



# KARNATAKA REGISTERED PHARMACISTS ASSOCIATION<sup>®</sup>

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# 2022

Doctors Cure Patients  
But Only  
Medicines  
can cure Diseases

Hold the Smile ,Keep the Laugh  
Lose the Pain and forget the fear

## HAPPY NEW YEAR

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# ORAC

## THE ANTIOXIDANT VALUE

You may be wondering why I am writing on this subject. It happened recently in my train compartment... (It is important to mention here that I prefer to travel in second class compartment so that I can meet or try to understand different sets of people). One group of ladies were discussing about ORAC food and were openly announcing that ORAC food will increase oxygen in Covid patients – particularly those who are in need of oxygen. I was not only shocked but worried too since wrong information will spread and may have some undesirable effect on society... hence, I thought it right to intervene and try to explain the actual fact that ... high value ORAC food has high antioxidant activity and does not increase the oxygen...

ORAC means oxygen radical absorbance capacity, it is an assay developed by scientists at the National Institute of Health and Aging to measure the antioxidant capacity of a range of substances found in nutraceuticals, pharmaceuticals and different foods - and now it has emerged as a lowest cost, highly efficient, and robust analytical method.

Antioxidants and oxidants are one of the old dichotomies; a proper balance must be maintained between oxidants and antioxidants as their imbalance within the human body leads to oxidative stress. Before this - it is important to understand the free radicals and antioxidants.

Free radicals are atoms or molecules having one or two unpaired electrons in its outer orbit/shell so they are highly reactive, to become stable either they have to grab the electron from the immediate neighbor molecule or release the unpaired electron/s. In this process these free radicals can readily oxidize and damage essential biological molecules, such

as lipids and proteins. Though free radicals may be of exogenous origin, they are usually endogenous and are constantly produced as a result of normal biological and metabolic processes. At any moment of time there are millions and millions of free radicals, but at the same time to prevent damage induced by free radicals, the human body produces a number of free radical scavengers or antioxidant defense systems like endogenous antioxidant enzymes: Superoxide dismutase (SOD), glutathione peroxidase (GSHPx) and catalase, which operate intracellularly and act as primary enzymatic antioxidant defenses. Zinc, Copper and Manganese are incorporated into the two types of SOD, which neutralize the superoxide anions. Selenium is a component of GSHPx, which plays an important role in the catabolism of hydrogen peroxide. Catalase contains iron and removes hydrogen peroxide from the cell. Extracellular free radicals are inactivated by circulating antioxidants, such as Vitamin E, Vitamin C and Betacarotene - which enter the body exogenously from our food intake. In plasma, Vitamin C forms the first line of defense. This antioxidant is water soluble and can neutralize free radicals and singlet oxygen (another reactive metabolite of oxygen but not a free radical, singlet oxygen contains an electron, excited to a higher orbit by energy capture. This oxygen metabolite may cause tissue damage). In membranes and lipoproteins, antioxidant protection is provided primarily by the fat-soluble Vitamin E, especially the alpha-tocopherol vitamin and beta-carotene. Tocopherols and carotenoids are transported in blood in plasma lipoproteins, predominantly low-density lipoprotein (LDL) and high-density lipoprotein (HDL).



Simply put antioxidants are chemical compounds that have sparsely populated outer electron shells. Thus, they are able to readily accommodate unpaired electrons, and therefore neutralize oxygen free radicals and at the same time they become inactive radicals.

When certain cholesterol rich proteins are oxidized, there will be a spurt of free radicals. In ischemic attacks, congestive heart disease, atherosclerosis, diabetes and in an acute phase of illness, oxidative stress is high and leads to the formation of peroxides, which are harmful to cells.

It is very important to maintain proper balance between oxidants and antioxidants as their imbalance within the human body leads to oxidative stress.

Oxidative stress has been linked to several diseases like heart disease, cancer, stroke, respiratory diseases, immune deficiency, Parkinson's disease, other inflammatory conditions and the acceleration of aging process.

As per the theory of free-radicals, in ageing and disease, high intake of antioxidants through foods slows down the progression of age-related degeneration and disease through quenching of the free radical chain reaction by donating electrons to a free radical without becoming destabilized themselves.

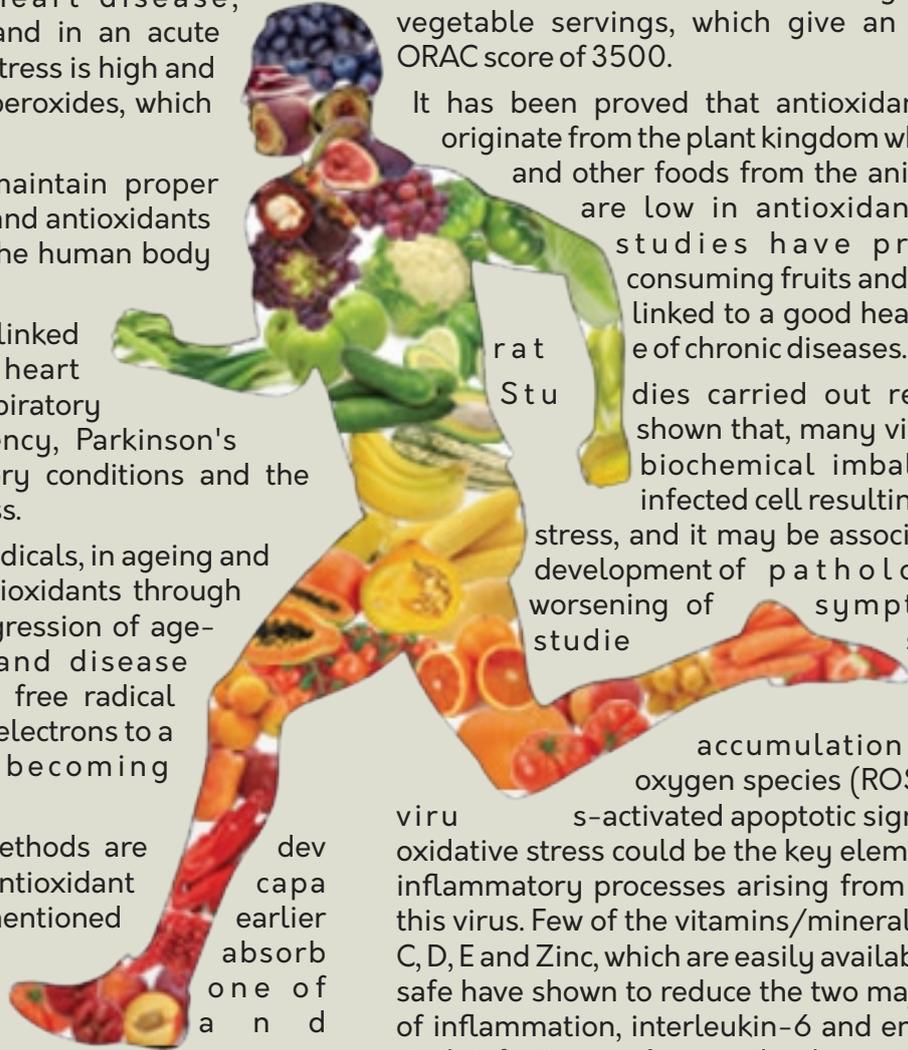
Over the years several methods are developed for determining antioxidant capacity of a substance. As mentioned earlier ORAC (The oxygen radical absorbance capacity) assay is one of the well-studied, reliable and cheapest. The ORAC assay measures the fluorescent signal from a probe that is quenched in the presence of Reactive Oxygen Species (ROS). Addition of an antioxidant absorbs the generated ROS, allowing the fluorescent signal to persist. The ORAC assay is unique in that its ROS generator, AAPH (2,2'-azobis(2-methylpropionamide) dihydrochloride), produces a peroxy free radical upon thermal decomposition. This free radical is commonly found in the body, making this reaction biologically relevant. Furthermore, AAPH is reactive with water and lipid soluble substances, so it can measure total antioxidant potential.

It is stated that "A significant increase in antioxidants of 15-20% is possible by increasing consumption of fruits and vegetables, particularly those high in ORAC value. However, in order to have a significant impact on plasma and tissue antioxidant capacity one can only meaningfully increase one's daily

intake by 3000-5000 ORAC units". Scientists who have worked in the area of antioxidants have stated that the body can effectively use 3000-5000 antioxidant or ORAC units per day. Any more than this seems to be of no added benefit because the antioxidant capacity of the blood is tightly regulated, and "excess" is most likely excreted by the kidneys. The UK FSA (Food Standards Agency), and the FDA recommend "5 a day" of fruit and vegetable servings, which give an approximate ORAC score of 3500.

It has been proved that antioxidant rich foods originate from the plant kingdom while meat, fish and other foods from the animal kingdom are low in antioxidants. Several studies have proved that consuming fruits and vegetables is linked to a good health and lower risk of chronic diseases.

Studies carried out recently have shown that, many viruses cause a biochemical imbalance in the infected cell resulting in oxidative stress, and it may be associated with the development of pathologies and worsening of symptoms. Few studies have shown that the reduction of accumulation of reactive oxygen species (ROS) retards the virus-activated apoptotic signalling, hence oxidative stress could be the key element related to inflammatory processes arising from the action of this virus. Few of the vitamins/minerals like vitamin C, D, E and Zinc, which are easily available, cheap and safe have shown to reduce the two major mediators of inflammation, interleukin-6 and endothelin-1 in viral infections. A recently done study with the improved oxygen radical absorbance capacity (ORAC) assay designed for lipophilic antioxidant, reveals that Natural Vitamin E (d-alpha tocopherol) is a chain breaking antioxidant. A very recent article by Feyaerts A.F and Luyten W concluded that "COVID-19 pneumonia and its progression to respiratory failure appear to be driven by an immune hyperreaction in which IL-6 plays an important role. Vitamin C can reduce these (and other) inflammatory mediators in various inflammatory conditions, and is clinically beneficial in (non-COVID-19) hypertensive and/or diabetic obese adult patients. Considering the weight of the evidence and because vitamin C is cheap and safe, an oral low dose (1-2 g/d) may be useful prophylactically, and in cases of severe COVID-19, a (very) high-dose regimen may be beneficial.



**Dr. Rekha K Shetty** MBBS

Medical Advisor



# KSPC's Pharmacist apron ABHIYAN

HAPPY NEW YEAR 2022

Take an Oath that during pharmacy practice and in pharmaceutical events, as relevant, thy shall wear the pharmacist apron.

It is said: **THE FIRST IMPRESSION IS THE LASTING AND BEST IMPRESSION.** In this vein, Karnataka State Pharmacy Council (KSPC) has launched a timely campaign motivating practicing community and hospital pharmacists to wear the professional apron at their workplace. In fact, in league with pharmacist associations, KSPC is distributing the KSPC apron with name plate, free of charge to all registered pharmacists, whose renewals are up to date. In addition, KSPC is launching informational campaigns to motivate pharmacists to wear the professional apron at their workspots.

The pharmacist is a knowledge professional who is well informed and trained in the preparation, properties, effects and use of medicines. Being the most accessible healthcare professional, as per various survey studies, the well informed pharmacist is always in high demand as patients seek the pharmacist's counsel. On healthcare matters, the pharmacist is a well-wisher and friend of all - to guide citizens on right use of medications and on other health advisories. During Covid-19 times, the pharmacist has gone extra mile - not only to produce medications and supplements in the factories, the community pharmacist is dispensing them with proper advisory and providing relevant medications at doorstep of elderly and those in quarantine. Hence, a doctor definitely diagnoses and recommends therapies, however, the pharmacist is the prime frontline healthcare professional who produces, promotes, dispenses and advices on right usage of medicines.

Many years back, the dashing iconic cricketer Sunil Gavaskar said - 'if you want to be a sportsman, first dress like a sportsperson!' Every committed professional wears an appropriate dress to ensure the person gets into the proper mood, state of mind, and the recipient perceives him/her in the correct manner. Hence, cricketers, tennis players, badminton sports personnel and athletes; doctors, nurses, armed force personnel, police and marketing professionals - all have their standard dress code for identity, to command respect, ensure credibility and build trust. It is time for hospital and community pharmacists to take their dress sense seriously and advance their professional practice.

Reliable and trusted journals like Scientific American, Forbes and Pharmaceutical Journal have all reiterated the benefit of right dress sense. Hence, the age old adage: dress for the job you want, not the job you have is very relevant here to motivate pharmacists to dress proper and aspirational. In plays, dress rehearsal is given the highest importance, since dress rehearsal creates right ambience and mood, and produces the best of performances. An apron wearing pharmacist will surely gain the confidence and stature to produce the best of pharmaceutical counseling and dispensing. Many studies uphold the importance of dressing to the occasion, since it boosts confidence and makes people focused on small details that is vital to be successful. A published study<sup>1</sup> on the pharmacist attire found that patients perceived the pharmacist wearing his/her white coat as more approachable. Further, patients indicated preference for the pharmacist wearing the white coat, regardless of community setting.

Wearing the right dress conveys social signals and even influences hormone levels that finally provide the right productive behavior. People make judgements of credibility, likeability, education level and trustworthiness based on the professional attire, hence, pharmacist apron in hospital and community pharmacy setting is a game changer approach. It is widely observed in studies that wearing an informal dress breaks down the command and respect; the casual element in dressing, erodes respect in recipient. The fulcrum of good professional practice is to firstly establish one's respect and stature.

It is time to take a cue from other professionals including nurses who are immaculate in their professional dress sense, to create the professional momentum in the practice of pharmacy by registered pharmacists. In this regard, Karnataka State Pharmacy Council (KSPC) has taken praiseworthy steps to ensure apron wearing habit by pharmacists. The KSPC apron abhiyan should be supported and patronized by all pharmacists.

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ORAC: Oxygen Radical Absorbance Ca



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# 60<sup>th</sup> National Pharmacy Week Celebrations



An initiative of Indian Pharmaceutical Association (IPA) “National Pharmacy Week (NPW)” is a channel to create awareness among the general public about the profession of Pharmacist and the role he plays to make a Healthier India. The theme for this year is “Pharmacist: An integral part of Healthcare”. The major focus of NPW celebrations is to create awareness among the public, other healthcare providers and the authorities, about the NPW theme. Acknowledging the invaluable contributions that the pharmacist make to the healthcare system, IPA, Mysuru branch is celebrating 60 th National Pharmacy Week celebrations from 13th – 18 th December, 2021 jointly with JSS College of Pharmacy, JSS AHER, Mysuru.

On the eve of National Pharmacy Week, 13th December 2021, the inaugural function of 60 th National Pharmacy Week Celebrations was organized at 11.00AM at Sri Rajendra Auditorium, JSS College of Pharmacy, Mysuru. The function was inaugurated by Dr. Surinder Singh, Vice Chancellor, JSS Academy of Higher Education & Research, Mysuru. After inaugurating the pharmacy week Vice chancellor mentioned the role of pharmacist in building health of the society. He also said that today there are many ways by which pharmacist can help patients based on their requirements. He emphasized the role of Pharmacists in the Covid 19 pandemic situation and appreciated the work rendered by the fellow pharmacists. The president of the event Dr. T M Pramod Kumar, Principal, JSS College of Pharmacy, Mysuru welcomed the guests. Other dignitaries present over the functions were Dr. P A Kushalappa, Director Academics, JSS AHER, Mysuru, Dr. Hanumathachar Joshi, Principal, Sarada Vilas College of Pharmacy and Dr. Manjunata M, Professor, Cauvery College of Pharmacy, Mysuru. The vote of thanks for the function was delivered by Dr. Chandan R. S, Secretary, IPA, Mysuru branch.



# Distribution Of Appreciation Kit To REGISTERED PHARMACIST Of Mysuru and Chamarajanagar District



On the eve of 60th National Pharmacy Week Celebrations, 17th December 2021, Karnataka State Pharmacy Council, Bangalore in association with JSS College of Pharmacy, Mysuru invited the Registered Pharmacist of Mysuru and Chamarajanagar district to felicitate with an APPRECIATION KIT. The function was graced by the presence of chief guest Dr. K. H. Prasad, District Health and Family Welfare Officer, Mysuru. Ms Shilpa Palaksha, Associate Professor, JSS College of Pharmacy, Mysuru welcomed the guests. Dr. TM Pramod Kumar, President of IPA Mysuru branch presided the function and other dignitaries present over the function were Dr. D. A. Gundurao, Vice President, Mr. Veerananarayana Reddy, Executive committee member, KSPC, Bangalore. After inauguration, Chief guest of the function distributed the Appreciation Kit to all the registered pharmacists of Mysuru and Chamarajanagar District. Dr Balamuralidhara V, Associate Professor, JSSCPM coordinate the program and Dr. MS Srikanth proposed the vote of thanks

To all of our amazing  
pharmacy professionals,  
**thank you.**



# DISTRIBUTION OF APPRECIATION KIT TO THE REGISTERED PHARMACISTS OF HASSAN DISTRICT

## DISTRIBUTION OF APPRECIATION KIT TO THE REGISTERED PHARMACISTS OF HASSAN DISTRICT

Sponsored by



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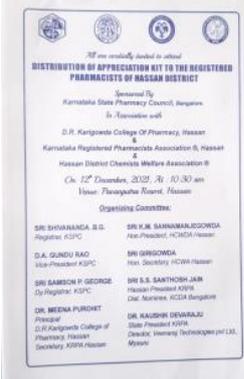


Hassan District Chemists Welfare Association (R), Hassan

On the Eve of

## 60<sup>th</sup> NATIONAL PHARMACY WEEK-2021

Date : 12<sup>th</sup> December 2021



Appreciation is the key motivation factor for the growth of a profession. With the thought to encourage the registered pharmacist of Hassan district, the Karnataka State Pharmacy Council (KSPC) in collaboration with D.R.Karigowda College of Pharmacy, Karnataka Registered Pharmacist Association (KRPA)® Hassan and Hassan District Chemists Welfare Association (HDCWA) ® organised a motivation event for the Hassan district registered pharmacist on 12th December 2021 at Pavanputra Resort, Hassan. The theme of the event was 'Distribution of appreciation kit to the registered pharmacists of Hassan District.' The appreciation kit consisted of a white apron with KSPC logo, a key chain and the name plate of the registered pharmacists with KSPC registration number on it.

The guests of honour of the event were ACD of Hassan District Sri Girish Gowda and Superintendent of Police Dr. Srinivas Gowda R, IPS. The event was graced by Shri D.A.Gundu Rao (Vice-President KSPC), Sri Sampson P.George (Dy.Registrar KSPC), Sri Y.Veeranarayana Gowda (KSPC Executive Committee member), Sri K.M. Sannamanje Gowda (Hon. President of HDCWA) and Sri Giri Gowda (Hon. Secretary of HDCWA). The proactive organizing committee members were Dr. Meena Purohit Principal of D.R.Karigowda College of Pharmacy, Hassan district KRPA president and district nominee KCDA Bangalore Sri Santhosh Jain and State President KRPA Dr. Kaushik Devaraju. Around 150 registered pharmacists of Hassan district attended the event.

The program started with the inauguration speech by Dr. Almas Shireen, Assistant Professor, at D.R.Karigowda College of Pharmacy followed by prayers to Almighty and remembrance offerings to Late Gen. Bipin Rawat and Late Puneeth Rajkumar. ACD Girish Gowda delivered a small talk on important role played by pharmacist in Health care system. IPS Dr. Srinivas

Gowda appreciated the efforts and dedication of the community pharmacist showed during the COVID-19 pandemic. KSPC members delivered talks on the important role of the registered pharmacist at a pharmacy and how they can bring a change in the health system by their knowledge. Sampson George stressed on the importance of pharmacy practice as a community pharmacist. An impetus talk was given by Sri Sunil Chiplunkar, Marketing Head of Group Pharmaceuticals, on importance of correct professional attitude and dressing sense. This talk emphasised more on utilisation and significance of appreciation gift apron and name plate given to the registered pharmacists. These thoughts were further elaborated by Dr. Meena Purohit and highlighted the pride of being a pharmacist and insisted every pharmacist to wear the apron with their name plate on it at their workplace to honour the pharmacist profession.

After the talk by Dr. Kaushik Devaraju on appreciation gesture by KSPC to fellow pharmacist the kits were distributed to the registered pharmacist. Around 30 registered pharmacists representing each taluk of Hassan were called on the stage and were made to wear apron and name plate. Mr. Mahaveer Singh, Associate Professor, and Ms. Mythree B.N., Assistant Professor at D.R.Karigowda College of Pharmacy, efficiently distributed the appreciation kits to all registered pharmacists who attended the program.

All the guests and the organizing members were felicitated. After the felicitation, MOU was signed between the KRPA Mysore and the founders of ChintaMoney. Function was concluded with vote of thanks followed by sumptuous lunch.

As a pharmacist, I want to express my gratitude to Shri Shivananda .B.G. Registrar KSPC and all members of KSPC for coming up with the brilliant idea of appreciation and motivating the registered pharmacist to work professionally and ethically.





# BLOOD DONATION CAMP on the eve of

## National Pharmacy Week

## CELEBRATIONS

Blood donation is the most important social service to humankind. Blood donation at the right time can save millions of lives all over the world every year. "Blood: Costs nothing to you and is priceless to someone else." A Blood donation camp was organized on 16th December 2021 at JSS College of Pharmacy, Mysuru in association with Indian Pharmaceutical association (IPA), Mysuru branch, Mysuru on the occasion of 60th National Pharmacy Week Celebrations. The program was inaugurated by Mr. L R Mahadevaswamy, Chairman, Zoo Authority of Karnataka (ZAK), Mysuru. Dr. T.M. Pramod Kumar, President IPA, Mysuru branch & Principal, JSS College of Pharmacy, Mysuru, Dr. Pallavi, Blood Bank Officer, JSS Hospital, Mysuru, Dr. G V Pujar, Vice Principal, JSS College of Pharmacy, Mysuru, Ms. Divyashree B, Assistant Administrative Officer, Dr. Umesh M, Coordinator of Blood donation camp, Dr. B M Gurupadayya, Treasurer, IPA Mysuru branch, Dr. Chandan R S, Honorary Secretary, IPA Mysuru branch, Dr. K L Krishna, NSS Program Coordinator, JSS AHER, Mysuru, Dr. M P Gowrav, NSS Program Officer were present during the event. More than 100 students and staff registered and screened for their eligibility to donate the blood through their blood pressure, weight, blood group matching and other procedures. The eligible volunteers were selected for blood donation and the program lasted up to 01:00 PM in the afternoon with a total of 51 units of successful blood donation from the student and staff volunteers.





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# INSPIRATIONAL PHARMACIST

## Pankaj Ramanbhai Patel

### THE PHARMA MAN



Pankaj Ramanbhai Patel is the Managing Director and the current Chairman of the fifth largest pharmaceutical company in India, The Cadila Healthcare. Patel made it to the 26th place on Forbes magazine's first annual list of the 40 richest Indians (2004) with an estimated net worth of \$510 million.

Pankaj Ramanbhai Patel was born in 1951, graduate from Gujarat University, and holds a degree as Bachelor of Pharmacy. He went on to pursue M.Pharm in Pharmaceutics & Pharmaceutical Technology from L. M. College of Pharmacy. He married Priti Patel, daughter of Dr. B.D.Patel. They have two children, a son and a daughter. Their son, Sharvil Patel, is Deputy Managing Director of Cadila Health and is married to Meha Patel. Their daughter Shivani is married to Pranav D. Patel, son of Dushyant D. Patel, and has two children. Pankaj R Patel has made commendable contributions to the world, in the field of health care.

He has been honored with the title "the Pharma Man of the Year" by the Federation of Indian Industry and Economists for contributing to the growth of the Indian Pharma Industry in the year 2004 and also World Pharmaceutical Frontiers ranked him in their First Pharma 40 list of world's most influential people in the field of healthcare. Mr. Patel is also the member of many prestigious associations like Indian Pharmaceutical Alliance, Indian Drug Manufacturers Association, Basic Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council, Gujarat Chambers of Commerce and Industry.

Pankaj Ramanbhai Patel's contribution to the world is highly appreciative. He played an active role in fighting against swine flu, which was spreading at a fast pace by securing approval for his group, from the Drug Controller General of India to launch his VaxiFlu-s, the first Indian-made H1N1 vaccine- and one of only few such vaccines in the world.

Inspired by his group's recent progress, Patel predicted in the year 2003 Zydus Cadila would rise up as India's third-largest pharmaceutical company by the year 2005; however his words didn't come true and the company faced losses, shifting Patel many places down the ladder of richest Indians.

Ramanbhai Patel, father of Pankaj Patel founded Cadila Laboratories in 1952. He was a lecturer in the L.M. College of Pharmacy, and started Cadila in partnership with Shri Indravadan Modi. Over the next four decades, they saw the company rise into one of India's most established pharmaceutical companies. Today, Pankaj enjoys 75% stake in listed flagship Cadila Health care and makes branded and generic drugs and rabies vaccines. For further discovery and development of cardiovascular drugs, he came into partnership with Eli Lilly. The Cadila Healthcare group's Zydus Wellness makes Sugar Free, the nation's most selling substitute for sugar. Its headquarters are located in Ahmedabad, Gujarat. Under Pankaj's leadership, the company has risen to being the fifth largest pharmaceutical company in India. The group has made significant discoveries in fields of health, such as manufacturing a drug named Roserin which reduced the cost of treating TB by 33%. The group's operations range from API to formulations, animal health products and cosmeceuticals. Its presence can be felt all across various countries of the world, including USA, Europe, Japan, Brazil, South Africa and 25 other emerging markets. It acts as an employer to 12,000 people worldwide. The group houses a world-class research and development center aiming at making fresh discoveries to improve people's lives.

Patel says he's prepared for the long haul: "**What we do tomorrow is more important than what we did yesterday**".

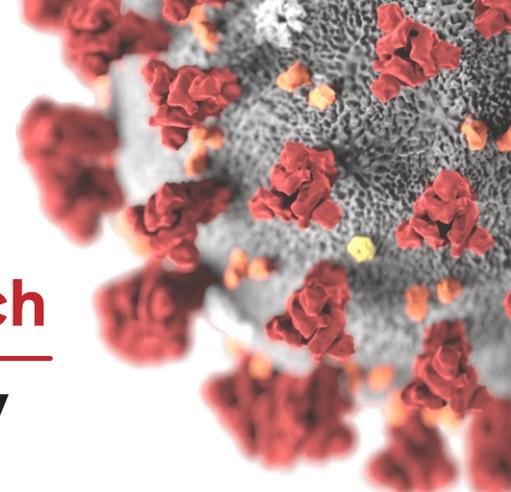
**Ms. Nayana P Kunderi,**  
Assistant Professor, Dept. of Pharmacy Practice,  
R R College of Pharmacy, Bengaluru



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# TERATOGENIC DRUGS

Proper knowledge regarding the risk of teratogenic drugs became apparent after the thalidomide disaster around 50 years ago. This tragedy has raised concerns over the safety of drugs during pregnancy and suggested international agencies to develop systematic preclinical reproductive testing protocols. Attributing the risk of fetal malformations to the use of medications is controversial and also difficult. Drugs that a pregnant woman takes affect the fetus in several ways. They can directly act and cause damage to the fetus or may also lead to abnormal development of the fetus resulting in either birth defects or even death. They might also alter the placental function through the constriction of blood vessels and reducing the supply of oxygen and nutrients in blood from the mother to fetus and thus resulting in underdeveloped and an underweight baby.

Generally, we consider randomized controlled trials as the gold standard for assessment of efficacy and safety of medications, but most of the times, pregnant women are excluded from such studies. Due to this, we need to rely on observational studies and the pharmacoepidemiologic data in order to provide evidence to support the decision making on the use of medications in pregnancy. Risk perception by health professionals will influence their level of counselling and treating the pregnant those need medication during their pregnancy. But, overestimating this risk is also a problem because it may lead to treating the patients insufficiently. At the same time, underestimating this risk may lead to hazardous treatment. Risk perception by the patients themselves influence their decision on the use of the medicine during pregnancy, and this risk that is perceived by the patients is found to be depended upon the information that is received from their consultant. In most of the recently conducted surveys, around 77 % of women stated that they need proper information regarding the use of medications during pregnancy.

Both the prescribed and over-the-counter drugs are common and also necessary for many pregnant women these days. The major challenge of physicians is the "teratogenic effects of the drugs". Most of the medications that are used during pregnancy do not cause a risk of congenital malformations. Misconceptions of these risks may lead to improper discontinuation of therapy and may even lead to termination of pregnancy. It may lead to limiting the decision-making process towards pregnancy. There is evidence for the association between health care knowledge and risk perception of teratogenic drugs and adherence to the prescribed medications during pregnancy.

In-utero exposure to some of the antiepileptics can lead to significant cognitive and behavioural teratogenic effects on the fetus. Obviously, we see valproate induced impaired cognitive development, and it also increases the risk of incidence of autism. Exposure to other antiepileptics like carbamazepine, levetiracetam, lamotrigine and phenytoin monotherapy was found to be associated with less cognitive and behavioural fetal effects when compared to valproate. All the old-generation antiepileptics were considered to be teratogenic. Several studies reported the teratogenic effects of phenytoin sodium, where it is found to be inducing toe, finger, renal, and facial malformations and also neural tube defects. But, administering Phenytoin sodium in a regulated and monitored concentration regimen induced a lower rate of neural tube defects than those previously reported.

## Concerns with OTC medications:

In India, drugs are easily available, and along with this, inadequate health services increased usage of drugs as self-medication for common complaints and infection conditions than the prescribed drugs. Hence people always face the threat of drug interactions and adverse drug reactions. Many of the OTC drugs can be used during pregnancy but only under a physician's supervision, even in which some of them are known to be unsafe. As mentioned on the product labels, women who are pregnant, who are planning to be pregnant in the near future or nursing mothers have to consult a physician/clinical pharmacist for sure before taking any OTC medication.



Aspirin is one of the OTC drugs that have to be avoided in the last three months of pregnancy. In the year 1990, FDA issued a warning that aspirin shouldn't be used during the last trimester of pregnancy unless and until it is directed by the physician to do so because it may cause complications either in the unborn child or during the time of delivery. Over the counter-NSAIDs (non-steroidal anti-inflammatory drugs) like ibuprofen carries the same warning as that of aspirin regarding its use in the III- trimester of pregnancy. Experts particularly say that there isn't much-known information regarding the effects of herbs and dietary supplements on a growing fetus to assess their safety in pregnancy. Hence it should not be assumed that a product that is sold over-the-counter and labelled as a natural product is safe to use in pregnancy.

### **Realistic risk perception**

Drug information regarding the use of drugs in pregnancy can intrinsically convey the teratogenic risks of the drugs. And if this information helps in perceiving the realistic risks, then appropriate choices regarding the use of drugs in pregnancy are made. Various aspects have to be considered while approaching realistic perception of risk of teratogenicity like pregnant women, beliefs about medicines, empowerment, and confidence and literacy in health care systems are some of the examples. Physicians need to consider the evidence level regarding the information of drug and choice of source of information are the elements to be considered. It is advised to measure the outcomes of interventions, as they may influence the perception of the risk of teratogenicity. However, we can't identify any literature sources that present such a numerical measurement of outcomes. The concept of literacy in healthcare involves the capacity to understand and process health information to make appropriate decisions regarding health. Low literacy in healthcare among pregnant women was found to be associated with the elevated perception of risk regarding the medications and negative beliefs regarding the medications. The fact that understanding drug information influences the risk perception and also further shows the need for presenting drug information in a way that people at all levels of healthcare literacy can be understood. Similar texts of information may be interpreted differently by the individuals because of their different beliefs towards the medications and also the level of health care literacy and the situational risk assessment. So, the use of more or less reassuring terms could be influencing the risk perceptions and also confidence in the use of medications.

Achieving better risk communication strategies is possible by understanding the risk perception of pregnant women leading to empowerment of pregnant women by improving the confidence in the use of the medications. Improved focus on the positive health consequences for treating conditions during pregnancy, for both the mother and the child, should be done for counteracting the overestimation of risks. Counselling pregnant women regarding the risk may help in reducing the risk perceptions of high teratogenicity. Customizing the drug information as per the needs, perceptions and beliefs of individual woman could aid in improving their adherence to the drug therapy.

Pregnant patients need to be counselled as per their individual needs. So, physicians should have reliable drug information with a high level of evidence. Specific information regarding a product isn't required here. Electronic prescription tools provide information that is evaluated by experts regarding the risks of drug use in pregnancy. Another suggestion is focusing on patient-specific information that is provided by the drug information centres and teratogen information services because it is such services have been found to influence both therapeutic decisions in general and regarding pregnancy.

The US Food and Drug Administration introduced the Pregnancy Lactation Labeling Rule (PPLR) in June 2015. The categories of pregnancy letters that are previously included in drug labels will be replaced by PPLR. PPLR has a narrative structure that provides detailed information, which is divided into the following subsections: clinical considerations, risk summary, pregnancy and data registry (only if applicable). The introduction of PPLR helps in creating greater focus in explaining the risks and benefits of drug use in the mother, fetus, and breastfeeding child. This will be considered as an important step toward achieving the suggested goals to make realistic risk perceptions regarding drug use in pregnancy.

Counselling the women about the risk of teratogens who had already exposed to the drugs leads to accurate identification of exposure and quantification of the magnitude of the exposure. This can be easier for the prescribed drugs, but it'll be difficult for drugs like ethanol or illicit substances or other OTC drugs. Drugs that are in use for a long period of time are often preferred while selecting the drugs to be used in pregnancy; even newer alternatives are available in order to assure the safety of the fetus.

# DRUGS CAUSING TERATOGENIC EFFECTS

S. No	Drug	Abnormality	Phase of Trimester
1.	Phenobarbital	Impaired growth, motor development, and fetal mortality	3 <sup>rd</sup>
2.	Valproic acid/Valproate	Cardiac anomalies, neural tube defects, dominantly spina bifida, and developmental delay	3 <sup>rd</sup>
3.	Carbamazepine	Craniofacial defects, abnormal IQ, growth retardation & NTDs	1 <sup>st</sup>
4.	Lamotrigine	Facial malformations in fetuses, especially facial cleft	2 <sup>nd</sup> & 3 <sup>rd</sup>
5.	Phenytoin	Growth deficiency, mental retardation, epicanthic folds, hypertelorism, and a short nose with anteverted nostrils	1 <sup>st</sup> & last
6.	Topiramate	Hypospadias and oral clefts to newborns	1 <sup>st</sup>
7.	Chloramphenicol	Bone marrow suppression, Gray baby syndrome	3 <sup>rd</sup>
8.	Fluoroquinolones	Carcinogenesis in fetuses, impairment of limb development	1 <sup>st</sup>
9.	Tetracyclines	Discoloration of bones and teeth, skeletal bone growth and cause hypoplasia of tooth enamel	2 <sup>nd</sup> & 3 <sup>rd</sup>
10.	Fluconazole	Craniosynostosis, Trapezoidocephaly, and midfacial hypoplasia	1 <sup>st</sup>
11.	Warfarin	Skeletal abnormalities, the stippled calcification of epiphysis, nasal hypoplasia, Central nervous system malformations	2 <sup>nd</sup> & 3 <sup>rd</sup>
12.	Propylthiouracil (PTU)	Aplasia cutis and choanal/esophageal atresia	2 <sup>nd</sup> & 3 <sup>rd</sup>
13.	Carbimazole	Aplasia cutis and choanal/esophageal atresia	1 <sup>st</sup>
14.	methimazole (MMI)	Aplasia cutis and choanal/esophageal atresia	1 <sup>st</sup>
15.	High doses of Vitamin A (Retinoic acid)	Miscarriage, neural tube defects, hydrocephalus, eye malformations, and cleft palate, hypoplastic aorta and cardiovascular transposition	1 <sup>st</sup> & 2 <sup>nd</sup>
16.	Diethylstilbestrol (DES)	Off-springs with several abnormalities of the genital tract, loss of pregnancy	2 <sup>nd</sup>
17.	ACE inhibitors	Sequelae of Oligohydramnios, Renal injury, malformations	2 <sup>nd</sup> & 3 <sup>rd</sup>
18.	ARBs	Sequelae of Oligohydramnios, Renal injury, malformations	1 <sup>st</sup>

1.	Ondansetron	Heart defects, Cleft palate (Less data)	1 <sup>st</sup>
2.	Promethazine	Newborn sedation and Respiratory depression	3 <sup>rd</sup>
3.	Metaclopramide	Risk of maternal tardive dyskinesia, intermittent porphyria	1 <sup>st</sup>
4.	Olanzapine,	High rates of low birth weight	All
5.	Amoxillin/Clavulonate	Risk of cleft lip/palate (Minor)	3 <sup>rd</sup>
6.	Sulfamethoxazole/trimethoprim	Birth defects including heart, neural tube and urinary tract	1 <sup>st</sup>
7.	Lithium	Heart defects, neonatal hypotonia, respiratory & feeding difficulties.	1 <sup>st</sup>
8.	Venlafaxine	Risk of neonatal withdrawal	3 <sup>rd</sup>
9.	Paroxetine	Increased risk of heart defects	1 <sup>st</sup>
10.	Risperidone ,	High rates of low birth weight	All
11.	Quetiapine,	High rates of low birth weight	All
12.	Clozapine	High rates of low birth weight	All



**Dr. A Pramod Kumar**  
Drug Safety Associate



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# Quiz

## RULES

1. Correct answers will be rewarded 1 point each (10 marks)
2. Answer of the quiz will be evaluated by panel of judges and their decision is final. (Max mark:10)
3. Those who get the highest marks, their photo will be published in our next bulletin and also a cash prize of Rs.500/- will be rewarded to them
4. The answer must be sent within 20<sup>th</sup> January 2022 to this E Mail ID- krpaindia@gmail.com
5. A confirmation mail will be sent to you on receiving your e-mail.

### 1. For what reason were hatters considered mad in the Victorian era?

- a) Hammering the head during hat adjusting
- b) Mercury poisoning
- c) Lead poisoning
- d) None of the above

### 2. What disease did Stephen Hawking have?

- a) Balo concentric sclerosis
- b) Lou Gehrig's disease ALS
- c) Multiple Sclerosis
- d) Creutzfeldt-Jakob disease

### 3. Which infectious agent causes diseases that are the most difficult to cure?

- a) Bacteria
- b) Virus
- c) Prion
- d) Fungus

### 4. Which disease is almost certainly fatal after symptoms have been shown?

- a) Malaria
- b) Dysentery
- c) Rabies
- d) Tetanus

### 5. Coconut water can be used as \_\_\_\_\_

- a) Fuel
- b) Blood plasma
- c) Cure for angin
- d) De-freezer

### 6. How many bones are in a human hand (including wrist)?

- a) 5
- b) 27
- c) 18
- d) 12

### 7. Which trait makes naked mole rat a subject of intensive scientific studies?

- a) Vision in complete darkness
- b) Longevity and resistance to cancer
- c) Spatial memory
- d) An extraordinary sense of smell

### 8. The pharmacy's symbol is the bowl of \_\_\_\_\_

- a) Hippocrates
- b) Asclepius
- c) Galen
- d) Hygieia

### 9. In which sport, diuretics are used as illegal doping?

- a) Cycling
- b) Marathon run
- c) Soccer
- d) Ski jumping

### 10. Which oil contains the least amount of cholesterol?

- a) Olive oil
- b) Sunflower oil
- c) Rapeseed oil
- d) All vegetable oils do not contain cholesterol



*Congratulations*

*to the winner of Nineteen Edition*

KRPA Quiz Competition

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