BJ Pharma
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Editorial

Vaccine Clinical Trials

Vaccines are either prophylactic or therapeutic in nature. While prophylactic vaccines are given to normal participants, therapeutic or curative vaccines may be given to patients suffering from particular disease. Many of the prophylactic vaccines are given to pediatric group. Indian council of medical research has given guidelines to conduct vaccine trials in India.

Vaccine trials are carried out in same way like other drug trial. However, they differ in few aspects. In phase 1 vaccine trials apart from safety measurement, other important objective is check immunogenicity by detection of the antibodies and description of the kinetic of the immune response (Peak of response and antibody decay curve). Information about induction of cell-mediated immunity, cross reactive antibodies and/or interaction with pre-existing antibodies which might affect immune system is also obtained. In Phase three trial, the effectiveness of vaccine is measured by protective rate. Protective rate is reduction in incidence of disease after vaccination as compared to that prevailed before.

Apart from above phases of clinical trial, sometime vaccine has to under go pharmacodynamic study. These studies are required when other route of administration is claimed, vaccine contains new adjuvant or excipient, to check the effect of simultaneous administration of other vaccines, efficacy and adverse events due to changes in vaccine strain, and interchangeability of vaccine. While bridging studies are required to support comparability of efficacy, safety and immunogenicity of new formulation and dose regimen to another. The need of doing bridging study should be justified in the protocol. The type of bridging study will be depended on the indication or change in route, population, manufacturing site or dose schedule.

Special concerns about vaccine trials: 1. Some vaccines may contain live attenuated or active organism, there is risk of infection in such vaccine trial e.g. MMR vaccine, rotavirus vaccine 2. If a participant in any of the group develop diseases, free treatment should be given to the participants.3. Risks of vaccines produced by recombinant DNA technology are not completely known, The guidelines issued by Department of Biotechnology should be followed. 4. Post trial access to vaccine should be available to control group. Post trial access to the vaccine should be given first to the community from which the participants were drawn. 5. In randomized control trial (RCT), if no effective vaccine exists as comparator then placebo can be used.6. Most vaccine trials involve children, which is a vulnerable population. Appropriate ethical guidelines should be followed when they are included in study.

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Contents

PSYCHOPHARMACOLOGY IN COVID 19 ERA

The COVID 19 pandemic has affected the lives of most of humanity. It has been a challenge to take care of the mental health issues directly or indirectly related to COVID infection. COVID 19 infection itself has given rise, in many cases, to delirium, catatonia, anxiety, depression, post traumatic stress disorder and some post COVID mental health issues like general asthenia, amotivation, impaired sense of reality and general distress. Added to this are issues like inability of neurotic patients to remain in the mandatory isolation or wear masks regularly or developing near behavioral addictions to food supplements supposed to be helpful in preventing COVID infection.

In COVID management, when juxtaposed with life saving drugs, psychopharmacological management is often sidelined; but in fact, taking care of mental health issues with judicious psychopharmacology and counseling has many far reaching benefits. To start with, the mental health symptoms (newly developed or pre-existing) are taken care of. This ensures the patient's better compliance with medical treatment and invasive procedures. It also minimizes the subsequent adjustment disorders. The healthy acceptance of psychiatric symptoms and their timely management is a major factor contributing to better post-covid rehabilitation.

Multiple organ systems are affected by COVID 19 infection. The involvement of gastrointestinal, renal, cardiovascular, pulmonary, immunological and hematological system can cause changes in the pharmacokinetics of the psychotropic medication and an increased propensity towards adverse effects. Also, the several treatments used for COVID 19 infection have potential neuropsychiatric side effects and interaction with common psychotropics. These difficulties can be circumvented by increased awareness, informedness (guidelines on managing mental illness in COVID 19 are freely available on MOHFW website) and alertness of the treating clinician.

Psychiatrists commonly encounter a subtle yet strong resistance to psychopharmacology in colleagues, friends and family. Although dealing with medical management day in and day out, when faced with personal recommendations to start antidepressants or anti-anxiety medications, often there is an automatic recoil - a natural apprehension about taking “mind altering medications”. It is difficult for the psychologically educated populace to accept mental weakness needing pharmacological support. It is common to hear 'determination to get out of it on their own.' Also, the apprehensions about possible side effects and dependence are far outweighed by the evidence based advantages of individually tailored psychopharmacology. Long term therapy has its own important role but there are few substitutes to psychotropics for the immediate control of acutely distressing symptoms.

Clinicians and patients alike have rapidly adapted their conventional medical practices to the demands made by the pandemic situation. Pre-existing psychiatric conditions as well as new psychiatric symptoms are increasingly being addressed virtually via several different platforms like video calling, skype, zoom, etc. and the Government has also facilitated this by validating online consultations and prescriptions.

Dr Minakshi Parikh
Professor and Head
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Latex Surgical Gloves

Allergic reactions:

- Type 1 immediate hypersenstitivity reaction: Contact urticaria (back of hands) with rhinitis, conjunctivitis, asthma and anaphylaxis
- Type IV hypersensitivity allergic dermatitis: on back of hands and fingers (slight redness to an exudative eruption)
- Risk of allergic reactions to the glove latex proteins and residual allergens in the patients and contact population

Mechanical Complications:

Hand Grip issues and perforation while using gloves

Granulomatous reaction to dusting powders: risk of delayed healing

Foley's self-retaining Catheters

Mechanical complications:

- Pain and Difficulty in insertion or removal of catheter
- Urethral trauma and bleeding from urethra / microscopic hematuria
- Bladder spasm
- Balloon fragments: Catheter balloon may burst, either during insertion or withdrawal or when it is indwelling. If not removed it can lead to stones and catheter blockage

Infections: present with suprapubic pain or tenderness, vague pelvic discomfort, costovertebral tenderness or acute onset of hematuria or pyuria. Risk of infection is directly proportional to the duration of catheterization

- Bacterial Colonization
- Chronic Infection and repeated use of antimicrobial can increase risk of development of antibiotic resistance.
- Septicaemia
- Kidney and Bladder damage: Encrustation formed around and within the catheter due to the crystals formed by bacterial activity is a medical emergency. Treatment is required to prevent the permanent damage to kidneys and bladder due to obstructed urine flow. This can present as lower amount of urine collection in urinary bag despite of normal kidney function. Patient may complain of suprapubic pain because of bladder distension. Obstruction of the catheter may lead to hydronephrosis and significant kidney damage
- Bladder stones: Crystals of struvite formed around the catheter resulting from Proteus mirabilis infection act as nuclei for stone formation within the bladder. Patient may complain of pain during micturition, hematuria or obstruction to urinary flow.
- Pseudo-polyps: Bladder wall is sucked into the drainage eye resulting in hemorrhagic polyps
- Pseudopolyps (lead to hematuria) &Stricture (causing thinning of stream) are the complications observed

Dr. Shamil Sheth

You are requested to report Medical Device Adverse Events to the MDAE reporting Centre, Department of Pharmacology, B. J. MedicalCollege, Ahmedabad.
Medical Device Adverse Event Reporting form can be downloaded from:
https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadNewsFiles/MDAEform.pdf

Highlights of Monthly Safety Alerts published by Pharmacovigilance Programme of India (Jan 2021- Feb 2022)

(1) DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms): Clobazam, Torsemide, Cefpodoxime

(2) Acute Generalized Exanthematous Pustulosis: Cefazolin, Etoricoxib

(3) Fixed Drug eruption: Ambroxol, Ibuprofen

(4) Sinus bradycardia: Remdesivir

(5) Interactions:

a. Rosuvastatin + Ticagrelor: Rhabdomyolysis

Possible mechanisms:

i) Renal impairment caused by ticagrelor, leading to decreased renal excretion of rosuvastatin

ii) Competition on transporter level (OATP1B1), leading to decreased biliary excretion of rosuvastatin

iii) Genetic polymorphism (OATP1B1 and/or UGT2B7), leading to increased competition on transporter level

https://who-umc.org/media/164007/rhabdomyolysisweb.pdf

b. Quetiapine + Valproic acid: Neuropsychiatric Adverse Events (Depressed level of consciousness / Coma and disorientation)

Possible mechanisms:

i) Quetiapine is metabolized mainly via CYP3A4 and CYP2D6 (lesser extent). Valproic acid inhibits both enzymes minimally in vitro at therapeutic concentrations.

https://pubmed.ncbi.nlm.nih.gov/24392714/

Source: https://ipc.gov.in/mandates/pvpi/pvpi-updates/8-category-en/931-drug-alerts-2022.html

Highlights of US-FDA safety communications (Jan 2021- Feb 2022)

(1) 31-03-2021: A potential increased risk of arrhythmias in patients with heart disease (heart failure, valvular heart disease, conduction system disease, ischemic heart diseases) who are taking lamotrigine.

(2) 01-09-2021: Increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with the arthritis and ulcerative colitis medicine tofacitinib (JAK inhibitor); particularly in patients who are smokers, with cardiovascular risk factors or who already have/develop a malignancy. Reserve these medicines for patients who have had an inadequate response or intolerance to one or more TNF blockers.

(3) 2-11-2021: Getting alcohol-based hand sanitizer in the eyes from splashing/touching the eyes can result in serious injury, including severe irritation and damage to the surface of the eye. Commonly seen in children; specially after COVID-19 pandemic.

Source: https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications

Notable New drug approvals by US-FDA(Jan 2021- Feb 2022)

Cabotegravir and Rilpivirine: co-packaged (Approval date: 21/1/2021)

- **Indication:** In HIV-1 infected adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen.
- **Mechanism of action:** cabotegravir: integrase strand transfer inhibitor, rilpivirine: NNRTI
- **Dosage:** Oral lead in dose: Tablet cabotegravir 30 mg and Tablet rilpivirine 25 mg (28 days)

Followed by: 600 mg cabotegravir and 900 mg of rilpivirine on last day of oral lead-in intramuscular

Continuation: 400 mg cabotegravir and 600 mg rilpivirine monthly intramuscular

- **Contraindications:** Previous hypersensitivity reaction to any of the above drugs
- **Warning:** Hepatotoxicity, Depressive disorders,
- **Adverse Drug Reactions:** Injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, rash

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212888s000lbl.pdfhttps://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021

Dasiglucagon (Approval date: 22/3/2021)

- **Indication:** To treat severe hypoglycemia in pediatric and adult patients with diabetes (>=6 years)
- **Mechanism of action:** Glucagon receptor agonist, increase in blood glucose by stimulating glycogen breakdown and release of glucose from the liver.
- **Dosage:** 0.6 mg/0.6 mL single-dose autoinjector or pre-filled syringe
- **Contraindications:** Pheochromocytoma, Insulinoma
- **Warning:** Hypersensitivity, Lack of Efficacy in Patients with decreased hepatic glycogen
- **Adverse Drug Reactions:** Nausea, vomiting, headache, diarrhea, and injection site pain

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214231s000lbl.pdf

Daridorexant (Approval date: 7/1/2022)

- **Indication:** In adult patients with insomnia: sleep onset and/or sleep maintenance
- **Mechanism of action:** Antagonism of orexin receptors (OX1R, OX2R)
- **Dosage:** 25 mg, 50 mg, taken orally within 30 minutes before going to bed
- **Contraindication:** Narcolepsy
- **Warning:** CNS depressant effect, complex sleep behaviors (sleep walking), cataplexy like symptoms
- **Adverse Drug Reactions:** headache, somnolence

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214985s000lbl.pdf

Research Publications of Department of Pharmacology

1. Gohil JB, Desai CK, Panchal JR, Patel RR, Rathod GH. An evaluation of trigger tool method for adverse drug reaction monitoring at a tertiary care teaching hospital. Indian J Pharmacol 2022;54:19-23.

2. Shah N, Desai C, Patel S, Vankar GK, Parikh M.Teaching clinical ethics to intern doctors by integrated seminar and online discussions. Adesh Univ J Med Sci Res 2021;3(1):11-7.

3. Faruqui AR, Xavier D, Kamat SK, Chandy SJ, Medhi B, Tripathi RK, Shetty YC, Raj JM, Kaushal S, Balakrishnan S, Atal S. Safety of hydroxychloroquine in healthcare workers for COVID-19 prophylaxis. The Indian Journal of Medical Research. 2021 Jan;153(1-2):219.

4. Patel S, Shah SP and Desai C. An Analysis Of Banned Fixed-Dose Combinations In India. Asian Journal of Pharmaceutical and Clinical Research. 2021, 14 (2):158-61.

5. Patel PP, Gandhi AM, Desai CK. Cinemeducation: A teaching-learning tool to teach professionalism and ethics in medical undergraduates. International Journal of Basic & Clinical Pharmacology. 2022 Mar;11(2):91-96.

6. Vegada BN, Karelia BN. Biological response modifiers in rheumatoid arthritis: metaanalysis of efficacy. Journal of Basic Clinical and Pharmacy. 2021 May; 12(4): 33-43.

7. Karelia BN, Singh AP, Modi S. Analysis of QTc prolongation due to bedaquiline in tuberculosis patients-A retrospective study. Journal of Biomedical and Pharmaceutical research. 2021 May-June;10(3): 58-62.

8. Karelia BN, Piparava KG, Patel PA. Prescription pattern study in type 2 DM in diabetic out patients at private clinic. European Journal of Molecular and Clinical Medicine. 2021; 8(4): 79-87.

9. Hiraparara RK, Karelia BN, Singh AP, Trivedi A. Adverse drug reaction profile of drugs prescribed in coronavirus disease - 19 patients – a cross-sectional study. Asian Journal of Pharmaceutical and Clinical Research. 2021 October; 14(10):33-36.

Contributions of the Department during COVID -19

1.Dr. Chetna Desai, Professor and Head, Department of Pharmacology, B. J. Medical College, Ahmedabad was allotted additional Charge as Manager, GMSCL, Gandhinagar during the COVID -19.

2. Dr. Samidh Shah (Assistant Professor) was posted at Gujarat Medical Services Limited (GMSCL). He helped in procurement of various COVID-19 equipment like ventilators, ECGs, multipara monitors, defibrillators, PPE kits, masks, gloves, and others and Facilitated the delivery and installation of PSA plant.

3. Dr.Vishal Mishra (Tutor) was posted at Gujarat Medical Services Limited (GMSCL). He worked as DGM-logistics and looking after delivery of various items for related to COVID throughout Gujarat.

4. All other Department members also performed various duties like floor manager/ liaison officer at 1200 bed hospital during COVID 19 crisis.

National Pharmacovigilance Week 2021

Department of pharmacology; B. J. Medical college, Ahmedabad celebrated the "National Pharmacovigilance Week 2021" during 17 to 23 of September 2021. In this week, Department conducted various activities like sensitization programs of clinicians, resident doctors, nursing professionals and pharmacist regarding pharmacovigilance ; organized a skit at OPD of the Civil Hospital to aware patients about pharmacovigilance. A poster competition also was held to create awareness among MBBS students about pharmacovigilance.

Day 1: Sensitization program for pharmacists regarding ADR Reporting


Day 5: Consumer Awareness Progamme for safe use of medicines


Day 6: Poster competition with theme of Safe use of medicines

Organizing team for National PharmacoVigilance week 2021: Department of Pharmacology, B. J. Medical College, Ahmedabad.

Workshop-cum-sensitization Programme on Pharmacovigilance at M & J Institute of Ophthalmology.

Department of pharmacology; B. J. Medical college, Ahmedabad organized a "Workshop Cum Sensitization Programme on Pharmacovigilance" at M & J Institute of Ophthalmology on 26th august 2021.

Online/offline: Advance Level Training in Pharmacovigilance

In collaboration with Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ghaziabad, Department of pharmacology; B. J. Medical college, Ahmedabad; organized an "Online/offline: Advance Level Training in Pharmacovigilance" at B.J. Medical College, Ahmedabad. Total 189 participants were registered (155 online and 34 offline)

Team Advance Level Training, Pharmacovigilance

Conference and workshops attended by faculties of the Department

1. Dr. Chetna Desai delivered guest lectures as resource person for the Induction cum training programmes organized by NCC, PvPI, Ghaziabad.

2. Dr. Chetna Desai deliverd guest lectures at the seminars and CBME workshops held by National Pharmacology and Therapeutics and ESIC Medical Collge, Hyderabad.

3. Dr. Bharti Karelia , Associate professor, B.J.Medical college, Ahmedabad attended a conference and workshop on 2nd September, 2021 at MEDUCON-2021, Department of Medical Education, JIPMER, Puducherry.

4. Dr. Bharti Karelia, Associate professor, B .J .Medical college, Ahmedabad attended a National Workshop on Pharmacoeconomics on 18th and 19th February, 2022 at Department of Medical Education, JIPMER, Puducherry.

Paper and Poster presentations by Resident Doctors, Department of Pharmacology

- Dr. Neel Patel, Third year resident doctor, Department of Pharmacology, presented a paper on "Evaluation of efficacy and safety of vasoactive drugs in Acute Esophageal Variceal Bleeding at a tertiary care Hospital" and a poster on "Study of Efficacy & Safety of Delamanid in patients of MDR-TB at Civil hospital Ahmedabad" on 19th and 21st November, 2021 at INTPCON, Surat.
- Dr. Kaushal Panchal, Third year resident doctor, Department of pharmacology, Presented a paper on "Use of dietary supplements among 2nd professional year medical students at a tertiary care teaching hospital"on 3rd September, 2021 at Meducon, JIPMER, Puducherry.
- Dr. Kaushal Panchal, Third year resident doctor, Department of Pharmacology, presented aposter on "An evaluation of prescribing pattern of anti-epileptic drugs in pediatric patients at a tertiary care teaching hospital: A prospective study"on 20th November at INTPCON, Surat.
- Dr. Lav Patel, Third year resident doctor, Department of Pharmacology, presented a paper on" A comparison of effectiveness of corticosteroids alone versus corticosteroids and cyclosporine in management of severe cutaneous adverse drug reactions" and a poster on "Drug utilization study in Department of Medicine and Surgery at a tertiary care teaching hospital" on 19th and 20th November, 2021 at INTPCON, Surat.
- Dr. Aniruddha Prajapati, Third year resident doctor, Department of Pharmacology, presented a paper on "COVID-19 related awareness among resident doctors: a questionnaire-based survey" on 28th June 2021 at Online national conference on "Drug targets and newer drugs for COVID-19" organized by Chettinad Hospital and Research Institute (CHRI) Kelambakkam, Tamilnadu.
- Dr. Aniruddha Prajapati , Third year resident doctor, Department of Pharmacology, presented a poster on "A study of drug utilization pattern in pediatric patients of nephrotic syndrome at a tertiary care teaching hospital" on 2nd September, 2021 at JIPMER, Poducherry.
- Dr.Karthik E, Third year resident doctor, Department of Pharmacology, presented a paper on "A study to compare the effectiveness of case based MCQ led tutorials vs traditional tutorials among second year undergraduate medical students" on 19th November, 2021 at INTPCON, Surat.
- Dr.Karthik E, Third year resident doctor, Department of Pharmacology, presented a poster on " An Intensive Monitoring of Adverse Drug Reactions in patients treated for Head and Neck Cancer" on 29th October, 2021 at National Conference on Medication Safety, NCMS, 2021
- Dr.Jaymin Chaudhari, Third year resident doctor, Department of Pharmacology, presented a paper on "Perception and Attitude of Undergraduate Medical students regarding online teaching learning method" and a poster on "Evaluation of efficacy and safety of the drugs used in chronic obstructive pulmonary disease at a tertiary care teaching hospital-Interim analysis" on 19th and 21st November, 2021 at INTPCON, Surat.
- Dr. Khushboo Prajapati, Third year resident doctor, Department of Pharmacology, presented a paper on "A Study of feedback of medical faculties on conducting online teaching during COVID-19 pandemic" and a poster on "A study of pharmacological management of diabetic foot at tertiary care teaching hospital" on 20th and 21st November, 2021 at INTPCON, Surat.
- Dr. Avani Desai ,Second year resident doctor, Department of Pharmacology, presented a paper on "Impact of vaccination on COVID-19 infection among resident doctors of tertiary care teaching hospital. -A cross sectional study" on 30th January 2022 at World Congress on Pharmacology.
- Dr. Shachi Jagrit,Second year resident doctor, Department of Pharmacology, presented a paper on"An Evaluation of Risk Factors and Pharmacotherapy in Post SARS-CoV-2 (COVID-19) Rhino-Cerebral Mucormycosis Patients in a Tertiary Care Teaching Hospital in Ahmedabad" on 3rd September 2021 at MEDUCOM, JIPMER.
- Dr.Miruthu Bashini,Second year resident doctor, Department of Pharmacology, presented a poster on "Evaluation of adverse drug reactions following Remdesivir therapy in COVID-19 patients" on 29 October 2021 at ICMS SRMC, Chennai

The story of artemisinin discovery began during the Cultural Revolution in China, as a government initiative, to aid the North Vietnamese in their war with the United States. Chloroquine-resistant Plasmodium falciparum malaria was a major problem during the war. In the US, these efforts culminated in the discovery of mefloquine; the North Vietnamese turned to China for help.

To program this research, Chairman Mao and Premier Zhou held a meeting on May 23, 1967 in Beijing and a secret nationwide program was framed, called project 523 (May 23rd), involving over 500 scientists in approximately 60 different laboratories and institutions to find a compound for treatment of drug resistant malaria. This work was considered as a military secret, so no communication to the outside world or publication in scientific journals was allowed.

In 1969, under the project 523 Youyou Tu, principle investigator at the Institute of Chinese Meteria Medica, China Academy of Chinese Medical Sciences (CACAMS) and her team screened more than 2,000 recipes of Chinese traditional herbs to check anti-malarial activity and compiled 640 recipes for further evaluation. The extracts from Artemisia annua L (Qinghao), a type of wormwood native to Asia, showed to inhibit parasite growth by 68% initially but the activity was not stable, varying from 12-40% in subsequent repeats. Professor Tu reasoned that the low inhibition could be due to a low concentration of the active ingredient in the preparation and began to improve the methods of extraction.

After reading the ancient Chinese medical description in The Handbook of Prescriptions for Emergency Treatments by Ge Hong (283–343 CE), she realized that traditional methods of boiling and high-temperature extraction could damage the active ingredient and switched from ethanol to ether extraction at a lower temperature. This extract, numbered 191, was tested in the mouse malaria Plasmodium berghei, and achieved 100% inhibition in October 1971. Findings were presented at a 523-meeting held in Nanjing on March 8, 1972. The first clinical trial was carried out in Hainan province between August-October 1972, on 21 patients achieving 95-100% inhibition.

These data were first mentioned in a Wellcome Trust publication entitled 'A present from Chairman Mao (Gardner, 2002)' which made these compounds known internationally. This is also how a first Western company, Rhône-Poulenc Rorer (RPR, now Sanofi-Aventis), decided to study the potential of these drugs and license one of them, injectable artemether, from Kunming Pharmaceuticals.

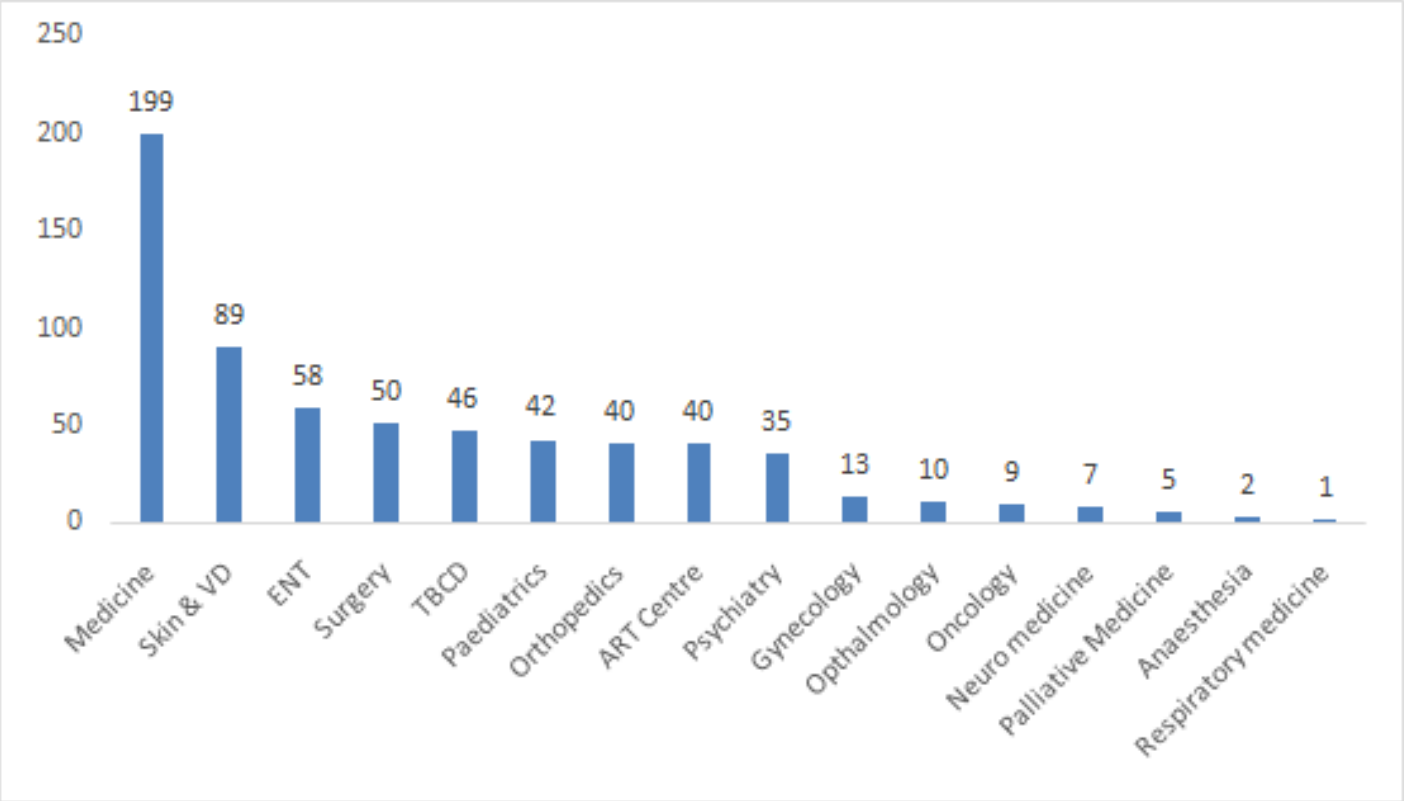
On December 7, 2015 scientist Youyou Tu was honoured with the noble prize for the discovery of artemisinin. Thus Project 523 reflects the spirit of collaboration between scientists and institutions leading to discovery of artemisinin and provided the path for future discovery of other antimalarials drugs.

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4674626/

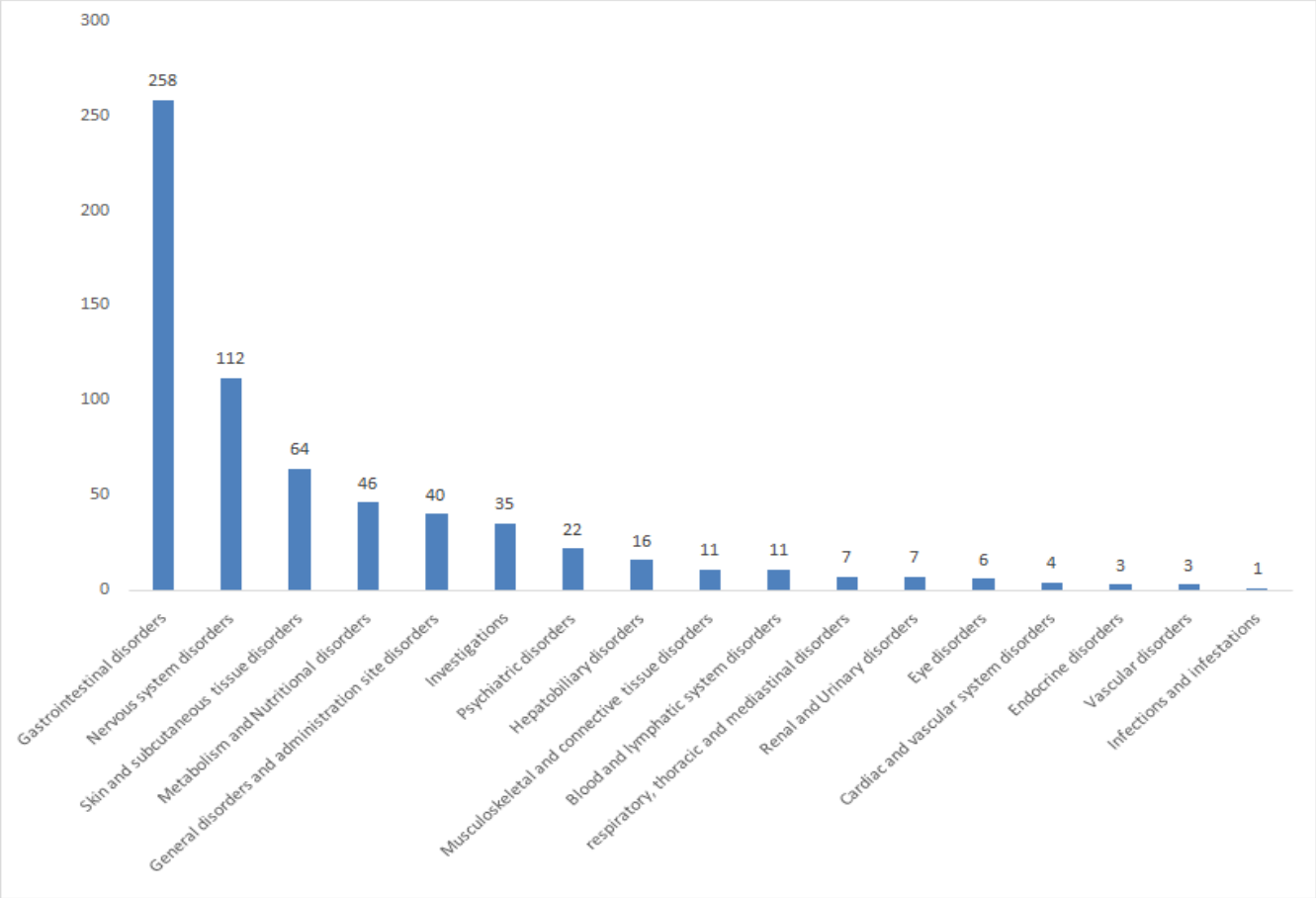
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4966551/

Dr. Lav Patel, Dr. Samiksha Sonar

Graph 1: Adverse Drug Reactions (ADRs) reported by different departments between January to December 2021 (n= 646)

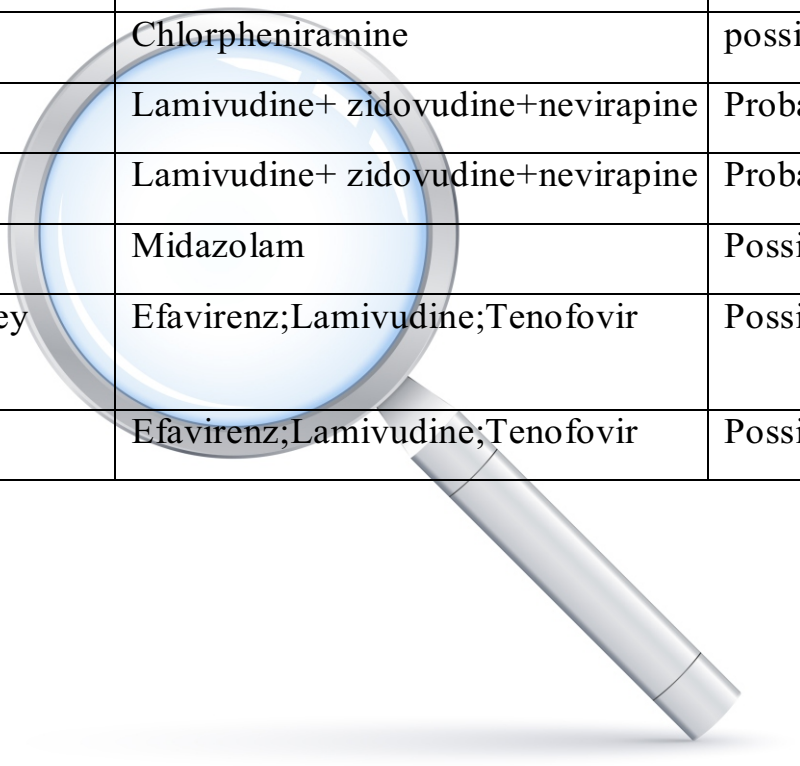


Graph 2: System Organ Classification (SOC) of Adverse Drug Reactions reported between January to December 2021 (n=646)



Tabel 1: Serious ADRs Reported by AMC during January to December 2021

Sr No.	Event	Suspected drugs	WHO UMC scale	Naranjo's Scale
1	Respiratory depression	Dextromethorphan	probable	probable
2	Drowsiness	Dextromethorphan	possible	possible
		Chlorpheniramine	possible	possible
3	Seizure	Dextromethorphan	possible	possible
		Chlorpheniramine	possible	possible
4	Anemia	Lamivudine+ zidovudine+nevirapine	Probable	Probable
5	Anemia	Lamivudine+ zidovudine+nevirapine	Probable	Probable
6	Sedation	Midazolam	Possible	Possible
7	Acute kidney injury	Efavirenz;Lamivudine;Tenofovir	Possible	Probable
8	Anemia	Efavirenz;Lamivudine;Tenofovir	Possible	Probable



For ADR reporting, please contact:

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Dr. Jigar Panchal 09979275367

Dr. Samidh Shah 09825507413

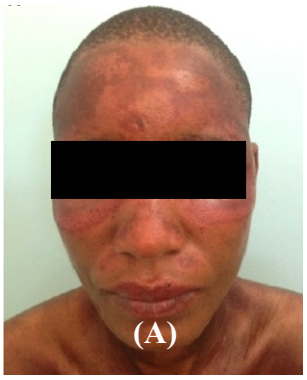
Dr. Prakruti Patel 09879542949

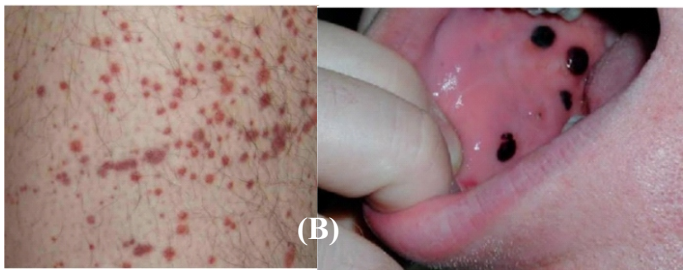
Tabel 2: Medical Device Adverse Events Reported by AMC during January to December 2021

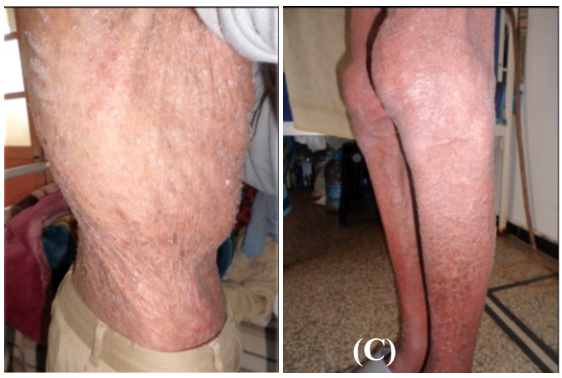
Device	Adverse Event	No of Adverse Event(s) observed
IUCD	Lower Abdominal Pain	03
Neostigmine Ampoule	Injury	01
Nasogastrictube	Erosion	01
	Insertion Attempt Failed	01
	Bleeding	01
N-95 Mask	Irritation in eyes	01
	Pain behind ears	02
	Redness behind ears	02
	Torn mask	01
Triple layer medical mas	loose fitting of mask	01
	discomfort and pain around ear	01
Goggles	Fogging of goggles	01
	Improper fitting and discomfort of goggles	01
Gloves	Numbness of hands	01
	Pitting of nails	01
	Softening of palm	02
	Itching and dryness of both the hands	01
	Improper fitting and discomfort of gloves.	01

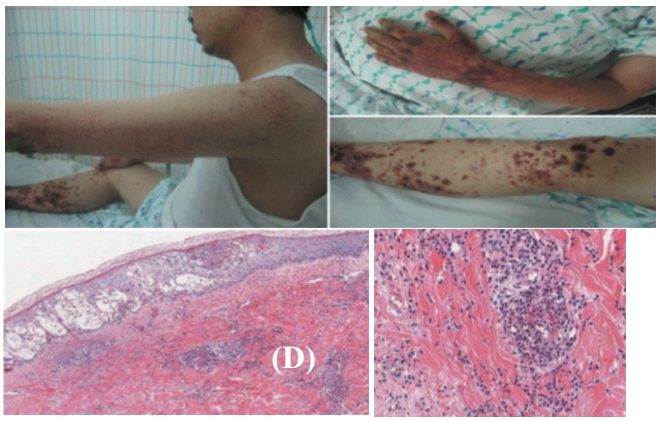
Medical Device Adverse Event Reporting form can be downloaded from:
https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadNewsFiles/MDAEform.pdf

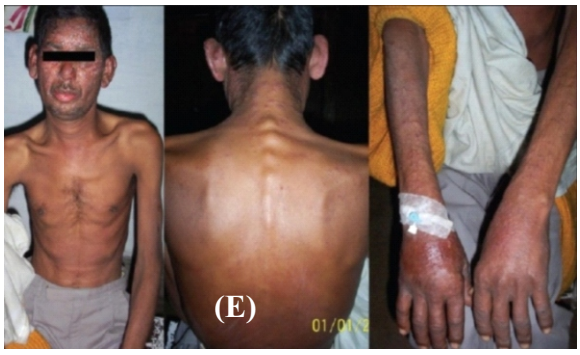
A total of 26.4 lakh patients were diagnosed with tuberculosis in the year 2019. Of these, 1,24,000 patients suffered from MDR- TB. These patients receive first line/ second line anti- tubercular drugs for prolonged periods and can develop a variety of skin lesions. The following section depicts different skin lesions which can be observed with anti-tubercular drugs. Try and identify the skin lesions and most likely causal anti-tubercular drugs for the same!

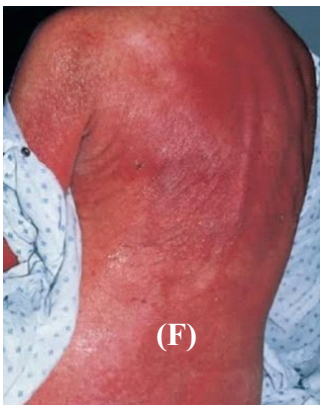












Answer key:
(A) Drug-induced subacute cutaneous lupus erythematous (DI-SCLE) - Isoniazid (B) Thrombocytopenic purpura (purple rash and haemorrhages in oral mucosa) – Rifampicin (C) Ichthyosis (Dry scaly skin over back and legs) – Isoniazid (D) Cutaneous leucocytoclastic vasculitis (Purpura with ulcerations over hands and legs, fibrinoid necrosis of vessel wall):Rifampicin, Pyrazinamide, isoniazid (E) Photosensitivity (Lesions on sun exposed parts, Swelling and erythema) - Isoniazid, pyrazinamide, fluroquinolones (F) Redman syndrome: Rifampicin overdose, linezolid

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