Banned Drugs, Integrated Approach to Therapeutics

2) Research Corner

Trends in Current Research, Areas of Research for UG & PG, Innovations & Techniques in Research

3) Vigilant Corner

Adverse Drug Reaction Updates, Widening the Horizon of Safe Therapeutics

4) Medical education Corner

Competency Building, Skill Development, OSPE, New Teaching & Learning Methods

5) Ethics & Regulations

Current Updates from Regulatory Bodies

6) Current affairs

Latest medical news

7) Cool corner

Mini quiz, Puzzle, Cartoons, Mnemonics, images

From Editorial desk

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Dr Jeyalalitha Rathinam

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Department of Pharmacology
Government Medical College, The Nilgiris
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Warm greetings to all.

Welcome to the third edition of '**RxFactor**', a one of a kind initiative from the NATIONAL ASSOCIATION OF PHARMACOLOGY AND THERAPEUTICS (NPT) . The first two editions of Rxfactor have been well received and we thank you all for the words of encouragement and appreciation.

RxFactor has been designed to encompass the range and breadth of Pharmacology and therapeutics ranging from Medical Education, Pharmaco-vigilance, Research and Therapeutics.

The current edition of Rxfactor newsletter has interesting and relevant articles on use of innovative approaches of teaching pharmacology to medical students, from case based learning to modular teaching sessions. One of the important role of the IMG is a communicator and a Professional and its important that students are trained for this. We have a write up on PharmaComm' where students are trained in the area of communications. We also have an interesting case report on the interaction of Itraconazole with Tinospora cordifolia which is a traditional medicinal herb. A novel initiative in the form of ADR Alert Card to improve patient safety and the reporting of adverse drug reactions is also highlighted. The importance of Standard Treatment Guidelines (STGs) and the Extract from NMDP group, quiz on Pharmacovigilance are some of the other notable inclusions.

Further, as always the 'cool corner' has a crossword & cartoons to add a fun element to pharmacology learning.

We would like to thank all the contributors of RxFactor for their efforts and support in making this issue of Rxfactor a grand success.

"An investment in Knowledge always pays the best interest". Benjamin franklin.

We look forward to a happy education and mutual learning with all our readers.

Jai Hind.

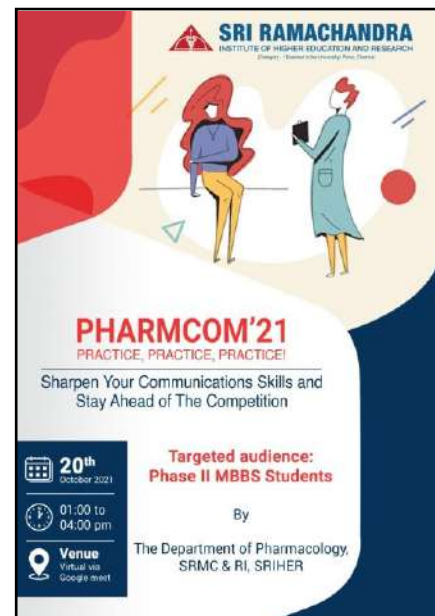
Dr Sushil Sharma

Dr Jeyalitha Rathinam

PHARMACOM 21: Communication skills in Pharmacology

Professionalism, which is an integral part of good medical practice, also demands effective communication skills along with knowledge, psychomotor skill, attitude and ethics. Better communication between doctor and patient builds confidence, improves compliance, and reduces mistakes and mishaps, thereby reducing malpractice suits. National medical commission (erstwhile MCI) of India reaffirms the need to include training in communication skills in the new MBBS CBME curriculum across the phases of course module.

To educate and imbibe the nuances of communication and interpersonal skills among the second year medical undergraduates, the department of Pharmacology, Sri Ramachandra Medical College & Research Institute, SRHER has conducted PHARMCOM' 21 - a distinctive "ROLE PLAY" competition on communication skills in pharmacology, on 20th October 2021 for second year MBBS students.



PHARMCOM 2021			
Date: 20/10/21		Time: 1-4 PM	
A1 1-18, 210 & 211 Communicate with the patient with empathy and ethics on all aspects of drug use Dr.K.Punnagai/ Dr.D.Malathy	B1 55-72, 216 & 218 Communicate with the patient regarding storage of medicines Dr.V.Gowri/ Dr.U.Kirthana	C1 108-124, 225 & 227 Demonstrate an understanding of the caution in prescribing drugs likely to produce dependence and recommend the line of management Dr.Alphines Stanley Xavier/ Dr.R.Nandhidha	D1 159-175, 234-236 Demonstrate how to optimize interaction with pharmaceutical representative to get authentic information on drugs Dr. Sowmya
A2 19-36, 212 & 213 Demonstrate an understanding of the legal and ethical aspects of prescribing drugs Dr.R.Kavitha/ Dr.S.Kapila	B2 73-90, 219 & 221 Demonstrate ability to educate public & patients about OTC drugs Dr.V.P.Karthik/ Dr.Km N Parikh	C2 125-141, 228 & 230 Communicate effectively with a patient on the proper use of prescribed medication Dr.K.Karthika	D2 176-192, 237-239 Motivate patients with chronic diseases to adhere to the prescribed management by the health care provider Dr.Nidharshan Mr.P.Suresh
A3 37-54, 214 & 215 Communicate with the patient regarding optimal use of devices Dr.D.Anusha/ Dr.K.Priya Gayathri	B3 91-107, 222 & 224 Explain to the patient the relationship between cost of treatment and patient compliance Dr.S.Ramya	C3 142-158, 231-233 Demonstrate ability to educate public & patients about drug dependence Dr.K.Kranthi	D3 193-209, 240-242 Communicate with the patient regarding optimal use of drug therapy Dr.V.Arjunaudhan Mrs.M.Saranya

All the second Year MBBS students (250) were divided into 12 groups and one communication competency topic in the new CBME pharmacology curriculum was allotted to each group. A facilitator was provided to each group to facilitate the presentation. Each group was given 5-7 minutes for the performance of role play and they were instructed to submit the recorded video link before the deadline.

The videos of the role play by 12 groups were displayed during the event. The performance was observed by whole class students (250), group facilitators and invited judges from various disciplines. The performance through video clips of all groups was assessed by judges based on the evaluation criteria and feedback was given to the students. Best three teams were selected based on the performance. Winners were awarded with medals & certificates and all the students received participation certificates.

The highlight of the programme is that all the 250 students have been actively involved in the competition with great enthusiasm. Feedback from the students was also obtained. Most of the students (90.4%) expressed that this method of learning was enjoyable, suiting their learning style & provoked interest to learn and implement effective communication skills in their future medical practice. Majority of the students (86.4%) stated that they gained more confidence with their communication skills after the PHARMCOM'21 event.

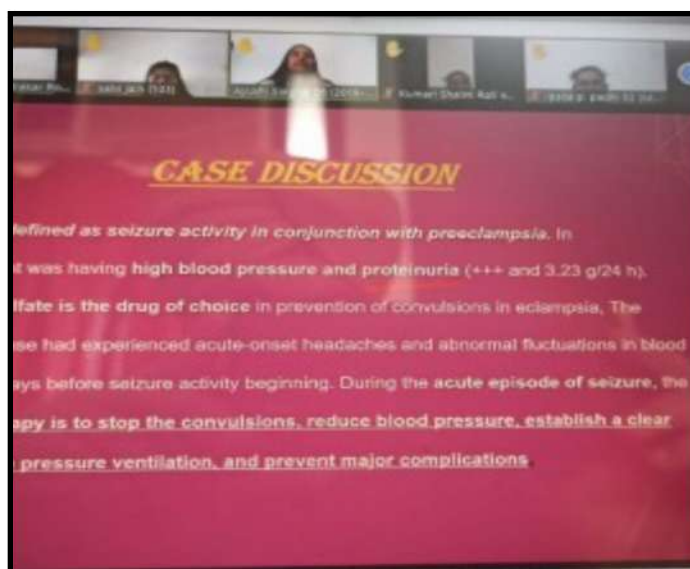
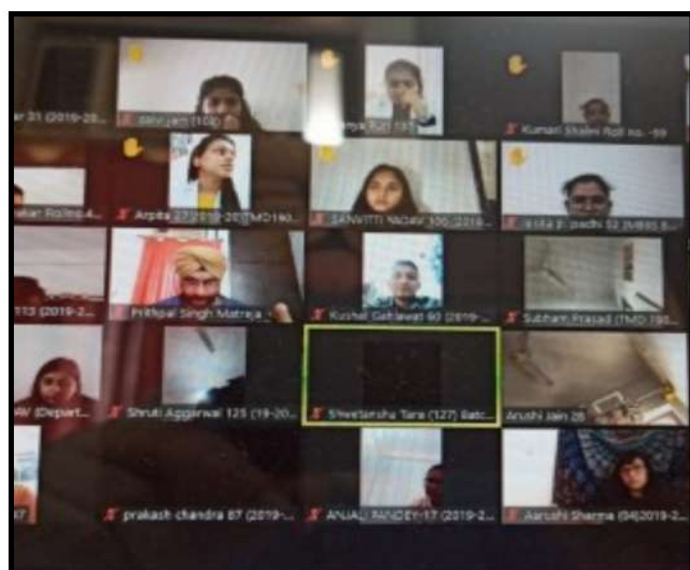
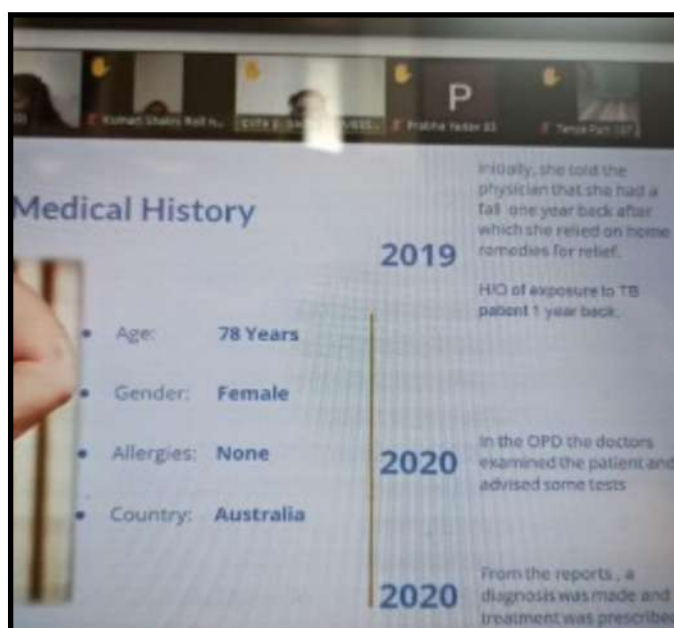
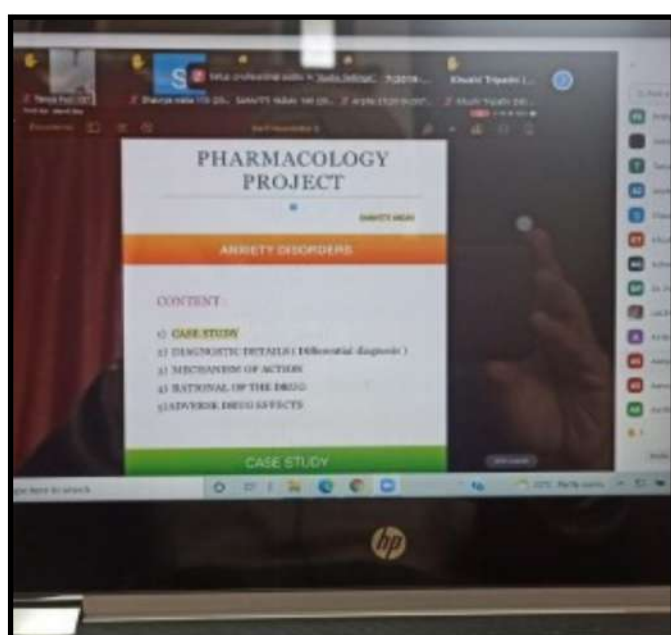
Dr.K.Punnagai, Professor & Head
 Dr.R.Kavitha, Professor
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 Department of Pharmacology
 Sri Ramachandra Medical College & Research Institute SRIHER,
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Case based learning conducted by Department of Pharmacology

Teerthanker Mahaveer Medical College & Research Centre, (TMMC&RC) Moradabad, Uttar Pradesh

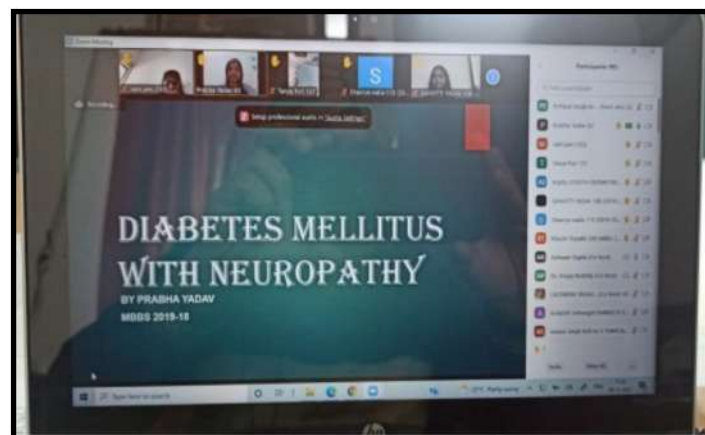
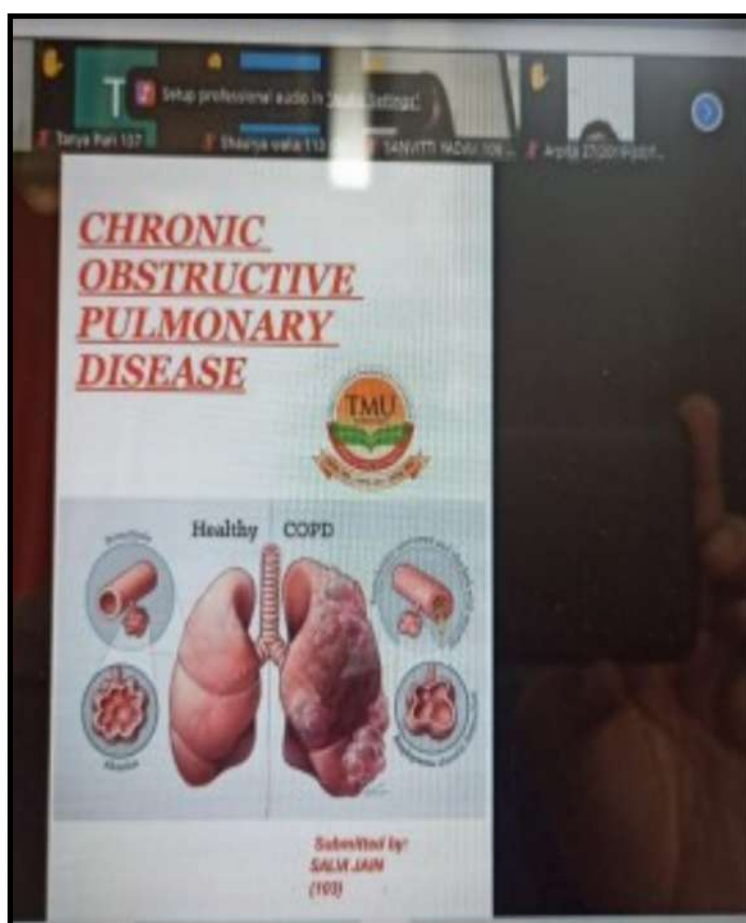
(06th December, 2021)

Department of Pharmacology conducted case based learning for the MBBS student of Batch 2019, this was one of its kind activities to involve all the students and inculcate in them the mode of self directed learning (as proposed by the new CBME curriculum by NMC). Each student was given an option to choose a particular disease on which they would like to work on. The students were given a disease to search for and write down all the aspects of the disease allotted to them including the etiology, pathogenesis, management differential diagnosis as well as clinical manifestation for which they were given an option to look into textbooks and internet. This was followed by an activity that these students had to follow up at least 5 patients of the disease allotted to them and write down all the details of treatment and manifestation of patients and even give the rationale for prescription of the drugs given to them by the Physician.



All students submitted their projects. These projects were then allotted to the faculty of Pharmacology Department (Dr. Prithpal Singh Matreja, Dr. Shilpa Patrick, Dr. Preeti Singh, Dr. Ruchi Choudhary and Mr. Lalendra Yadav) for evaluation of the project. The faculty evaluated the project on the completeness and essential details of the study. Based on the evaluation 14 projects were selected to be presented for Online Judgment.

The students were directed to present one case and prepare the same under the guidance of faculty, with focus on treatment and rational for the drug usage. The time allotted for presentation was 5 minutes and a maximum of 10 slides for presentation. The event was held online and all the students attended the meeting. The Judges for the case presentation were Dr. Ashwani K Gupta from GMCH, Bharatpur; Dr. Pooja Reddy from Sri Aurobindo University, Indore and Dr. Prithpal Singh Matreja (TMMC&RC). The students were evaluated on the detailed discussion of the case which was followed by Question and Answer from the judges. The results of the event were as follows – Second Runner Up was Khushi Tripathi, First Runner Up was Kumari Shalini and winner of the Event was Ayushi Singhal. The session ended with words of encouragement from the judges.



Dr. Prithpal Singh Matreja
Professor and Head
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Owing to the fragmented nature of the medical curriculum, many of the concepts learned in the first and second professional years are partially forgotten by the time the students come to the third professional, resulting in fragmented knowledge. Further, many common topics are taught as a part of various subjects, with differing emphasis and orientation putting the student in a disadvantageous position.

Modular teaching is one of the best methods that is proven to give maximum benefit for students in terms of understanding and application of competencies of a particular topic which are crucial in day-to-day medical practice for a medical graduate.

A Module is a set of learning opportunities with respect to a well-defined topic that contains specific objectives, teaching-learning activities (online/offline/blended approach) and evaluation activities. Modular teaching adopts a varied approach to the learning process in contrast to integrated teaching and optimizes learning outcomes.

The Medical Education Unit (MEU) of AIIMS Mangalagiri is regularly coordinating and conducting the modular teaching sessions with a view to ensuring best teaching-learning for the students. The process involves at least 2-3 brainstorm sessions among the faculty of all involved departments. The core competencies are identified along with the most appropriate TL method for the same. It is important to ensure that there is no repetition or redundancies. The competencies are then organized in a logical manner to ensure they are all connected in a seamless manner. A Lesson plan for the Modular session on Diabetes Mellitus prepared by the MEU in consultation with the concerned departments concerned is as under.

LESSON PLAN FOR MODULAR TEACHING				
Topic	Diabetes Mellitus			
Date & Time	26.11.2021 (2.00 – 4.00 PM)			
Target Students	Final Year MBBS (2018 Batch)			
Departments Involved	Physiology, Biochemistry, Pharmacology, Ophthalmology, Community Medicine, General Surgery, Endocrinology, Nephrology			
Organized by	Medical Education Unit			
Competency	Domain	T-L method/Tool	Department	Duration
Pre-Test		Google form	MEU	10 minutes
Briefing session			MEU	3 minutes
Describe the burden of diabetes mellitus at Global and National level	Cognitive	Lecture/PPT	Community medicine	4 minutes
Enumerate the epidemiological risk factors for diabetes	Cognitive	Lecture/PPT	Community medicine	4 minutes
Describe the mechanism of insulin secretion	Cognitive	Lecture/PPT	Physiology	5 minutes
Describe the regulation of insulin secretion	Cognitive	Lecture/PPT	Physiology	5 minutes
Interpret the laboratory reports of Diabetic patients	Cognitive	Case-based learning	Biochemistry	5 minutes
Demonstrate capillary blood glucose measurement using Glucometer	Psychomotor	Video Demonstration	Biochemistry	5 minutes

Demonstrate capillary blood glucose measurement using Glucometer	Psychomotor	Video Demonstration	Biochemistry	5 minutes
Counsel a patient diagnosed with DM on the life-style modifications required	Affective	Roleplay	Community medicine	5 minutes
Enumerate the drugs used in the management of DM with their common adverse effects	Cognitive	Lecture/PPT	Pharmacology	5 minutes
Outline the initial treatment and dose escalation of oral anti-diabetics	Cognitive	Lecture/PPT	Endocrinology	5 minutes
Formulate a plan on the initiation and escalation of insulin treatment in a diabetic patient	Cognitive	Lecture/PPT	Endocrinology	5 minutes
Administer Insulin by Sub-Cutaneous (SC) route	Psychomotor	Demonstration	Pharmacology	5 minutes
Recognize and manage a case of hypoglycemia	Cognitive	Case based learning/PPT	Endocrinology	5 minutes
Demonstrate the correct technique of direct ophthalmoscopy	Psychomotor	Video Demonstration, Patient simulation	Ophthalmology	5 minutes
Distinguish between a normal retina and diabetic retinopathy (abnormal retina)	Cognitive	Case based learning/PPT	Ophthalmology	5 minutes
Recognition and early detection of Diabetic nephropathy	Cognitive	Lecture/PPT	Nephrology	5 minutes
Describe the measure to be taken for prevention of diabetic kidney injury	Cognitive	Lecture/PPT	Nephrology	5 minutes
Perform clinical assessment for diabetes related complications in the foot	Psychomotor	Demonstration/PPT	General Surgery	5 minutes
Instruct the patient regarding daily foot care to avoid complications	Psychomotor Affective	Demonstration/ Role play	General Surgery	5 minutes
Summary	Cognitive		MEU	5 minutes
Post Test & Feedback		Google form	MEU	10 minutes

As can be seen from the lesson plan, the module covers all the domain specific competencies viz cognitive, psychomotor and affective domains through appropriate TL methods. Various TL methods including Lecture, PPT, Demonstration, Role play , Videos etc are employed to ensure that the relevant competencies is covered in a most effective manner so that the students are able to appreciate and integrate all the relevant aspects of the module in a seamless manner.

Dr. Sushil Sharma

Professor & Head

Department of Pharmacology

All India Institute of Medical Sciences (AIIMS)

Mangalagiri (AP)

VIGILANCE QUIZ

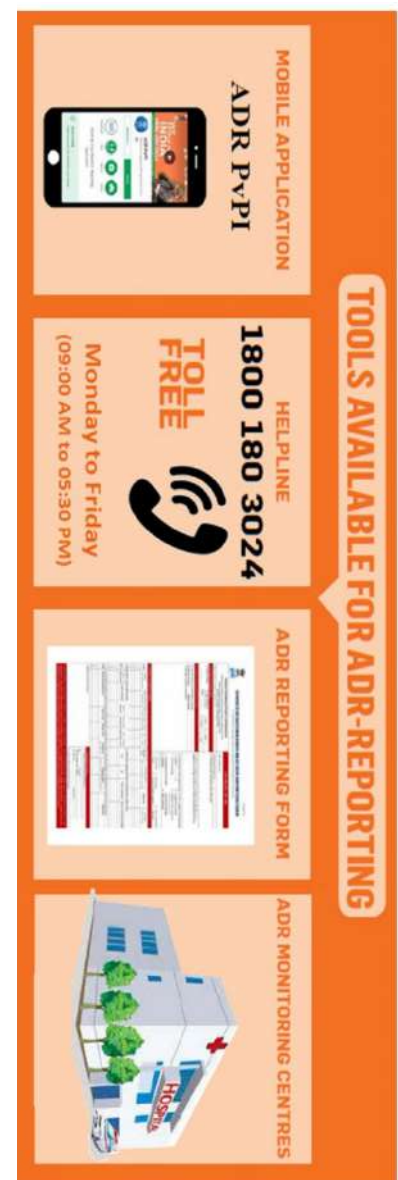
1. When was PvPI successfully launched in India? [2010]
2. Which year MvPI was started in India? [2015]
3. When AEFI (Adverse Event Following Immunization) reporting was added to PvPI? [2015]
4. When was reporting of adverse events of blood and blood products named as HvPI? [2012]
5. Who can report ADRs? **All healthcare professionals** (clinicians, dentists, pharmacists, nurses) and **patient/ consumers** can report ADRs to NCC or AMCs. The **pharmaceutical companies** can also send individual case safety reports for their product to NCC.
6. What are the details that are mandatory while filling an ADR form?
Patient details, Suspected ADR, Suspected Drug/Medication, Reporter Details
7. What are the levels of causality in WHO-UMC scale for reporting an ADR?
Certain, Probable, Possible, Unlikely, Unclassified
8. What are the levels of causality in Naranjo scale?
Definite, Probable, Possible, Doubtful
9. What National Health Programs collaborate with PvPI?



10. What is GVP? **Good Vigilance Practice**
11. What is MDMC? **Medical Devices Monitoring Centre**
12. What is PSUR? **Periodic Safety Update Report**
13. What is SAE? **Serious Adverse Event**
14. What is MedDRA? **Medical Dictionary for Regulatory**

Dr. T. Rajathilagam

Associate Professor, Pharmacology,
ESIC Medical College & PGIMSR, Chennai



A case report

Abnormal uterine bleeding in an adult female after itraconazole and *Tinospora cordifolia*

Introduction:

Itraconazole is a broad-spectrum antifungal agent from the class of triazole. Considering its favourable pharmacodynamic and pharmacokinetic profile and demonstrated efficacy against wide range of superficial fungal infections, it is commonly used in dermatological clinical practice. In refractory cases, it is a valuable addition to other the antifungal drugs and is well-tolerated when given up to 400 mg/day.¹ Integrative medicine is practice of blending of conventional and evidence-based complementary medicines for the benefit of the patients.² In India, use of traditional medicines (e.g. Ayurvedic preparations) is not uncommon. Although it has potential for drug interactions,¹ according to best of our knowledge, there are no reported cases of abnormal uterine bleeding, i.e. deviation from the normal menstrual cycle³ due to drug interactions with itraconazole with complementary medicines in Indian patients. We present a case of adult female on oral itraconazole tablet who presented with abnormal uterine bleeding after starting an ayurvedic preparation for the treatment of joint pain.

Case presentation:

A 40-year-old female diagnosed with recurrent fungal infection was started on itraconazole 200 mg twice daily for one month followed by 100 mg twice daily for next two weeks. Her fungal infection was very well controlled with given course of oral itraconazole.

During the course of her itraconazole therapy, she suffered from viral infection for four days with symptoms of high-grade fever and malaise. After about 10 days of this episode of viral infection, she developed significantly disabling severe joint pain and muscle pain.

For the relief of symptoms of joint pain and muscle pain she resorted to use over the counter analgesics which provided only temporary relief of symptoms. After no satisfactory relief of the joint pain, she started *Tinospora cordifolia* preparation on her own. After four days of starting this, she presented with abnormal uterine bleeding. Her regular menstrual cycle was expected after 15 days of this episode. She stopped *Tinospora cordifolia* preparation immediately after noticing uterine bleeding. Itraconazole was also stopped as her had almost completed six weeks therapy of itraconazole. Uterine bleeding continued for four days after stopping both the medicines. Bleeding was maximum on second day and then gradually decreased over next two days. Her menstrual cycles were regular (28 days cycle) before this incidence of bleeding episode.

Her obstetric history included a caesarean section and one normal delivery. She did not have history of diabetes, hypertension or any other comorbidity. She was not receiving any medication known to cause bleeding (e.g. anti-coagulant, antiplatelet agent etc). Vital signs were normal on all four days of uterine bleeding. There were no other significant findings on clinical examination. After stopping both medicines, her menstrual cycles are back to normal duration (28 days).

Discussion:

Abnormal uterine bleeding can be due to either structural or non-structural causes. Polyps, endometrial abnormalities, anticoagulant medications, and coagulopathies are some of the causes of uterine bleeding.³ In our patient, there was no history or presentation of any of these causes. In 2017, Brzezinski and colleagues⁴ have reported a case of iatrogenic metrorrhagia in an elderly female patient receiving simvastatin after starting itraconazole for the treatment of onychomycosis. Disturbance of withdrawal bleeding has also been reported during concomitant use of itraconazole and oral contraceptives.⁵ Itraconazole has a potential for drug interactions due to metabolism involving cytochrome P450 enzyme 3A4 system.¹ Clinical presentation and history in our case suggests, possibility of drug interaction of itraconazole and ayurvedic preparation. The causality assessment suggests 'probable' relation with the suggested medications.

Conclusion:

Abnormal uterine bleeding was reported after intake of *Tinospora cordifolia* preparation in a patient receiving itraconazole. It is difficult to ascertain the reason (pharmacokinetic or pharmacodynamic) of this interaction. Further studies are necessary to establish mechanism responsible for such interaction.

References:

Pierard GE, Arrese JE, Pierard-Franchimont C. Itraconazole. Expert Opin Pharmacother 2000;1(2):287-304.

Borse SP, Singh DP, Nivsarkar M. Understanding the relevance of herb–drug interaction studies with special focus on interplays: a prerequisite for integrative medicine. Porto Biomed J; 4(2): e15.

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Meyboom RH, van Puinenbroek EP, Vinks MH, Lastdrager CJ. Disturbance of withdrawal bleeding during concomitant use of itraconazole and oral contraceptives. N Z Med J 1997;110(1049):300.

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Assoc Professor

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**Beware of drug
interactions**

Need of Standard Treatment Guidelines



The Scientific approach to heal the needy by Allopathic medical practitioner is based on the knowledge gathered by evidence over a period of time. Obviously it will not remain constant and often treatment is improvised based on the result of better drugs. Dynamic and challenging environment to quest for best practice to help people is considered the hallmark of this modern system of medicine.

The knowledge, attitude and practice to adopt standard treatment protocol is required to standardize the therapy. The guidelines are already in place and there is no need to invent the wheel everyday by everyone. All it need is to accept the offer and implement. Advantage of the guidelines are many. It is possible to do uniform treatment, it will save patients and in the event of any damage caused by the doctor and if litigation is caused them court may also take the STG into consideration to ensure that the physician is prescribing as per the guidelines. Resistance to antibiotics will be prevented. The level of care will be better. Sticking to the STG is rational and logical. National standards are incorporated into the STG as they are in the various programs launched by the government of India. STG is a manual and available in Amazon both in hard copy and kindly edition in a nominal price.

Key features of STGs-

Simplicity: The numbers of health problems are limited and for each health problem a few key diagnostic criteria are listed. Drug and dosage information is clear and concise.

Credibility: Guidelines developed by the most respected clinicians in the country and revisions based on actual experience.

Use of the same standard for all levels of health care: Doctors and other health care providers use the same standard treatment as it is a referral criterion which differs and the first choice treatment for a patient depends on the patient's diagnosis and condition-not on the prescriber.

Provision of standards to drug supply: Most importantly, drug supply should be matched to the recommended treatments and drugs on the list of essential drugs.

Regular updating: As bacterial resistance patterns change or other factors alter therapeutic preferences, the standards are revised to reflect current recommendations.

Dr Pinaki Chakravarty

Professor and Head

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Adverse Drug Reaction Alert Card – An approach towards preventing and reporting of ADRs

Enhancing patient safety

Introduction:

Adverse Drug Reactions (ADRs) are among the leading causes of morbidity and mortality. Approximately 5-25% of hospital admissions are due to ADRs and 6-15% of hospitalized patients experience serious adverse drug reactions, causing a significant prolongation of hospital stay.

Patients are usually unaware of their 'ADR status', do not take it seriously and are unable to recall the offending drug. This vastly increases chances of recurrence to levels which are easily preventable. Currently, any unforeseen ADR occurrence is seen to be the responsibility of the medical professional, and they are at blame. This adds to the stress on the profession since neither patient nor doctor is aware of the drug sensitivity of the patient. By providing 'ADR Alert Card' to the patient, they will be made more aware of their ADR profile. This card will provide ADR history of the patient and hence minimize/prevent recurrence of the ADR. This will also make them more responsible towards providing information about their own ADR status to the healthcare professional thus be a part of their own health management.

To overcome the difficulties faced for ADR reporting to the national pharmacovigilance centre, as well as to avoid or minimize the ADR, we have introduced ADR Alert Card. This ADR Alert Card will not just help in combating the infrastructural burden of patient admissions, but also reduces the cost and improve hospital workflow. With the implementation of the card system in our hospital, we will be the first to do so in Maharashtra, and may be in India, setting a benchmark and a gold standard in pharmacovigilance and ADR reporting protocols. We have copyright certificate from the for the same from the Copyright office, Government of India. (Registration no.- L-111544/2022, dated 31/01.2022)

The Card will help tackle the issue of under-reporting through multiple ways. It will help enhance awareness of all Healthcare Professionals towards ADR reporting. This will improve the 'ADR reporting culture' of the institution and enhancing contribution to the PvPI/National Pharmacovigilance Programme.

Most importantly, it will enhance patient reporting of their own ADRs. PvPI reporting helpline number is present on card, which can be utilised by patient to report their own ADR occurrence to the helpline AMC. As it has been observed in multiple studies across the world, patient involvement in ADR reporting is imperative to increase number of ADRs 'captured' by the reporting system, reducing national and institutional healthcare burden as well as contributing to worldwide database and allowing ADRs to surface from the invisible portion to the visible part of the iceberg.

The Adverse Drug Reaction (ADR) Alert Card as shown in figure 1 has been designed keeping into view its resourcefulness as a source of pre-validated medical information about the patient. Cards will be provided to IPD and OPD patients who developed an ADR. The card is of 'credit card' size to be easy to carry in a wallet/purse. Patients will be instructed to keep the card with them whenever they visit any healthcare professional in order to prevent further recurrence. They will also be instructed to keep a photo of the ADR Alert card on their mobile phones.

Name of Clinic/Hospital/Institute ----- Adverse Drug Reaction Alert Card Name: _____ Age/Sex: _____ Blood Group: _____ Contact Number: _____ Emergency contact: _____ Major illness, if any: _____ Drug Reaction Reporting Helpline (PvPI): 1800 – 180 - 3024	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 33%;">DRUG</th> <th style="width: 33%;">REACTION</th> <th style="width: 33%;">DATE</th> </tr> </thead> <tbody> <tr><td style="height: 50px;"></td><td></td><td></td></tr> <tr><td style="height: 50px;"></td><td></td><td></td></tr> <tr><td style="height: 50px;"></td><td></td><td></td></tr> </tbody> </table>	DRUG	REACTION	DATE									
DRUG	REACTION	DATE											

ADR ALERT Card advantages:

- ADR Alert card has following advantages as compared to the available options.
- Improvement in ADR reporting - as patient himself can report it on the PvPI no. given on the card.
- Making patient himself responsible for the prevention of ADR - by making him aware about his own ADR status and giving him responsibility of showing his ADR ALERT CARD to the health professional.
- In an emergency, this card can be used as a source of important health information. His blood group, history of major illness and history of adverse reaction could be immensely helpful for the health professional to decide further action.
- Emergency contact no given on the card can help in notifying the relatives.
- Card can be made in different vernacular languages to make it user friendly
- It is easy to carry in the wallet/purse/pocket.

Dr Sarita Mulkalwar

Professor

Department of Pharmacology

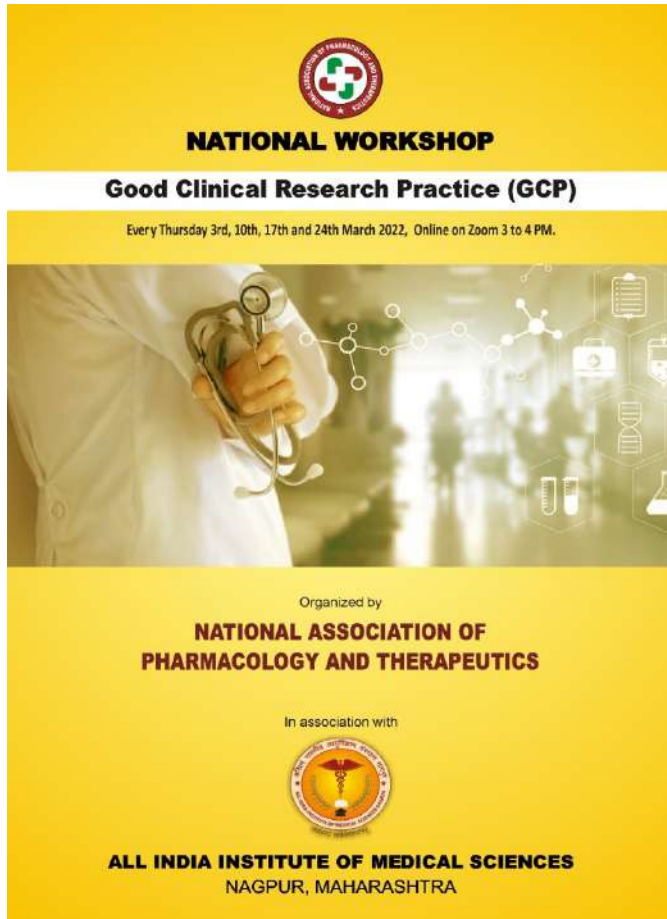
Dr. D Y Patil Medical College and Hospital, Pune. Maharashtra

National Association of Pharmacology and Therapeutics

NPT ACTIVITIES

National Online GCP workshop 2022

3rd March 2022 to 24th March 2022



NATIONAL WORKSHOP
Good Clinical Research Practice (GCP)

Every Thursday 3rd, 10th, 17th and 24th March 2022, Online on Zoom 3 to 4 PM.

Organized by
NATIONAL ASSOCIATION OF PHARMACOLOGY AND THERAPEUTICS

In association with
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
NAGPUR, MAHARASHTRA



SPEAKERS

 Dr. Umika Tulla Professor, Emerita Clinical Pharmacology, KEM, Mumbai, Maharashtra	 Dr. Ushama Pargal Professor Dr. CO, Dept of Clinical Pharmacology & Therapeutics, Nizam Institute of Medical Sciences, Hyderabad, Telangana	 Dr. Nitya Gogtay Professor & HOD, Clinical Pharmacology, KEM, Mumbai, Maharashtra	 Dr. Savita Verma Professor, Pharmacology Pt. B.D Sharma Post Graduate Institute of Medical Sciences, UHS, Rohtak, Haryana
 Dr. Deepak Dabale Dean (Curriculum) Professor & HOD, Pharmacology, All India Institute of Medical Sciences (AIIMS), Nagpur	 Dr. Thumini Kalbar Associate Professor, Pharmacology, Govt. Medical College, Nagpur, Maharashtra	 Dr. Melvin George Associate Professor, Clinical pharmacology, SRM Medical College, Chennai, Tamil Nadu	 Dr. Sukanta Sen Dean (Student Affair) Professor & HOD, Pharmacology, ICMR Institute of Medical Sciences & Research, Kolkata, WB

MODERATORS

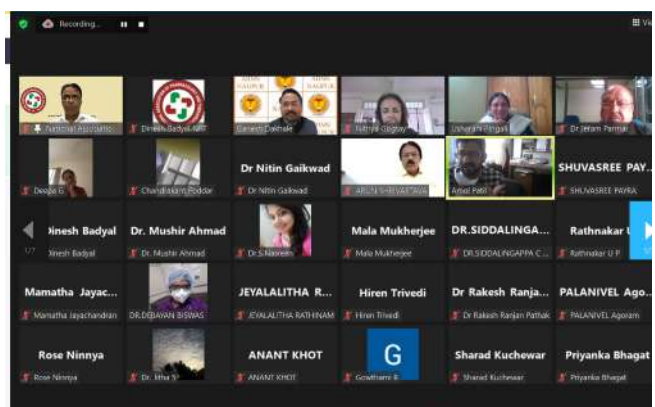
 Dr. Chetana Desai Professor & HOD, Pharmacology, S.J. Medical College, Mumbai, Gujarat	 Dr. Divyesh Badiya Professor, Pharmacology, Christian Medical College, Ludhiana, Punjab	 Dr. Sneha Ambekar Professor & HOD, Pharmacology, All India Institute of Medical Sciences (AIIMS), Jodhpur, Rajasthan	 Dr. Chetan Acharya Professor, Pharmacology, Govt. Medical College, Surat, Gujarat
 Dr. Subhrajit Ghosh Clinical Director Academic and research dept., Posterior Hospital, Kolkata, WB	 Dr. Nitin Gaikwad Professor, Pharmacology, All India Institute of Medical Sciences (AIIMS), Raipur	 Dr. K. Prasad Professor & HOD, Pharmacology, SRM Medical College & Research Institute SHRIER, Chennai, Tamil Nadu	 Dr. Anil Patel Associate Professor, Pharmacology, Post Graduate Institute of Medical Education & Research, Chandigarh, Punjab

The National Online GCP workshop 2022 organized by National Association of Pharmacology and Therapeutics with grand success. The workshop has been organized in association with AIIMS Nagpur with weekly session 3rd March 2022 to 24th March 2022. More than 380 delegates across the country has been trained successfully by eminent faculties and specialists.



General Elements of Informed Consent (Beauchamp & Childress - 1994)

- Disclosure
- Understanding
- Voluntariness
- Competence
- Consent



A grid of participants in a Zoom meeting, including names like Dr. Nitin Gaikwad, Dr. Mushir Ahmad, Dr. Mala Mukherjee, Dr. Siddalinga, and others.

VOTE OF THANKS



Dr. Ganesh Dakahle

Professor and Head

Department of Pharmacology

All India Institute of Medical Sciences

Nagpur, Maharashtra

**ORGANIZING SECRETARY
National Online GCP workshop 2022**

Dear colleagues

An event of this dimension can't happen overnight. The wheels start rolling 4 months in advance. It requires meticulous planning and execution and an eye for details. I have been fortunate enough to be backed by a team of very motivated and dedicated colleagues who know their job and are result oriented.

I convey deep regards and hearty thanks to Chairperson of the workshop Dr Urmila Thatte madam for her sincere efforts and pain taken to organize such a wonderful online workshop. My words are not enough to express the gratitude to Dr Padmaja Udaykumar who is the president of NPT for her constant source of inspiration for all of us and madam is always ready to give guidance to the association. I would also like to acknowledge the contribution of our secretary of the NPT Dr Dixit for his active involvement throughout the workshop.

I am also deeply indebted to Dr C.M. Kamaal who is national coordinator of NPT. He has worked very hard for the success of this workshop. It was his brain idea to organize such a workshop after success of prior two CBME workshop. He has put tremendous efforts for this workshop behind the scene and played a very pivotal role since the inception of this workshop. Other notable contribution was put by Dr Badyal K Badyal who was the basic DNA of the workshop and provided all infrastructure for the workshop.

I also wish to express my gratitude to all eminent speakers Dr Urmila Thatte , Dr Savita Verma Dr Melvin George, Dr Nithya Gogtay, Dr Usharani Pingali, Dr Mrunalini Kalikar , Dr Sukanta Sen who has given their best for this workshop. All speakers were the stalwarts in their respective fields and had given 100 percent during their presentation. Sincere thanks from the bottom of my heart to all of them.

I also take this opportunity to say thanks to all our moderators Dr. Nitin Gaikwad, Dr Sneha Ambwani, Dr Chetan Acharya, Dr K Punnaigai, Dr. Chetna Desai, Dr Amol Patil, Dr. Subryojyoti Bhoushmik and Dr Dinesh Badyal who did the wonderful job as moderators within specified time period as well as taking important questions during the discussion. They conducted all the sessions flawlessly

Lastly I am also thankful to all the participates for their active participation throughout the workshop. I hope we will continue this bonding in future also with more interest and enthusiasm.

Thanks all.

Long Live NPT

Dr. Ganesh Dakahle

BLOCK YOUR DATES



NAPTICON-2022

First National Conference of National Association of Pharmacology & Therapeutics



28th-29th October 2022



Organized by

**Department of Pharmacology
Father Muller Medical College Mangalore, Karnataka**

Organizing Chairperson

**Dr Padmaja Udaykumar
Professor and Head
Department of Pharmacology & Therapeutics
Father Muller Medical College
Mangalore, Karnataka.**

What is EXTRACT

Extract are the collections of some important points taken from the discussion in National MD Pharmacology group. NMDP is a group of eminent pharmacologists from all over the country. The head of departments of pharmacology, deans, directors of institutions and people with significant contribution in the field of pharmacology are members of NMDP family. National association of Pharmacology and Therapeutics is promoted by NMDP group.

CDSCO publishes updated list of banned drugs in India: List contains 518 drugs and FDCs which are banned in the country. No firm or individual can import or manufacture these drugs for sale in India.

Provisional relaxation in norms for faculty appointment and promotion criteria by NMC: NMC has extended the period for acquiring requisite Medical Education Technology and Biomedical Research qualification for the purpose appointment and promotion by one year. It is one time relaxation applicable till 31st December 2022.

Dextromethorphan poisoning- 16 cases admitted in a children hospital: Dextromethorphan is part of many cough syrups and can lead to confusion, dizziness, CNS depression if given in overdoses or in very young children. Patients/Guardians must be properly educated about the adverse effects of OTC cough syrups.

Recommendation for continuous therapy with second generation Anti-histaminics in Chronic urticaria and Allergic rhinitis: Continuous treatment is better because it reduces Minimum Persistent Inflammation (MPI).

COVID Vaccination: Vaccination of children aged 12-15 yrs is commencing from 23rd March 2022. Booster for Health Care Workers and Frontline workers started from 10th January 2022. Senior citizens also eligible for booster dose if prescribed by doctor. For children aged 15-18 yrs from 3rd January 2022.

Major safety concerns with Anti-Covid pill Molnupiravir: Molnupiravir can cause teratogenicity and mutagenicity, cartilage damage and damage to muscles.

Favourable effect of Hydroxychloroquine on glucose and lipid metabolism: Hydroxychloroquine (HCQS) has both, anti-inflammatory and immunomodulatory effect. Release of inflammatory mediators from immune cells and adipocytes causes a chronic low grade inflammation in T2DM patients which is involved in insulin resistance. 400mg daily dose of HCQS reduces HbA1c, improves glycaemic control and reduces insulin requirement.

Exercise for Essential Drug List: Prepare an EML of Anti-hypertensive drugs for a primary health care facility.

EXTRACT



Source: Group discussion NMDP

Big Crackdown on Fake Medicines: Government makes it mandatory for API/Medicine manufacturers to have QR code with all details on Medicine/API products.

Anti-diabetes pill Semaglutide launched in India: Oral semaglutide- a glucagon like peptide (GLP-1) receptor analogue molecule. Drug mimics incretin hormone and was available only in injectable form till now.

Distance from which sample can be taken from the location of Ethics Committee: Guidelines mention that sample collection should be done within 50 kms of location of Ethics Committee for Clinical trials and BA/BE studies. However due to lack of clearcut guidelines for Academic trials or other projects, it will be upto local ethics committee to decide the acceptable distance to them for governing a research project.

All adverse effects should be reported: It will help in developing a reporting culture, add to the incidence of ADRs and generating signals.

First Nasal spray for COVID-19 launched: Nitric oxide nasal spray (NONS) is designed to kill COVID-19 in upper airways. It will be used for treating adult patients who are at high risk of disease progression.

Publication of PG Thesis: P.G.Thesis work can be published after acceptance by Internal and External examiners, even before passing examinations.

Compiled by:

Dr Ruchi Bahgal

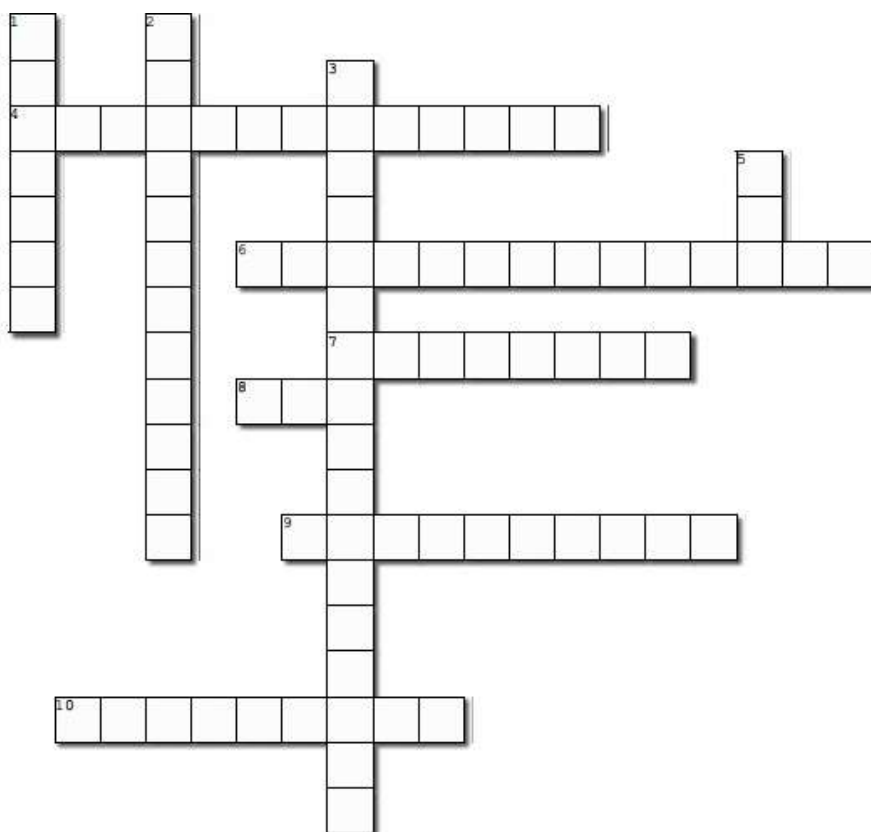
Associate Professor

Department of Pharmacology RDG Medical College, Ujjain, Madhya Pradesh

COOL CORNER

CROSSWORD (Macrolides)

Dr Divya Shanthi (Assistant Professor) Dr Dhivya Elango M (Senior Resident) ,



Across

4. This ketolide antibiotic can cause worsening of Myasthenia Gravis
6. The macrolide which is cleared through kidney
7. The salt of erythromycin that can cause cholestatic jaundice
8. Macrolides bind to this ribosomal subunit to inhibit protein synthesis
9. This macrolide is the drug of choice for toxoplasmosis in pregnancy
10. Erythromycin is a CYP450 enzyme -----

Down

1. Erythromycin acts on this receptors to produce diarrhoea
2. The long acting macrolide that can be used as single dose for chlamydia
3. The typical ECG change that happens when macrolides are used with terfenadine/astemizole
5. Clarithromycin is also used for this infection in AIDS patient



Answers for Crossword
on next page

From the book: "Drug Autobiographies in Pharmacology"
Dr. Sushil Sharma

COOL CORNER



NATIONAL ASSOCIATION OF PHARMACOLOGY AND THERAPEUTICS

Promoting Pharmacology and Therapeutics for a better tomorrow

Image Courtesy :
Dr. C.M. Kamaal
Professor and Head
Department of Pharmacology
SMMH Govt. Medical College Saharanpur UP

Amazing drug molecules

'Drugs with paradoxical actions: causing adverse effects similar to the conditions for which they are indicated'

Drug Class	Examples	Indication(s)	Reported ADRs
NSAIDs	Indomethacin	Analgesic	Frontal headache
Antiarrhythmics	Quinidine	Arrhythmias	Long QT & torsades des Pointes
	Ibutilide		
	Dofetilide		
	Amiodarone		
	Disopyramide		
	Procainamide		
	Adenosine		Atrial fibrillation
Antimicrobial Agents [AMA]	Clindamycin	Microbial Infections	<i>Clostridium difficile</i> infections
	Ampicillin		
	Cefotaxime		
	Ceftriaxone		
	Ceftazidime		
	Ciprofloxacin		
	Levofloxacin		
	Moxifloxacin		
	Vancomycin		
	Metronidazole		
Anticancer Drugs	Alkylating Agents	Cancer Chemotherapy	Acute Myeloid Leukemia, Bladder Cancer
	Estrogens	CA Prostate	CA Endometrium, CA Breast and CA Liver
	Glucocorticoids	Acute Leukemias Hodgkin's Lymphomas	Non -Hodgkin's Lymphoma
Anti-Seizure Drugs [ASDs]	Gabapentin	Epilepsy	Aggravates myoclonic epilepsy syndromes
	Carbamazepine		Aggravates Childhood absence or juvenile myoclonic epilepsy
	Phenobarbitone/ Benzodiazepines		Aggravates tonic/ myoclonic/ atypical absence seizures of Lennox-Gastaut syndrome
	Phenytoin/ Carbamazepine		
Antihypertensive agents	α Blockers	Hypertension	Na ⁺ and Water Retention leading to the development of pseudo-tolerance to their antihypertensive efficacy
	$\alpha + \beta$ Blockers		
	Vasodilators		
	Sympatholytics		

References:

Goodman and Gilman's. The Pharmacological basis of Therapeutics 13th Ed
Harrison's Principles of Internal Medicine 20 th ed.

Answers to Crossword

Q.No	Across	Q.No	Down
4	Telithromycin	1	Motilin
6	Clarithromycin	2	Azithromycin
7	Estolate	3	Torsades de pointes
8	50S	5	MAC
9	Spiramycin		
10	Inhibitor		

Dr. Madhavrao

Associate Professor
Dept of Pharmacology,
All India Institute of Medical Sciences
Mangalagiri, (AP)

SPOTLIGHT

In spotlight a life member profile is chosen and their credentials are highlighted



SPOTLIGHT



Dr. Savita Verma

Profile

1. Principal Investigator Covaxin Study Group Bharat Biotech, Indian Council of Medical Research and Iqvia Pvt. Ltd.
2. Currently Professor, Pharmacology, Pt. B D Sharma PGIMS, UHS, Rohtak, Haryana
3. Fellowship of International Medical Sciences Academy, 2018.
4. Received COVID-19 Warrior Award on 15th August, 2020 & Woman Achievers Award, Ayushman India award and state President award 2021.
5. Acted as Principal investigator for 10 clinical trials
6. Received FAIMER Fellowship, 2020.
7. Over 60 publications to her credits

National Association of Pharmacology & Therapeutics

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www.nationalpharmacology.org



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About the organization

A national organization of medical doctors specialized in pharmacology /clinical pharmacology and therapeutics. Envisaged to provide strong leadership to promote pharmacology and therapeutics for a better tomorrow. The association is fostered by NMDP (National MD Pharmacology), a prestigious group of eminent pharmacologists.

Aims and objectives

- Empowering medical doctors specialized in Pharmacology/Clinical Pharmacology and Therapeutics.
- Promoting academic and clinical research in Pharmacology/Clinical Pharmacology and Therapeutics.
- Enhancing the standard of teaching/training in Pharmacology/Clinical Pharmacology and Therapeutics
- Promoting Pharmacology/Clinical Pharmacology and Therapeutics for the benefit of patients and society.



BENEFITS OF LIFE MEMBERS

- Receive notifications on of the organization
- Keep yourself updated in the world of pharmacology and therapeutics .
- Get connected with fellow pharmacologists of the country.
- Contest for various posts in the organization.
- Receive of the permanent membership e-certificate through email, enhance your profile by writing MNPT
- Participate in general body meetings (GBM) to speak and to vote.
- Participate in conferences/seminars/workshops/symposiums/training sessions at subscribed charges.
- Receive an e-copy of the official publications (i.e. News letter, Journal, academics, research material etc.

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For more details queries WhatsApp 9528540756

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R_x FACTOR

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NATIONAL ASSOCIATION OF PHARMACOLOGY AND THERAPEUTICS

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