Edition 16

KARNATAKA REGISTERED PHARMACISTS ASSOCIATION ®

CH 51, 6th Main, 5th Cross, 1st Floor, Above Sri Krishna Bakery, Saraswathipuram, Mysuru-570009.
Ph: 9738366942 Web : www.krpaindia.com Email : krpaindia@gmail.com

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EDITORIAL TEAM

EVIDENCE VS EMINENCE BASED MEDICINE

The Role of Pharmacist

The decision-making paradox pertaining the evidence-based medicine and eminence-based or practice-based medicine is becoming more and more difficult as well as important in modern medicine. So where does the answer lie? Is it necessary for one side to be victorious over the other for the patients to receive the best possible therapy or care, or there can be a middle course where both practices can coexist and contribute to medical science? The literature available on both approaches suggests that no single approach is viable blindly in every situation. In this text, we shall discuss the facts and some opinions regarding the issue which has gone undiscussed for far too long in a country like India where 1/3rd population of the world seeks to benefit from healthcare.

EVIDENCE-BASED MEDICINE

Dr. Gordon Guyatt, A Canadian physician and Distinguished University Professor in the Departments of Health Research Methods, Evidence and Impact and Medicine at McMaster University in Hamilton, Ontario, first coined the term 'Evidence-Based Medicine' (EBM) in 1991. The term was first formally defined by Dr. David Sackett, former professor of medicine at McMaster University, often viewed as the father of this movement, and his colleagues in 1996. They stated evidence-based medicine is the “conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”.

The practice of evidence-based medicine simply implies making the best clinical decisions based on the integration of personal clinical integration with the best available external clinical evidence, whether in the form of investigative tests or imaging performed or from medical literature. The idea is to move as close to evidence to promote rational drug use via rational prescribing. It is a process of lifelong, self-directed learning in which clinical data and literature provide us information about the diagnosis, prescribing, and therapies. Once the information is made available to us, we-

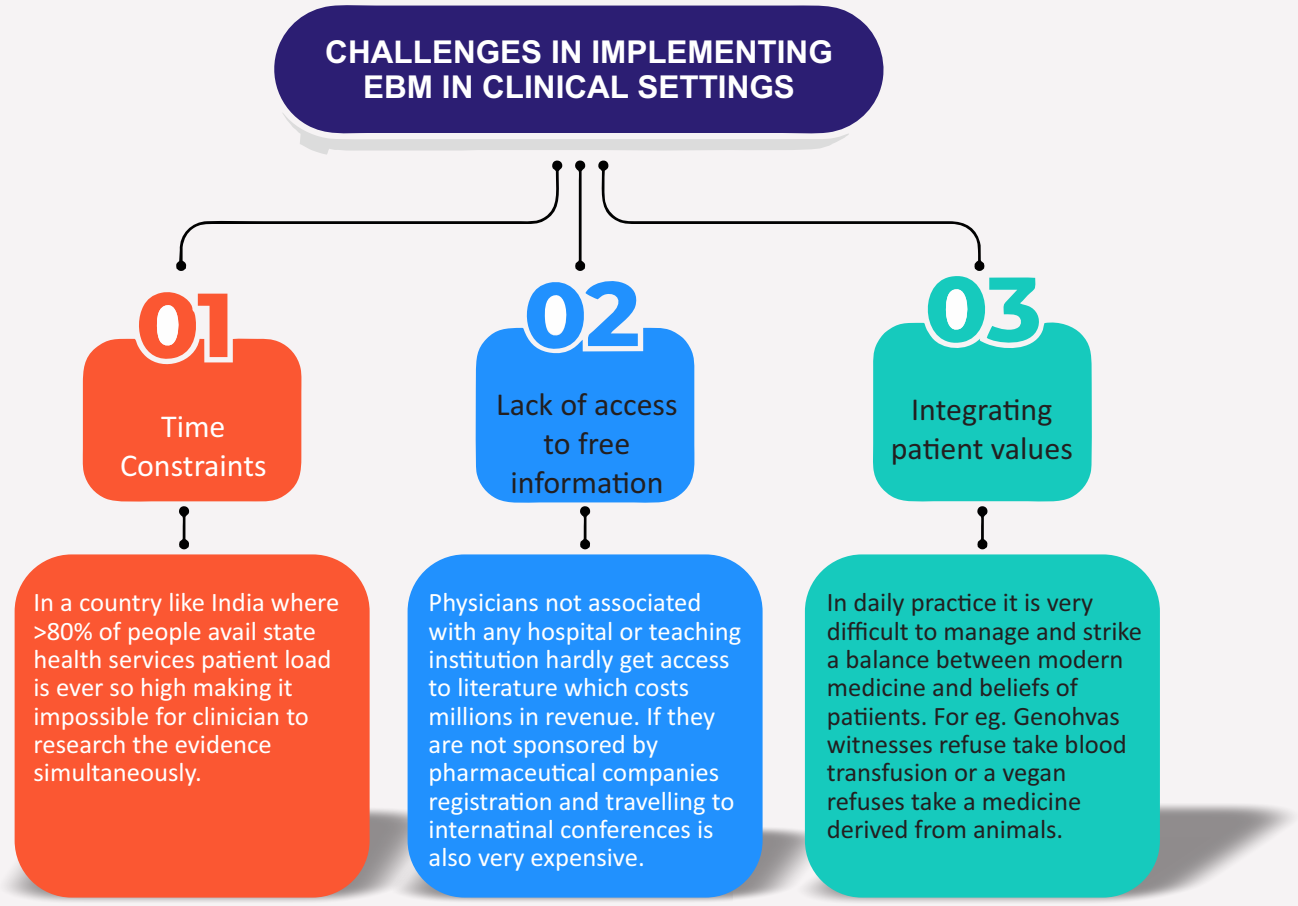
1. **Convert information into answers**
2. **Track down the best evidence to support the answer.**
3. **Scruitanize the evidence for verification and cross verification**
4. **Integrate the clinical appraisal with clinical expertise.**
5. **Evaluate performance.**

Condition / drug	Truth
Warfarin	• Warfarin is approved for use in the prevalence of arterial fibrillation and related stroke. • Good treatment quality is assessed by INR and TTR based on proper evidence.

EMINENCE BASED MEDICINE

Eminence-based medicine, also known as practice-based medicine is a practice that emphasises clinical decisions which are made by relying purely on the opinion of the medical specialist(s) or any prominent health professionals rather than relying on critical appraisal of scientific evidence available. Many of us may think that prominent health professionals possess more skills and knowledge and therefore their opinion on a particular health matter should be sufficient to justify a clinical decision. But the problem with such a method is it fails to eliminate biases and henceforth fails to statistically or scientifically reduce associated risks. Prescribing is a delicate art and one must keep Murphy's Law which roughly states that “anything which can go wrong will go wrong”. But by utilizing the entire clinical appraisal and making smart informed decisions and ultimately removing as much bias as possible from the practice of prescribing, we might be able to decrease the chances of things going south, therapeutically.

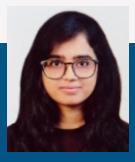
Condition / drug	Truth
Surgery	• The preference of modern technique in surgery is eminence-based practice, because of the heterogenicity of the cases. • Although, evidence-based medicine is necessary for understanding the usage of tools.
Antibiotics	• Antibiotics are having poor co-relation between in-vivo and in-vitro studies. • So the use of antibiotics depends on the experience of healthcare professionals as well as evidence-based guidelines for the prevention of antibiotic resistance.



ROLE OF THE PHARMACIST:

A Pharmacist can assist, educate and facilitate the choices in rational use of the drug by providing EBM. The basic principle of EBM is to make all practical decisions based on the literature, about quantitative, qualitative, and theoretical studies. It is believed that EBM is difficult to practice, and one of the ways is to bridge the gaps in the knowledge of the practitioners by enhancing supportive information systems, and this bridging needs to be practiced by clinical pharmacists at all levels primary, secondary and tertiary care healthcare centers. Pharmacists across the country are in dire need of training, so they can educate various healthcare professionals about this concept, changing the protocols of medicine, and assist inpatient counselling. This change need not be seen as a challenge to current practices but a modification and partnership between multiple professions for better healthcare delivery.

Evidence-based medicine is particularly a triangle of individual expertise; patient value, preference, expectations, and external best research evidence; where clinical expertise (practice-based medicine) plays a major role in developing evidence-based guidelines. In the perception of improved patient health care service, encouragement of evidence-based medicine with the help of practice-based medicine often leads to improved health care professions. Pharmacists have a crucial role in the health system to maintain the rational use of medicine and provide pharmaceutical care to patients because they are the drug experts who are academically trained for this purpose. The “rational use of the pharmacist's workforce” will lead to “rational use of medicines”, thus improving the outcome of pharmacotherapy as well as decreasing the global health costs.


Charmi M. Chhatrala
1st year M.Pharm
Department of Pharmacy Practice
JSS College of Pharmacy, Mysuru.


Dibaneja Khonglein
1st year M.Pharm
Department of Pharmacy Practice
JSS College of Pharmacy, Mysuru.


Lakshay Attri
1st year M.Pharm
Department of Pharmacy Practice
JSS College of Pharmacy, Mysuru.

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A Primer on Covid-19 VACCINES

The pandemic has put pharmaceutical sciences onto the center stage. Pharmacy courses have become hot property. Colleges are seeing immense demand for seats to various pharmacy courses. Pharmacists are invited to webinars and asked to write articles on Covid-19 and the pandemic. Thus, pharmacists are the cynosure of society.

The pharmaceutical sector is not the ken of only the pharmacists. All those who participate in pharmaceutical operations through diverse streams are a part of the sector. For instance, Dr. Krishna Ella BSc (Agriculture) MS in plant science (University of Hawaii) and PhD from the University of Wisconsin Madison founded Bharat Biotech - now-famous world-over for COVAXIN, which contains the whole inactivated virion: SARS-CoV-2. Dr. Krishna Ella made a switch from plant pathology to human and yeast molecular biology. The encouragement he received from his teachers and the change in thinking process thereby - in Madison, made him take the risky and plunge into vaccine production through his establishment of Hyderabad-based Bharat Biotech. This world-class company is the leader in hepatitis vaccine production and is the world's largest producer of rabies virus vaccines. Pharmaceutical science is a challenging field and it is open to anyone who can offer value to the development of the pharmaceutical sector.

The onus is on pharmacists to dive deep into knowledge and innovation. Vaccinology provides another opportunity for pharmacists to prove their mettle. Covid-19 vaccine research is agog with action. Vaccine researchers are looking at several ways to present the SARS-CoV-2 antigen in such a way that it does not cause infection but stimulate the immune system to produce circulating antibodies and create cell memory against this antigen. The target of most vaccine researchers is to use the RNA gene or subunit of the spike protein S of the SARS-CoV-2 virus for stimulating the production of antibodies. A successful vaccine would generate enough antibody immunoglobulin G in the blood and immunoglobulin A in the mucosa. Both these types of immunoglobulin antibodies help destroy the single-stranded positive-sense RNA virus SARS-CoV-2 that causes Covid-19.

Covaxin (from Bharat Biotech) provides 6 micrograms per 0.5 ml of the whole virion inactivated SARS-CoV-2 virus strain NIV-2020-7070, where NIV stands for National Institute of Virology. Aluminum hydroxide gel in the Covaxin vial helps in vaccine efficacy and other inactive ingredients in the vial are required for the stability of the vaccine. The whole inactivated virion technology is also used in the production of seasonal influenza vaccines, rabies vaccines, and hepatitis A vaccines. This proven technology does not cause any viral disease on vaccine injection to subjects, yet stimulates antibody production and is safe. Covaxin is given in two doses each of 0.5 ml, 4 weeks apart. The efficacy of Covaxin as per phase 3 data is 77.80%, this data has been submitted to DCGI.

Covishield manufactured by Serum Institute of India (SII), Pune is based on viral vector technology innovated for the SARS-CoV-2 virus by Oxford University and AstraZeneca. World-over the vaccine is popular as the AZ-Oxford vaccine or AstraZeneca Oxford vaccine. In this technology, the DNA virus adenovirus is used as a vector or carrier of the RNA gene that produces the spike protein of SARS-CoV-2. So the DNA of the adenovirus that is found in chimpanzees is taken, genetically engineered with help of special enzymes, so that only the viral RNA gene portion that codes for the spike protein of the SARS-CoV-2 virus, gets fused into the chimpanzee adenovirus DNA. This is the recombinant technology at work. The resulting adenovirus that acts as a vector is a GMO or genetically modified organism. Thus, the Covishield vaccine contains GMOs. The generic name of Covishield is ChAdOx nCoV-19 coronavirus vaccine (recombinant). Each dose of Covishield is 0.5 ml, and each dose provides ChAdOx nCoV-19 coronavirus vaccine (recombinant) 5 X 1010 viral particles (vp). ChAdOx refers to the chimpanzee adenovirus, Ox is Oxford, and nCoV-19 is novel coronavirus 19.

After Covishield is injected into a person, the adenovirus gets into the human host cell. The virus is broken down and the recombinant DNA gets into the nucleus of the host cell. There the adenovirus recombinant DNA produces the corresponding mRNA (messenger RNA, photocopy of DNA), which goes to the ribosome (protein factory) of the host cell. The spike protein is manufactured by the host cell ribosome and this goes to the surface of the host cell. Immediately T lymphocyte cells break down this abnormal host cell with spikes, and the spike protein fragments stimulate B lymphocytes to produce specific antibody immunoglobulin M and G that help destroy the spike protein antigen. Thus, when a vaccinated individual is exposed to the SARS-CoV-2 virus in society, the B lymphocytes produce corresponding antibodies that help destroy the SARS-CoV-2 virus that has entered the human body. Hence, vaccinated individuals seldom suffer severe Covid-19 and hospitalization. Due to extensive vaccination in Israel, wearing masks and social distancing is no more required.

Covishield contains non replicating adenovirus, hence there is no danger. Adenovirus is chosen as a vector because this DNA virus is commonly present in the respiratory system of humans. Adenovirus causes non-fatal common cold infection. The adenovirus vector technology is a 50-year-old technology, hence, there is high confidence in the same.

Covishield is given in two doses, the second dose is 6 to 8 to 12 weeks after the first dose. Covishield efficacy rate is generally reported as 73.43% but some studies have said it is up to 100%. With a dosing interval of 12 weeks, the efficacy rate of Covishield is 78.79% as reported.

Sputnik 5 Covid-19 vaccine invented by Gamaleya National Center of Epidemiology & Microbiology, Russia - a leading center for virus research, their competence is on adenovirus vector technology. However, they use the human adenovirus and not the chimpanzee adenovirus. The efficacy claim of Sputnik 5 is reported from 91% to 97.6%. Sputnik 5 is a two-dose vaccine (the second dose uses a different adenovirus vector than the first dose to enable better efficacy), dose interval is 3 weeks. Single-dose Covid-19 vaccine Sputnik Light is the first dose of Sputnik 5 and is also said to generate a good level of antibody production for a protective effect from Covid-19.

The specific mRNA that codes for the SARS-CoV-2 spike protein is presented by the Pfizer mRNA vaccine brand name Comirnaty and Moderna's mRNA vaccine. When the mRNA vaccine is injected into a person - the vaccine mRNA is wrapped in a lipid nanoparticle – this is taken up by host cells. The mRNA goes directly to the host cell ribosome (protein factory) and the spike protein is manufactured. The spike proteins come up to the surface of the host cells, T cells destroy the abnormal cell, the released spike protein antigen stimulates appropriate antibody production by B lymphocytes in the host body. mRNA vaccines are also two-dose vaccines (the Pfizer vaccine doses are given three weeks apart).

Biological Evans, Hyderabad is on the verge of launching an antigen recombinant protein (subunit of the spike protein) based vaccine in collaboration with Baylor College of Medicine, the USA at a projected cost of Rs. 110 per dose, this too is a two-dose vaccine (28 days apart). The brand name of this vaccine is Corbevax.

Zydus Cadila is using a plasmid DNA technology platform, however, this technology platform has not been used widely in vaccine production. The spike protein RNA gene is combined into the circular plasmid DNA of certain bacteria – the recombinant plasmid thus created is injected intradermally. The brand name of these three-dose vaccines is Zy-CoV-D. This vaccine is stored between 2 to 8 deg centigrade. The plasmid is a circular DNA present in bacteria outside the main nuclear DNA. The phase 3 trials are on for this vaccine candidate.

In the Covid-19 vaccine constellation, work is on for an oral vaccine too! A company by the name ORAVAX (Israel – India partnership), is creating an oral vaccine with a triple antigen VLP (virus-like particle). The three antigens of this VPL are spike protein (S), membrane protein (M), and small membrane protein (E).

Except for the mRNA vaccines that require -70 deg C storage, other vaccines are stored between 2 to 8 degrees Celsius.

As per WHO the efficacy threshold for any COVID-19 vaccine is 50%. In current pandemic times, the benefit outweighs any risk associated with vaccination. Hence, taking the vaccine is most vital to avoid severe COVID and restore routine living.

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Mr.Sunil S Chiplunkar
M Pharm (Pharmacology) MBA (Marketing) PGDHRM (PhD)
VP – Business Development, Group Pharmaceuticals, Bangalore,
Email: 1969sunilchiplunkar@gmail.com

DRUG UTILIZATION EVALUATION

Drug utilization evaluation (DUE) is defined as structured, ongoing initiatives that interpret the pattern of drug use in relation to predetermined criteria and attempt to minimize inappropriate prescribing. It is a systematic process designed to maintain the appropriate and effective use of medications.
The main aim is to improve the quality of health care and its costs. It focuses on various medical, social, and economic aspects of drug use. The Medical aspects include the risk and benefits of drug therapy, social aspects that can be related to misuse of drugs and economic issues that come with the cost of drugs.

DUE plays a key role in helping the health care systems to improve understanding, interpreting, evaluating, and improving the rational prescribing, proper administration of medications. Because of its expertise in medication therapy management, pharmacists play an important role in this process. Pharmacists who participate in DUE programs can positively influence the quality of treatment for patients, both individually and as a group, by avoiding unnecessary or inappropriate medication administration, preventing adverse drug responses, and improving overall drug effectiveness. DUE allows the pharmacists to document and evaluate the benefits of pharmacist interventions in improving therapeutic, humanistic, and economic outcomes while demonstrating the overall value of the role of the pharmacist in healthcare.

DUE is classified into 3 categories:

1. Prospective Study
2. Concurrent Study
3. Retrospective Study

Let us now look at, Prospective study, before the patient receives any drug, the pharmacist should be able to identify and fix the drug-related issues. Herewith their regular practice, our pharmacists should conduct the prospective evaluations of drug utilization by evaluating the prescription and recommend accordingly while analyzing patient background information for potential drug-related problems. By doing so, The prevalence and outcomes of diseases are simple to calculate, at the same time multiple diseases and disorders can be investigated, allows to study the calculation of incidence, facilitates the study of rare exposures and also avoids selection bias at enrollment. However, It should follow a large number of subjects for a long period, very expensive and time-consuming, not good for rare diseases, doesn't suit for diseases with long latency and differential loss follow up can introduce bias

Concurrent study: It allows the pharmacist to notify the prescribers of potential problems and intervene in areas such as drug-drug interactions, duplicate therapy, overuse or underuse, and excessive or insufficient dose.

Prospective study:

It is a form of a cohort study in which participants are enrolled before they develop the disease or outcome that is being studied. After the participants have been registered, they are tracked for a period of time to see who receives the desired outcome. Typically, the research is carried out with a specific aim in mind, and participant's progress is monitored on a regular basis using the same data collection procedures and questionnaires for each person in the study.

So it benefits, The prevalence and outcomes of diseases are simple to calculate, multiple diseases and disorders can be investigated, and researchers are not required to deal with ethical issues such as who receives which treatment, Although unfavorably, Cohort studies are expensive and time-consuming, confounding variables can be a significant issue, sample sizes are usually quite large, selection bias could be a problem. To be continued...

SUVVADA PRUDHVI RAJ
1st year M.Pharm
Department of Pharmacy Practice
JSS College of Pharmacy, Mysuru.

Role of Clinical Pharmacist in Augmenting Patient Safety

What is Patient safety?

The Institute of Medicine (IOM) defines patient safety as "the prevention of harm to patients." The emphasis is placed on a care delivery system that (1) prevents errors; (2) learns from errors that do occur; and (3) is based on a safety culture that includes health care workers, organizations, and patients. Where the definition of prevention of harm stands for “the freedom from accidental or preventable injuries produced by medical care.

According to the reports by the World Health Organization (WHO), one in four patients is harmed by the care received in primary and ambulatory care settings. Adverse events claimed to be responsible for a large proportion of hospitalizations. Specifically, the global cost associated with medication errors has been estimated by the WHO as USD 42 billion per year. Given that medications are the most used therapeutic intervention, ensuring safe medication use and implementing practices to promote medication safety should be a top priority. It is therefore not a surprise that patient safety has become a global emergency and many nations are placing patient safety on their national health priority agendas.

Millions of individuals are injured or die each year as a result of detrimental and low-quality health care. Many medical practices and risks linked with health care are emerging as substantial threats to patient safety, contributing significantly to the burden of harm caused by unsafe care. The preceding are some of the most concerning patient safety situations.

Medication errors: According to National Coordinating Council for Medication Error Reporting Programme (NCCMERP), "A medication error may be defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use." Medication errors are a primary cause of damage and preventable harm in healthcare systems; the cost of medication errors is estimated to be US$ 42 billion per year globally.

While pharmacists' contributions to medication safety have traditionally been limited to distribution, as prescription therapy has become more nuanced, pharmacists' roles have extended, and many patients—including those with serious illnesses—can now receive care at home or in the community.

According to the American Pharmacists Association, Pharmacists in all settings, have eight fundamental medication-related obligations that are tied to increasing patient safety. These eight obligations are enlisted below, along with instances of how they can impact patient safety.

- **Ensure access to medication:** A clinical pharmacist could greatly contribute to evaluating the financial ability of the patient to pay for treatment by looking into alternate medications or payment options that the patient otherwise could not afford, ultimately improving adherence and safety.
- **Supply medication information:** Educating the patients and caregivers on safe and effective medication practices. Medication errors and drug interactions can be minimized by reviewing medications and their proper dosing with patients or providers.
- **Evaluate medication appropriateness:** Assess medication appropriateness, effectiveness, and safety for each patient.
- **Improve medication adherence:** Reviewing the medication usage pattern of patients by suggesting changes in medication, dosing, or additional therapies if required will enhance patient adherence.
- **Provide health and wellness services:** A clinical pharmacist can also actively participate in delivering several direct health and wellness services like blood pressure screenings which can reveal poorly controlled hypertension.
- **Medication management:** A pharmacist's comprehensive review may detect which of numerous medications is triggering an adverse effect, simplify a patient's pharmaceutical regimen, uncover gaps in meeting treatment goals, or prevent the prescription of medications that have unfavorable interactions.
- **Assess health status:** Determine the current patient's status and medication effectiveness; deliver the counselling for medication therapy.
- **Coordinating care transitions:** A pharmacist can also assist with medication management across care transitions. At potentially error-prone transitions in care, pharmacist-led medication reconciliation may highlight potential interactions or omissions from the medication list.

Pharmacists play a crucial role in medication safety programme planning and implementation at the system level. The development of risk-specific guidelines/protocols for high-alert medications could be one of these endeavors. Pharmacists also play a vital role in the detection and evaluation of medication error data and reporting of same to health care organizations. Thus, Pharmacists hold a central role in safeguarding medication and patient safety across the healthcare system.

Priya J Aradhya
Research Scholar
JSS College of Pharmacy, Mysuru
JSS Academy of Higher Education & Research, Mysuru.

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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 20th July 2021 to this E Mail ID- krpaindia@gmail.com

A confirmation mail will be sent to you on receiving your e-mail.

1. Myotics are drugs which:

a) Constrict pupil of the eye
b) Constrict the blood vessels
c) Dilate the blood vessels
d) Dilate the pupil of the eye

2. Mydriatics are drugs which:

a) Constrict the pupil of the eye
b) Dilate the pupil of the eye
c) Dilate the blood vessels
d) Contract the blood vessels

3. Selection of the site of injection depends upon-

a) Route ordered by the physician
b) The quantity of medication to be given
c) The characteristics of medication to be given
d) All of the above

4. 5% glucose saline means-

a) Each 100ml contains 5gms glucose and 5gm sodium chloride
b) Each 100ml contains 5gms glucose and 0.9gm sodium chloride
c) Each 100ml contains 5gms glucose and 0.4gm sodium chloride
d) Each 100ml contains 0.5gms glucose and 0.9gm sodium chloride

5. Repeated injections on the same spot can cause-

a) Induration of the skin and scar formation
b) Injury to the nerves
c) Injury to the walls of the blood vessels
d) All of the above

6. 1.5% dextrose in normal saline (NS) is-

a) Isotonic fluid
b) Hypotonic fluid
c) Hypertonic fluid
d) None of the above

7. The Poison Act was passed in-

a) 1875
b) 1919
c) 1940
d) 1996

8. Which of the following is not a synthetic opium alkaloid

i. Carbon, Hydrogen and Oxygen
ii. Carbon, Nitrogen and Phosphorus
iii. Carbon, Nitrogen and Oxygen
iv. Carbon, Hydrogen and Sulphur

9. Which penicillin antibiotic is effective both orally and parentally-

a) Amoxicillin
b) Cloxacillin
c) Ampicillin
d) Ofloxacin

10. The rate of absorption of a drug is affected by-

a) Route of drug absorption
b) Solubility of the drug
c) Site of administration
d) All of the above

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The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. Neither the people associated with the publication of the Newsletter nor the organization shall be liable for any damage incurred as a result of use of the contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the newsletter does not endorse them.

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