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UPDATES

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Team Synergia congratulates the graduates of the Class of 2017 and wishes them a successful future.

Please send your contributions, feedback and suggestions to : synergia.kcp@gmail.com

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APPROVALS

BRAND NAME (ACTIVE INGREDIENT)	INDICATION	SPONSOR	APPROVAL
Brineura (cerliponase alfa)	Treatment of late infantile neuronal ceroid lipofuscinosis type 2	BioMarin	April 2017
Rydapt (midostaurin)	Treatment of FLT3 positive acute myeloid leukemia and mastocytosis	Novartis	April 2017
Tymlos (abaloparatide)	Postmenopausal women with osteoporosis at high risk for fracture	Radius Health	April 2017
Ingrezza (valbenazine)	Tardive dyskinesia	Neurocrine Biosciences	April 2017
Austedo (deutetrabenazine)	Chorea associated with Huntington's disease	Teva Pharmaceuticals	April 2017
Alunbrig (brigatinib)	Advanced ALK-positive metastatic non-small cell lung cancer	Ariad Pharmaceuticals	April 2017
Zerviate (cetirizine ophthalmic solution 0.24%)	Ocular itching associated with allergic conjunctivitis	NicOx	May 2017
Kevzara (Sarilumab)	Treatment of active rheumatoid arthritis	Sanofi	May 2017
Imfinzi (durvalumab)	Advanced or metastatic urothelial carcinoma	AstraZeneca	May 2017
Radicava (edaravone)	Amyotrophic lateral sclerosis	Mitsubishi Tanabe Pharma	May 2017
Baxdela (Delafloxacin)	Acute bacterial skin and skin structure infections	Melinta Therapeutics	June 2017
Haegarda (C1 Esterase Inhibitor Subcutaneous)	Prophylaxis to prevent Hereditary Angioedema attacks	CSL Behring	June 2017
Rebinyn (Coagulation Factor IX (Recombinant), GlycoPEGylated)	Hemophilia B	Novo Nordisk	June 2017

SOURCE: Center-watch, USFDA, Current as on June 2017, compiled by Rejitha Thomas, Asst. Professor

- DISCLAIMER ·

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Dr Raju Koneri Professor of Pharmacology Dean, Karnataka College of Pharmacy Chairman, BOS - Pharm D RGUHS

EXPERT REVIEW

EVIDENCE-BASED MEDICINE

Evidence-Based Medicine (EBM) is an approach to medical practice intended to optimize decision making by emphasizing the use of evidence from well-designed and well-conducted research. Beginning in the late 1960s, several flaws became apparent in the traditional approach to medical decision-making. Alvan Feinstein's publication of Clinical Judgment in 1967 focused attention on the role of clinical reasoning and identified biases that can affect it.

In 1972, Archie Cochrane published Effectiveness and Efficiency, which described the lack of controlled trials supporting many practices that had previously been assumed to be effective. In 1973, John Wennberg began to document wide variations in how physicians practiced. Through the

1980s, David M. Eddy described errors in clinical reasoning and gaps in evidence. In the mid 1980s, Alvin Feinstein, David Sackett and others published textbooks on clinical epidemiology, which translated epidemiological methods to physician decision making. Toward the end of the 1980s, a group at RAND showed that large proportions of procedures performed by physicians were considered inappropriate even by the standards of their own experts. These areas of research increased awareness of the weaknesses in medical decision making at the level of both individual patients and populations, and paved the way for the introduction of evidence-based methods. Medical knowledge grows every day, so that previously accepted facts rapidly become old and it seems impossible to follow such explosion of scientific information. Evidence-based medicine is fast becoming one of the key concepts in clinical and reimbursement practices in the developed world, recently embraced by medical practitioners, policy-makers, and the general public, The practice of evidence based medicine is a process of lifelong, selfdirected, problem-based learning in which caring for one's own patients creates the need for clinically important information about diagnosis, prognosis, therapy and other clinical and health care issues. Evidence based medicine is not "cookbook" medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care. One of the main reasons why there is such a great interest in approach to Evidence Based Medicine is the growing number of examples, in which current medical practice

cannot cape pace with the available clinical evidences. For example, despite the strong evidences during seventies that the treatment such as thrombolytic therapy and use of aspirin are efficient in treatment of acute myocardial infarction, it took almost one decade that these treatments become routine in treatment procedures for the patients with acute myocardial infarction Dawes M (2005) et al, has reported Sicily statement on evidencebased practice which has five steps of EBM in practice:

1. Translation of uncertainty to an answerable question and includes critical questioning, study design and levels of evidence

2. Systematic retrieval of the best evidence available

3. Critical appraisal of evidence for internal validity that can be broken down into aspects regarding:

- Systematic errors as a result of selection bias, information bias and confounding
- · Quantitative aspects of diagnosis and treatment
- The effect size and aspects regarding its precision
- · Clinical importance of results
- · External validity or generalizability
- 4. Application of results in practice
- 5. Evaluation of performance

A good clinical question should have four essential components structured in the PICO format (Patient or problem, Intervention, Comparison, Outcome).

PICO format:

- The patient or problems who are the relevant patients, what kind of problem we try to solve?
- The intervention what is the management strategy, diagnostic test or exposure (drugs, diagnostic test, foods or surgical procedure)?
- Comparison of interventions what is the control or alternative management strategy, test or exposure that we will compare?
- The outcome what are the patient-relevant consequences of the exposure in which we are interested?

For example; physician calls down to the pharmacy and asks the pharmacist which medication has been shown to work better for hypertension in a patient with congestive heart failure, an ACE inhibitor or an angiotensin receptor blocker (ARB)?, the pharmacist in this context could use the PICO model like this: P = patient with congestive heart failure; I = ACE inhibitor; C = ARB; O = lower blood pressure. Another example would be a physician who calls down to the

EXPERT REVIEW

UTI [urinary tract infection] positive for Pseudomonas aeruginosa, would a quinolone be more effective than an aminoglycosid P = patient with UTI caused by P aeruginosa; I = aminoglycoside; C = quinolone; O = effective against P aeruginosa. Pharmacists should be well versed in EBM, so they may answer clinical questions with accuracy. EBM helps in detection of adverse drug reactions, drug-drug interactions. EBM helps to promote the rational use of medications making sure that patients receive the right medicine in the right dose for the right diagnosis at the right time at the lowest possible cost, suitable to patients's individual requirements. EBM also allows the pharmacist to better scrutinize physician orders so as to identify a more suitable medication or a less expensive alternative. Many studies have suggested that proper EBM training improved the pharmacist knowledge and decision making process. Query/Problem based pharmacotherapy courses promote the active participation of pharmacist in the healthcare process. Perhaps consulting a good database may make incorporating evidence-based medicine into Pharmacist's practice a little more manageable. There are some very good databases that offer evidence-based medicine content. Micromedix, Lexicomp etc are some of the databases commonly used by clinical Pharmacist. Practice of Evidence based medicine significantly decreases the medication errors and improves the quality of health care. EBM is not commonly practiced by Indian Clinician may be because they are not aware of the same. Clinical Pharmacist by practicing EBM not only strengthens the knowledge base of clinician, but improves patient care, decreases the medication error and ensures that the treatment is cost effective. Practice

of EBM revolutionalises the role and practice of Clinical Pharmacist in patient care and strengthens the profession.

PCI SPONSORED WORKSHOP ON SENSITISATION OF SYLLABUS FOR B PHARM & M PHARM COURSES

14 Jul 2017 | Krupanidhi College of Pharmacy



HERBAL REMEDIES IN MENTAL HEALTH

Mental health includes our emotional, psychological, and social well-being. It affects how we think, feel, and act. It also helps determine how we handle stress, relate to others, and make choices. Mental health is important at every stage of life, from childhood and adolescence through adulthood. Many factors contribute to mental health problems, including:

- Anxiety & Panic Disorders
- Bipolar Disorder
- Eating Disorders
- Schizophrenia
- Substance Abuse & Addiction etc.

Since our body is incapable of producing antioxidants that can cancel the effects of all the oxidative free radicals, these have to be taken in the form of dietary supplements as well as some from the herbal therapy. Herbs having antioxidant properties, overcomes the effects of oxidative compounds that are already present in the body. Over the past decade attention has been developing on the use of herbs in the treatment of mental and emotional difficulties due to their safety and efficacy without any adverse effect in the treatment. Some of the herbs were listed down which have special effect on Mental illness. Those are: (next page)



Dr. Praveen Simpi Asst. Prof DEPT. OF Rasashastra & BK N.K JABSHETTY AYURVEDA MEDICAL COLLEGE BIDAR

Brahmi (Bacopa monnieri)

Whole Plant - powder 2 gm & Juice extract, 10 - 20 ml

Open and clarify the mind, Strengthen memory and intellect, Support focus and concentration, Encourage a balanced emotional state, Promote daytime energy and night time sleep.

10-12 Seeds can be chewed daily & oil 5-15 drops

It is a brain tonic, It promotes intellect, sharpen memory and helps better learning, It improves intelligence quotient of mentally retarded people, It is a powerful stimulant.





Whole plant powder, 3-5 gm

Antistress: help the body relieves stress, Anticonvulsant: prevents or relieves convulsions, Antidepressant: alleviate depression, Immunomodulatory: modifies the immune response or the functioning of the immune system, Nervine: used to calm the nerves, Restorative: ability to restore health, strength, or well-being, Sedative: promoting calm or inducing sleep. Tranguilizer: reduce tension or anxiety.

Root part

1

Tranquilizes the mind, Traditional uses include amnesia, Best drug of choice in insomnia, Act as Neuroprotective, Antidepressant: alleviate depression.



calamus)

4



Root powder, 1 gm with milk daily

It is used for the treatment of high blood sugar. Hence called as universal medicine for lowering blood pressure, It cures insomnia, hysteria and hypertension, Sarpagandha is used for the treatment of Schizophrenia, It is used as a sedative and tranquilizer & amp; a certain form of insanity, Rauwolfia serpentina is believed to cure anxiety, psychosis and epilepsy.

Root powder 1-3 gm & oil 5-10 drops

Root of jatamansi has been clinically proved out as a memory enhancer and neuroprotective can be a fruitful remedy for, Alzheimer's disease, It helps maintaining the proper stimulation of nervous system due to its sharp property and sweet taste, It is a good aphrodisiac agent.





Seed powder 1-3 gms

Acts as a restorative nutrient for the nervous system, Decreases symptoms of stress and anxiety. Calms nerves, Strengthens and tones the sexual glands.





Stigma – 30 mg per day with Milk

Saffron extract is known to help treat depression, reduce stress, and to be a mood enhancer, It is also widely used as an aphrodisiac. It is widely used to combat Alzheimer's disease and used in the fight against the growing menace of insomnia, common to today's highly stressed lifestyle habits, Potassium also helps maintains the blood pressure and keeps heart diseases at bay

Root Powder 3-5 gm with Milk

Anxiety. reduce symptoms of anxiety, A brain condition called cerebellar ataxia, Parkinson's disease. a combination of herbs including ashwagandha improves Parkinson's symptoms, Anti - Stress, Altering immune system function, Preventing the signs of aging.



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HEALTH CARE 2.0

SCANADU SCOUT®

The Scanadu Scout is a revolutionary investigational device designed to measure blood pressure, temperature, heart rate, and pulse oximetry using your smartphone and Bluetooth LE to emulate an Emergency Room in your pocket. You will simply place the Scanadu Scout on your forehead for 10 seconds and in a snap, your stats are displayed on your smartphone. Scanadu Scout will use a 32-bit RTOS Micrium platform, NASA's choice for SAM (Sample Analysis at Mars) on the Rover Curiosity (uC/OS-II Kernel Drives Extraterrestrial Scientific Investigations). The Scanadu app will come in Android and iOS versions. It will support Bluetooth 4.0, more specifically Bluetooth 4.0 Smart Low Energy (LE).



DEXCOM G4 PLATINUM

Dexcom G4 PLATINUM is a high-performing Continuous Glucose Monitoring (CGM) system that works with Share technology (Bluetooth) built into the Receiver for remote glucose monitoring. Continuous glucose monitoring (CGM) is a small wearable device that tracks your glucose throughout the day and night, notifying you of highs and lows so you can take action. It starts with an accurate sensor. Dexcom CGM is not only appealing, but delivers results consistently and accurately. While meters give a number for a single point in time, CGM provides dynamic glucose information by showing where glucose is, where it's going and how fast it's getting there. It is light and compact. It also has the longest FDA-approved sensor life available, you'll only need to change sensors once a week. Whether you have type 1 or type 2 diabetes, CGM can help you make more informed treatment decisions and can lead to better glycemic control. It is along with Dexcom CLARITY which is a unique cloud-based reporting system that allows you and your healthcare professional to access and track your glucose data anywhere2 and quickly identify critical glucose patterns. It is now approved for children young as 2 years.





This is my first work experience and probably the best, not because this is my first job but due to the impact AIMS have created on my mind as to how an employee should be treated and challenged without putting sheer pressure on them as you see or listen elsewhere. I had this sublime opportunity to work as a clinical pharmacist in one of the best multi speciality hospitals in India - Amritha Institute of medical sciences. As a CP, I am posted in 2 main departments of the hospital- Hotline and oncology chemodilution unit. I started off with me being posted in the Hotline department for a period of 2 months. It is here where the patients are provided with imported drugs, new drugs, highly restricted antibiotics and drugs which are almost exclusive and not available in the usual hospital formulary under short notice. I was very sceptical at first and didn't know as to how I would fit in, but this turned out to be quite fulfilling and a different experience altogether. This enabled me to learn and experience different aspects of the patient care other than the usual clinical aspects. To add to the excitement I was also exposed to various distinct fields like inventory management of high cost medications too (oncology medicines, highly restricted antibiotics, and bone marrow transplant medications). Most of the new anti-cancer agents are targeted therapies - the drugs whose development is purely based on a pre-determined tumoral or endogenous target. From a clinical pharmacist point of view, these new entities deserve renewed attention and thus requiring us to study the different clinical importance of such medications. "Dosing schedule" refers to the optimum therapeutic



dose of a drug at optimal interval between doses. This department have a major role in providing both inpatients and out-patients to get their medications at the right time, right strength, right dose and right quantity. Here the request for the drugs is made in a specially designed hotline form with the following fields:

- · Patient's Name
- MRD Number
- Drug Name
- Dosage (size and frequency)
- · Time period under medication

The filled form would give a clinical pharmacist an idea of a patient's current status and overall medication needs. At this juncture, we are the ones bestowed upon with the responsibility of the respective medication to any particular patient. We must enquire about the requirement of a specific determined drug to a patient in their respective wards and must consult and give the doctor your opinion as to whether the medicine should be reconsidered if needed. The quantity requirement of a specific medicine is calculated for the undergoing time period and this is then pre-ordered to last till the end of a medication therapy. In case of inpatients who are admitted for a longer duration in the hospital, the drugs are administered by the nursing staff at the apt time only after consulting and taking prior approval from the clinical pharmacist. Medications such as emergency medications, high risk drugs, antidotes, stat medications or in case of casualty, can only be administered with the prior and proper approval of a clinical pharmacist depending upon the severity. If any medications are to be administered in an emergency situations without the knowledge of a CP, a form should be handed over immediately specifying the usage of the medicine and it is the responsibility of the CP to maintain a healthy stock of the concerned emergency drugs. Antibiotics restriction report is a monthly report made by us monitoring the total usage of each brand of highly restricted antibiotics in each ward and each department. This report helps us to understand the unwanted use of such antibiotics and also restricts the consumption to an extent and allows the use of such antibiotics only to the most needy patients. After a period of 2 months I was given training for the oncology chemodilution department which was yet another distinct experience. Here the focus is on patient care and accredit us with the different clinical regimens and protocol used for each type of malignancy for every patient. Unfortunately and regretfully, oncology

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patients fight with their disease are mostly futile and every opportunity they have is a salient one. As patients revisit for their treatments every fortnight or every three weeks, we build a relationship with them and their families thereby making it a personal journey too. Oncology trained clinical pharmacist have a crucial role in the care of a cancer patient through medication review, improving medication use including chemotherapy drug preparation, calculation of required drug dose and cross checking of the order sheet for any dosage correction or diluents correction. Our role has also been expanded to encompass drug inventory control, which includes purchasing drug and compounding supplies, minimizing overstocking, and finding alternatives to items in short supply. Oncology CP is mainly to identify, prevent, and manage any drug related problem including drug choice dosage, administration issues, side effects and the drug dilution issues. Also we have a major role in assuring safe, effective and cost-effective drug therapy. In my point of view, one of the major problem arising in oncology department are medication errors, drug dosage errors, dilution errors and even demographic errors can also occur which are mostly seen in the hospital and we have a major role to overcome these errors by speaking with the concerned doctors. When it comes to chemodilution, the medications used in cancer treatment need to be handled and stored in specific ways to avoid spoilage or injury. As a Oncology CP, we ensure that the drugs are kept at the proper temperature, monitor expiration dates, and pay special attention to inventory and check the correct dosages of medication given to adult patients based upon the body surface area and special attention is paid when the medications are administered for paediatric patients as a small error in dosage of the paediatric patients can be fatal. When we are not mixing medications, we spend our time with patients. Since you are the person who mixes the medicines needed for chemotherapy, we must ask the

patient about medication side effects. With this information, you tweak the prescription in an effort to improve the patient's quality of care by interacting with the respective doctor either by changing the dose or by changing the brand currently taking by the patient by substituting it with the original brand. In addition to direct patient care, another rewarding aspect of this job is you can practice with newer and updated medications used in cancer chemotherapy which helps to find out which ones most effectively treat each type of cancer.

In conclusion, my first job was full of experiences; good, bad, bitter and happy moments I can't even remember but they sharpened me to be a better person and be more professional in my work. I perceive this opportunity as a big milestone in my career development and I am glad to have had the opportunity to participate in this experience.

There are a lot of impressions i take home with me and also some ideas which I hope to implement in my work for improvement, especially concerning patient care. I enjoy watching patients get better right before my eyes and knowing that i had a hand in it. Last but not the least I'm feeling oblige in taking the opportunity to sincerely thank my principal, Dr. Raman Dang and special thanks to all my worthy teachers who have been always helping and encouraging me throughout my 6 years of study.

I have no valuable words to express my thanks, but my heart is full of the favours received from each person in all the good and bad moments.

LATEST NEWS

Carbon dioxide insufflation procedure available at Amrita Hospital for the first time in Kerala for patients with diabetes, kidney related issues and the elderly can now avail the carbon dioxide insufflation procedure that has been made available at Amrita Institute of Medical Sciences, Kochi.



Dr. Arya Gigi Clinical pharmacist AMRITHA INSTITUTE OF MEDICAL SCIENCES



Nimmi N John Assistant proffesor M Pharm Pharmacy Practice Krupanidhi College of Pharmacy

REVIEW ARTICLE

CHRONOTHERAPEUTICS THE NEED OF THE HOUR!!!

Chronotherapeutics is the future of pharmacotherapeutics which deals with treating a patient according to his biological rhythm in order to achieve maximum therapeutic benefit. Biological clock controls individual's biochemical, physiological and behavioral process. FDA has suggested additional parameters for chronotherapeutics such as drug administration time of the day, patient's normal habits and sleep patterns. The effect of drug differs with time of administration, normal circadian rhythms and sleep habits. There are some diseases where chronotherapeutics plays a vital role eq cardiovascular diseases, asthma, peptic ulcer, cancer, arthritis, hypercholesterolemia, epilepsy and diabetes mellitus. One of the most common disease with largest circadian variation is bronchial asthma. Exacerbation of asthma progresses at night, So an early morning hour medication gives a maximum effect. Whereas oral prednisolone administered at 3 pm is highly effective for nocturnal asthma. Because studies reveal that cortisol levels were higher at the time of awakening and lowest in the middle of the night. In peptic ulcer patients, there will be a maximum acid secretion, ulcer pain and exacerbation during night. So ranitidine given as bed time dose is more effective in reducing acid secretion and promotes ulcer healing. Where as in Arthritis, OA peaks at night where as RA peaks at morning and decreases through out the day. So the optimal dose timing for NSAIDS is mid afternoon for OA where as for RA drug should be given with evening meal. It is known that chronobiological cycles for normal cells and cancer cells are different. Blood flow to tumors and tumor growth rate are greater during activity phase than rest phase and usually midnight therapy was shown to be more effective. A right choice for the time of administration of cancer drugs should be made after observing the cell cycle changes of the cancer cells in the patients. Clinical pharmacists and pharmacy practitioners should take into account that the application time is important as the dose and route for certain drugs, especially those of narrow therapeutic range. Variables like sex, race and phenotype should be considered before drug administration. If the symptoms of a disease are distinctly circadian phasedependent (like symptoms of myocardial infarction, angina pectoris, nocturnal asthma, peptic ulcer), pharmacists should also warn the patients for the correct time of administration of the drug circadian rhythms have an important impact on drug effectiveness and toxicity. Chronopharmacology aims to improve the understanding of circadian changes in both desired effects (chronoeffectiveness) and tolerance (chronotolerance) of medications. Therefore, pharmacotherapy may be applied by the appropriate timing of conventional tablets and capsules, which can be applied according to the rhythmic markers. This occasion can increase their therapeutic effects and/or reduce their side effects. This article is aimed to give awareness to the health care team about the pivotal role of biological clock in maximizing health care. It enhances desired efficacy and reduces undesired effects. Thus it is an approach to optimize and personalize a treatment for better patient care.

G R A D U A T I O N I





PHARM D

PHARM D (PB)



RIJU PATHAK Overall University 3rd Rank-Pharm D Overall Excellence Award (International) Green Chem Awardee -PharmD University 6th Rank (Pharm D 5th year) 3

ARJAN ARYAL University 3rd Rank (Pharm D



YALLA UJWAL TEJA University 6th Rank (Pharm D 5th



PATEL TRUSHITKUMAR B Pharm D Overall Excellence Award (National)



HOMESH CHOUDHARY Overall Excellence Award Pharm.D PB

M PHARM



BISHWO RAJ DHUNGANA Overall Excellence Award (International)



PREETA CAROLINE Overall Excellence Award (National)



RUBY JAISWAL Topper - Green Chem Awardee 2017 MONISHA J MPharm (QA) RGUHS 6th Rank 2016



GIRIJA D N MPharm (QA) RGUHS 5th Rank 2016

PHARM



BIBI ROUSHDA NADAIR Overall Excellence Award (International)



ASIF N M Overall Excellence Award (National)



REKHA Topper - Green Chem Award



D

SUSHMA HEMBROM Overall Excellence Award SYED HAIDER ALI A

Topper

Green Chem

Awardee

PHARM

CHAUDARY JITHESHKUMAR P Board o Examining Authority Drugs Control Department 10th Rank

ONE DAY WORKSHOP ON BASIC TECHNIQUES IN FIRST AID



Dr Rajesh K and his team members from Emergency Medicine department of PES Institute of Medical Sciences and Research (PESIMSR) provided hands-on training for delegates, on various techniques in first aid. The training includes Cardio Pulmonary Resuscitation (CPR) techniques for casualty in different situation, the differences in the techniques to be used for various age groups (pediatrics, adolescents and adults) and the first aid measures for Fire burns, Fractures, Poisoning, insect bites and etc. The workshop was organized on 18 April 2017.

EAM SYNERGIA

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