# JSS ACADEMY OF HIGHER EDUCATION & RESEARCH, MYSURU

**(DEEMED TO BE UNIVERSITY – ACCREDITED 'A+' GRADE BY NAAC)**

## JSS COLLEGE OF PHARMACY, OOTY

**(ISO 9001:2015 CERTIFIED)**

**ALL INDIA COUNCIL FOR TECHNICAL EDUCATION & RESEARCH, NEW DELHI SPONSORED**

**Quality Improvement Program (QIP)**

**On**

**Pharm D Education: Training for the Academic Practitioners**

**1st – 14th March 2019**

Venue: Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty

# PROGRAM REPORT

**ORGANIZED BY**

**Department of Pharmacy Practice**

**JSS College of Pharmacy, Ooty**

**Report on**
**All India Council for Technical Education (AICTE), New Delhi Sponsored**
**Quality Improvement Program (QIP)**
**On**
**Pharm D Education: Training for the Academic Practitioners**

Date: 1st – 14th March 2019

Venue: Seminar Hall, JSS CoP, Ooty

Program Organized By:
Dept. of Pharmacy Practice
JSS College of Pharmacy
Ooty

Program report submitted by
DR S Ponnusankar
Professor & Head, Dept. of Pharmacy Practice
Program Co-ordinator

**Day: 1 (01st March 2019) [Friday]**

All India Council for Technical Education (AICTE), New Delhi sponsored Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners was inaugurated by the president of the function Dr. CG Betsurmath, Executive Secretary, JSS Mahavidyapeetha, Mysuru. Dr K Bangarurajan, Joint Drugs Controller, CDSCO, New Delhi; Dr Smita Kulkarni, Scientist F and Deputy Director, National AIDS Research Institution (NARI), ICMR, Pune; Dr Hiriyan Ravikumar, Joint Director of Health Services, The Nilgiris; Dr M Easwaramurthy, Principal, Govt. Arts College, Ooty; Dr Srinivas Reddy, Managing Director, TANTEA, Ooty; Prof. K. Chinnaswamy, President, Indian Association of Colleges of Pharmacy, Chennai were the Guests of Honor. Dr B Suresh, President – Pharmacy Council of India, New Delhi & Vice Chancellor, JSS Academy of Higher Education & Research, Mysuru was the chief guest of the program and provided the key note address. During his key note address, he emphasized about the importance and objectives of continuing education for the pharmacy professionals and different pedagogies to be used for the teaching of pharmacy students.
Dr S Ponnusankar, Program Coordinator of the QIP program briefed about the objectives of the program such as:

- Build interest and skills to understand the new teaching pedagogies, learning methods and research
- Prepare and choose the various or appropriate pedagogical methods which enhance student learning
- Build the general work habits, attitudes and exposure to work as mentor in facilitating the professional development of the students
- Build values on the principles of evaluation of answer scripts and setting question paper
- Develop personality and understand the human relationships in academic environment.

Dr SP Dhanabal thanked all the participants for their interest to participate in the program.

***Lecture 1:***
***TEACHING METHODOOGY – Interprofessional Education***
***Topic: Pharmacotherapy Course work – Preparation, presentation and assessment***
Presented by: Ms. M. Deepalakshmi, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

Ms. M. Deepalakshmi, started her presentation with the greetings to all the participants and she brief about the importance of interprofessional education and followed by setting the objectives of the program.

Integrated Teaching: Integration in education can be defined as the coordination of different teaching-learning activities to ensure the harmonious functioning of the educational process for more effective learning by students. The purpose of integration is to increase the effectiveness of the teaching-learning process.

Types: Horizontal Vertical.

Steps of Module Development:
1) Choose the topic, problem or task (must know)
2) Identify the participating departments
3) State the learning objectives
4) Plan evaluation
5) Choose alternative T-L methods
6) Identify learning resources
7) Plan time table
8) Trial implementation
9) Revise by feedback

Benefits of Learning Modules for Students:

- As there is unified presentation of common medical problems, contradictory concepts and opinions could be minimized by planning
- Irrelevant areas also can be eliminated at the planning stage
- There is also avoidance of the repetition of subject matter
- Students are able to observe good examples of multi-disciplinary cooperation.

Benefits of Learning Modules For Teachers:

- Provides an opportunity not only for inter-departmental cooperation but also for sharing ideas and learning from other disciplines
- Research problems can be identified and research projects can be initiated.

Problems of Integrated teaching:

1) Lack of adequate weightage in evaluation renders it irrelevant from achievement point of view
2) Too many modules may result in complex schedules that few may able to keep up with
3) Modular learning can also lead to fragmented learning of subjects and fragmentation of assessment

Pharmacotherapy Course Work

Pharmacotherapy is the area of pharmacy practice that is responsible for ensuring the safe, appropriate, and economical use of drugs in patient care.

Course Objective(s)

1. Understand the basic mechanisms of selected diseases and interpret these mechanisms in relation to drug therapy
2. Recognize major signs and symptoms of selected disease states
3. Design an effective drug treatment regimen for selected disease states
4. Tailor general therapeutic protocols to individual patients
5. Assess the risk versus benefit of drug therapy in a given patient
6. Interpret drug response using subjective and objective criteria, including laboratory measures and physical findings
7. Evaluate the safety and efficacy of drugs in a given therapeutic class
8. Formulate approaches to monitor patient response to a given drug regimen

This pharmacotherapy coursework is aimed at training the students in learning the basic concept to advance practice of therapy in hospital settings. After the presentation; clinical cases on asthma; epilepsy, hypertension; congestive cardiac failure; myocardial infarction; stroke and peptic ulcer disease.

***Lecture 2:***

***Topic: Evidence Based Medicine (EBM) – Approaches to Clinical problem solving***

Presented by: Dr Aneena Suresh, Lecturer, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

Evidence based medicine (EBM) is the conscientious, explicit, judicious and reasonable use of modern, best evidence in making decisions about the care of individual patients. EBM integrates clinical experience and patient values with the best available research information.

Why EBM?

- Cost
- Delay of "bench-to-bedside" research
- Managing the literature
- Counter misleading marketing
- Dealing with conflicting results

5'A's of EBM

●Ask question ●Access information ●Appraise evidence ●Apply findings ●Assess the process

Foreground questions: Asked for specific knowledge about managing patients with a particular disorder. It has 4 components (PICO analysis):

- P - Patient/Population
- I - Intervention
- C - Comparison
- O – Outcome

Challenges in adopting EBM

- Technology and online information resources must be available to the clinicians.
- Understanding of the epidemiological study designs and concepts of biostatistics should be clear
- Attitude of the clinician- one must realize that clinical performance depends upon regularly updating knowledge and not merely on practical clinical experience.

During her presentation, she narrated several examples of evidence based medicine concept and outcome of introducing the same at the hospital settings. Further, she also discussed about the methods to be adopted in teaching the evidence based medicine and the resources required for the same.

***Lecture 3:***

***Topic: Clinical Pharmacy Services – Our Experiences at Public Care Hospital***

Presented by: Dr S Ponnusankar, Professor & Head, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

**"Personally, I'm always ready to learn, although I do not always like being taught"**
**- Winston Churchill**

Clinical Pharmacy Services is a patient-centered, outcome-oriented activity which requires the qualified clinical pharmacist to work in concern with the patient and the patient's other

healthcare providers. The goal of clinical pharmacy services include to promote health; to prevent disease; to assess, monitor, initiate and modify medication use; to assure that drug therapy regimens are safe and effective; and to optimize the patient's health-related quality of life and achieve positive clinical outcomes.

The benefits of such services are Decrease medication misadventures; Increase patient compliance to therapy; Empowers patients to take in-charge of their own health and treatment; Decrease healthcare cost and demand; Decrease morbidity and mortality and Increase patients' quality of life.

In this presentation, the author demonstrated the establishment of clinical pharmacy program at public hospital and various models used to achieve the outcome. He also share his experiences in implementing various training method(s) at practice site.

**Day: 2 (02nd March 2019) [Saturday]**
***TEACHING METHODOOGY – ICT Enabled Teaching Methods***

***Lecture 4:***
***Topic: ICT Enabled Teaching methods – modern tools***
Presented by: Mr C Jayakumar, Asst. Professor, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

It is a challenge for the teachers to educate the present generation since our education system hasn't changed yet. We still have the old tradition methods in teaching our children. Is it right time to bring a change over? If not, as teachers shall we upgrade ourselves to their expectations? Answers to these questions may be difficult since it depends on the environment you work, the acceptance from the workplace to switch over to a new methodology, the cost involved to bring in a change and many more

…. But as an individual we can bring in some changes that help both the teachers and students to achieve the goal by introducing the technology! The presentation is prepared keeping in mind that to achieve the maximum possible goal regarding the education of the present generations.

The presentation is divided in to two major categories:
1. Free Tools for creating the multimedia lessons
2. How to use them – Hands on training

Free Tools for creating the Multimedia Lessons:
Since there are lots of tools available on the internet, he focused on the following categories in the presentation. All the multimedia lessons may be brought as sections as below:

1. Creating a podcast
2. Creating a demonstration Video
3. Creating a Video Lesson
4. New technology called "Lightboard"

Our tools of interest are

1. Audacity (audio editor)
2. Camstudio (screen capturing software and editor)
3. Epic pen (digital writing on any surface)

***Lecture 5:***

***Topic: How to use Microsoft - Power Point Effectively***

Presented by: Mr HN Vishwas, Lecturer, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

**Microsoft PowerPoint: Virtual presentation software**

- PowerPoint is a complete presentation Graphics package.
- PowerPoint offers various advantages like, word processing , outlining, graphing and presentation management

**Microsoft PowerPoint:** virtual presentation software developed by **Robert Gaskins** and **Dennis Austin** for the American software company Forethought, Inc. The program, initially named "**Presenter**", was released for the Apple Macintosh in 1987. **"In July 1987, Microsoft Corporation purchased the rights of PowerPoint for $14 million".** PowerPoint 3.0 was created at Microsoft's Graphics Business Unit in Silicon Valley over the five years 1987–1992. PowerPoint 3.0 was localized into all major languages very rapidly, and soon became the international standard for presentations. **"Till date Powerpoint remains to be one of the most Popular Software"**

**Few Advantages of Powerpoint for Teachers:**

- Once Prepared, useful for long-time.
- We no need to draw Complex structures, Figures on Black board.
- Large amount of Information can be conveyed to the Students within short duration of time.
- No need of dictating the Notes.

**Important aspects of a Presentation:**

- Presentations are systematic arrangement of Information.
- Presentations are used for Conveying information such as Lesson, Business proceedings, Procedures, Research Findings etc.,
- Powerpoint Presentations are arranged as series of individually designed "slides" that contain images, text, or other objects.
- Success of any Presentation does not depend solely on those who is delivering the lecture
- **A 'Memorable presentation' is remembered rather than the presenter.**
- **Memorable Presentations** are very important in delivering the ideas effectively.

**Before Creating a Powerpoint Presentation:**

- Check out the design templates
- Try to incorporate a 'Design' which suits your topic of Discussion.
- Some people prefer Plain Blank White Design. (It is Elegant, Many students feel boring when they see this design)
- Use standard position, color and styles
- Do not unnecessarily change or drag the Position of Text box/Image until unless it is required
- Only use necessary or essential information
- Do not over crowd the Information and add unnecessary information.
- Content should be easily understood by the audience
- Use colors that are contrasting but not distracting.
- **Remember the Color Rule of Powerpoint** (Use Dark Colored Text when using Light Background. Use Light Colored Text when using Dark Background)
- Transitions or Animations can be used for Presentations

- Animations should be Relevant and Consistent.

***Graphics, Images and Clipart:***

- Should enhance and complement the text, not overwhelm it
- Should balance the slide
- Few images in a slide make it more pleasant for the audience.

**Inserting ClipArt's/Smart arts/Video**

- Go to 'Insert' Option.
- Click on section of 'Clipart'/'Smart art'/ 'Movie'
- Search relevant 'Key words' Ex: Computer. , Insert the Proper Smart arts, or browse and add the video.

**Before Inserting Text in Powerpoint slide**

- Text should not be more than 6-8 words a line. Generally no more than 8-10 lines a Slide/Page
- No long sentences. Emphasis important information with 'Larger font'
- Avoid abbreviations and acronyms until unless necessary
- Don't over use punctuation marks
- Try to Reduce the usage of Text in Powerpoint by using 'Notes' Section in Power point
- Keep font size at between 16 to 48
- Fancy fonts can be hard to read (Cause Eye Strain)
- Commonly used font sizes are: Heading: 32-36, Slide Material: 28-30, Points: 20-24

**'Notes' section is also known as 'Speaker Notes'**

- During the Presentation, Speaker notes are not visible to the audience.
- Speaker notes help presenters to:
  - Recall important points
  - Remember key messages
  - Remember Stats or Complex information
  - Store other information which may be required for future

**Converting PPT into a Video**:

If Powerpoint Version is 2010 or above, there is an inbuilt option to convert Powerpoint directly into Video. If the Powerpoint Version is before 2010, then software needs to be downloaded and then PPT can be converted into Video. Ex: iSpring River, Digital Office Pro.

Few advantages of converting Powerpoint to video is,

- Sharing on platforms like Facebook and YouTube.
- Powerpoint software not required to see the presentation.
- Video can be burnt into CD/DVD and given as Promotional material.
- Person without the knowledge of Powerpoint can see and understand the Presentation.
- The audience will not be able to delete or change the content of the Presentation.

He concluded his presentation as**:** What makes a Good presentation is: **careful planning**, **practicing** the presentation and **speaking clearly** at a slow pace.

Hands on training

The participants are taught how to use the above tools with the explanation and hands on training. The presentation also covered the free resources to find audio, video and pictures on the internet. The presentation required the participants to submit the content prepared by them to show on the screen for further discussion.

**Day: 3 (05th March 2019) [Tuesday]**

**Field visit:** Govt. District Headquarters Hospital, Ootacamunmd

Dr S Ponnusankar, Professor & Head, & QIP Program Co-ordinator welcomed the QIP participants at the practice site (GHQH, Ooty) and took them to the Drug and Poison Information Center. Activities of the Dept. of Pharmacy Practice at GHQH, Ooty was briefed to them and training offered to the students were elaborated to them with the various forms such as patient profile form, patient counseling documentation form, drug information query request and documentation form, pharmacist intervention form, quality assurance form etc. After explaining the services and training offered at the hospital, Dr S Ponnusankar took them to the hospital tour.

Out-patient services: The hospital visit started with out-patient registration and how the patients are registered electronically and their details are documented were explained to them. Further, the role and services offered by pharmacy / nursing students at Non-communicable diseases (NCD) clinic such as patient counseling, BMI calculation, BP measurement, random blood glucose estimation were discussed. Data documentation from NCD clinic were explained and the how the data is useful in organizing group counseling programs for hypertensive, diabetic, asthmatic patients were organized was explained.

Out-patient clinic: QIP participants were taken to OP clinic and they had interaction with Dr Ashok Indiresan, Dr. Suresh, Dr. Suresh Balaji , Dr. Logharaj and understand the role of physician in secondary care hospital settings. They also learned about the e-prescribing system followed at our hospital and how this e-prescription minimizes the medication errors.

Out-patient dispensary: Participants were explained about the Tamilnadu Medical Services Corporation (TNMSC) and its role in procurement and distribution of drugs across the state. After the patient prescription is initiated at the OP clinic, they are directed to the OP dispensary and their drugs are dispensed. They also learned about drug indent and maintaining minimum stock level (MSL) of various drugs. Further, Dr S Ponnusankar explained about the history of pharmacy services offered at the hospital.

Drug & Poison Information Center: The drug and poison information services offered to the hospital by the dept. of pharmacy practice was explained along with the resources used. Further, he also explained about the documentation of services for future reference.

In-patient services: QIP participants were taken to wards such as Male Medical ward I, Pediatric ward, Male medical ward II, Female medical and surgical ward, ICU and ICCU and explained about the services offered at each ward and training received by our students. Further, they also visited Anti-Retroviral Therapy (ART) center and learned about the services offered by the Govt. of Tamilnadu for the AIDS patients.

Blood Bank: Participants visited the blood bank and interacted with the in-charge staff nurse and learned about the functioning of the blood bank. He also explained about the Volunteer Blood Donors Club of JSS CP, Ooty and the policies and procedures of the club in volunteering the blood donation.

After the visit to all the wards, participants were posted in Male Medical Ward I & II, Female medical ward, ICU & ICCU, Poisoning ward, Paediatric ward, Orthopaedic ward, surgical ward, OBG clinic for the interaction with the interns and Pharm D students to better understand about the teaching and learning

methods. Further, the students were requested to interact with them regarding the training procedures and forms used to document the clinical pharmacy services at GHQH, Ooty. After a brief meeting and interaction with the hospital superintendent, the visit was concluded.

***Lecture 5:***
***Experiential Learning***
***Topic: Clerkship & Internship Evaluation and Assessment (PCI regulations)***
Presented by:
Dr Khayati Moudgil, Clinical Resident, Dept. of Pharmacy Practice, JSS CoP, Ooty (Clerkship)
Dr Keerthana, Clinical Resident, Dept. of Pharmacy Practice, JSS CoP, Ooty (Internship)
Mr. BS Roopa, Lecturer, Dept. of Pharmacy Practice, JSS CoP, Ooty (Project work)

Dr Khayati discussed about the PCI regulations of the clerkship training to be provided to the Pharm D students. She also discussed about the clerkship rotation preparation; allotment of evaluation of clerkship and submission of documents through the preceptors.

Dr. Keerthana started her presentation about the internship and covered the following during the session:

• According to PCI regulations, Phase II of Pharm D curriculum - consists of internship or residency training during sixth year involving posting in specialty units.
• It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently
• It involves six months in general medicine department and two months each in three other specialty departments. Every student has to undergo one year internship as per Appendix-C of PCI regulations

<u>Specific Objectives of Internship:</u>
• To provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team
• To promote health improvement, wellness, and disease prevention
• To demonstrate skills in monitoring of the national health programs and schemes
• To develop leadership qualities to function effectively as a member of the health care team
• To communicate effectively with patients and the community.

<u>Assessment of internship:</u> Satisfactory completion of internship shall be determined on the basis of the following:-
• Proficiency of knowledge required for each case management, the competency in skills expected for providing clinical pharmacy services, Responsibility, punctuality, work up of case, involvement in patient care, Ability to work in a team, Initiative, participation in discussions, research aptitude.

A score of less than 3 in any of above items will represent unsatisfactory completion of internship.

Ms. BS Roopa started her presentation about the project work to be conducted during the V year Pharm D program and Pharm. D regulation as per the Pharmacy Council of India, 2008 was discussed. The topics covered during the discussion was:

- Objective of performing the project work in V Pharm D
- Approach to the project work by staff ad students
- Contents of project work presentation
- Evaluation aspects
- Report Writing

It was emphasized that the V Pharm D students should take up the project work in the area of community and clinical pharmacy. The steps involved by the in approach for the V Pharm D project work was discussed and the following best practices were shared with the participants.

The orientation would be given on emphasizing the importance of the project work to V Pharm D students. The requisition form would be distributed to the team members of each group in order to provide the preference of the group to be guided by the faculty based on the research interest. The completed requisition form by the group would be submitted to staff In-charge, further the forms would be submitted to Head of the Department of Pharmacy Practice for allocate the guide for the group. The decision of allocation of the guide will be announced. Then the student's should approach respective guide.

The calendar of events of project work would be prepared by Project Coordinator staff, the calendar includes:

1. Issue of Project application form
2. Submission of filled in application form
3. Scrutiny of the submitted application forms
4. Allotment of Project Guide and issue of orders
5. Submission of the project proposal & Presentation of the proposal
6. IRB Meeting
7. Submission of Materials Requirement to the Department
8. First Review (internal assessment) of project work
9. Second Review (internal assessment) of project work
10. Third Review (internal assessment) of project work
11. Best of two internal marks statement announcement
12. Submission of report writing

The project presentation by the students should include as follows:

1. First internal assessment, the presentation should include: Introduction, Aim and Objectives, Literature review, Methodology and study design, Plan of work, Plan of analysis, References
2. Second internal assessment, the presentation should include: Aim and objectives, Work completed. Future work to be completed, and Descriptive analysis.
3. Third internal assessment, the presentation should include: Results including final, Discussion and Conclusion, References

The project work evaluation shall be performed on basis on following criteria for the total marks of thirty:

1. Write up of the seminar/Project Work (7.5)
2. Presentation of work (7.5)

3. Communication skills (7.5)
4. Question and answer skills (7.5).

Similarly the project work will be evaluated for University Viva Voce examination on the basis of following criteria:

1. Write up of the seminar/Project Work (17.5)
2. Presentation of work (17.5)
3. Communication skills (17.5)
4. Question and answer skills (17.5).

After the completion of the project work, the students should submit the report of the work, of 40-50 pages, and follow the guidelines of preparing the report as stated in regulations.

***Lecture 6:***
***Experiential Learning***
***Topic: Demonstration of PharmAcademic software***

Presented by:
Dr GK Sadagoban, Lecturer, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

PharmAcademic an Experiential Learning Management System (ELMS) was purchased from McCredie Group – USA and it was used by our students from the year 2016. A dedicated group of pharmacy educators and informatics pharmacist developed that to meet the needs of continuous experiential education monitoring and accessing the clinical ward related activities through online portal. At present we are using PharmAcademic for developing Internship / Externship Scheduling (Rotation System), Site Research Center & Selections / Preference, Evaluations, Time Tracking, Student & Site Requirements, Competency Tracking, Messaging Center and Experiential Modules. For experiential learning management this type tools will be really helpful to track and assess the students' performance and ease the work of precepting learning in the experiential site.

**<u>Day: 4 (06th March 2019) [Wednesday]</u>**
***Clinical Pharmacokinetics & Therapeutic Drug Monitoring***
***Lecture 7:***
***Topic: Clinical Pharmacokinetics and Population Pharmacokinetics***

Presented by:
Dr KP Arun, Asst. Professor, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

The series of sessions on the said topic were delivered with a broader objective of understanding the basic concepts and applications of clinical pharmacokinetics in practice.

Pharmacokinetics is generally defined as, 'what the body does to the drug?' which involves the process of Absorption, Distribution and Elimination (Metabolism and Excretion). Clinical pharmacokinetics is the study of the relationships between drug dose regimens and drug concentration time profiles. Three basic parameters influence these relationships are Clearance (CL), Volume of Distribution (VD) and Elimination half-life (t1/2). As the VD is used to calculate loading doses and CL is used to calculate maintenance doses, these are known as 'Primary Pharmacokinetic Parameters'. The elimination half-life gives an indication of

how long it takes for steady state drug concentrations to be reached on multiple dosing and how long it will take for drug concentrations to decline if the drug is stopped.

The bioavailability of a drug formulation F is the fraction of the dose administered which is absorbed and reaches the systemic circulation. A drug given intravenously usually has a bioavailability of 100% or F=1. The same drug given orally has to cross barriers in the gut mucosa and first pass metabolism in the liver so the bioavailability may be reduced, and F will vary between 0 – 1 depending on the formulation.

In linear pharmacokinetics the CL is constant as 'k'. The steady state (SS) drug concentration is directly proportional to the dose. It follows that if we know a drug concentration represents SS we can make empiric a dose alterations by simple proportion. But few drugs, in particular phenytoin exhibit non-linear pharmacokinetics, in this case due to saturable hepatic metabolism. In this case dose increase will produce disproportionate increase in drug concentration and may even lead to toxicity. With phenytoin, very small dose increase is made with repeat monitoring of the plasma drug concentration.

There are many factors influencing the pharmacokinetics and or pharmacodynamics of the drugs which includes the genetic polymorphism of the individuals. The approach of precision medicine take this into consideration to optimize the dosage regimen and thereby the outcomes of the treatment. The pharmacometric approach will also be helpful in achieving the precision medicine for a population and at individual levels.

In clinical practice the principles of pharmacokinetics are used to relate drug doses with concentration time profiles. If there is a close relationship between drug concentration and clinical effect and toxicity, therapeutic drug monitoring (TDM) can be used to optimize clinical effect and minimize toxicity. There is great variability in drug handling between individuals so the application of the principles of clinical pharmacokinetics and TDM are very important to individualize drug therapy, especially for narrow therapeutic index drugs such as Digoxin, Lithium and Phenytoin.

Thus, the application of the principles of clinical pharmacokinetics helps to attain precise dosage regimens of drugs for individual patients to get the ideal concentration-time profile, optimal benefit at minimal risk.

**Day: 5 (07th March 2019) [Thursday]**

***Lecture: 8***

***Topic: Stress Management***

Presented by: Dr Suresh Babu, General Physician, Jeevan Clinic, Ooty

Stress is the "psychological, physiological and behavioural response by an individual when they perceive a lack of equilibrium between the demands placed upon them and their ability to meet those demands, which, over a period of time, leads to ill-health".

The following 7 tips have been adapted from The American Psychological Association to support individuals in getting the best out of a stress management plan:

Understand your stress

How do you stress? This can be different for everybody. By understanding what stress looks like for you, you can be better prepared and reach for your stress management toolbox when needed.

Identify your stress sources
What causes you to be stressed? Be it work, family, change or any of the other potential thousand triggers.

Learn to recognize stress signals
We all process stress differently so it's important to be aware of your individual stress symptoms. What are your internal alarm bells? Low tolerance, headaches, stomach pains or a combination from the above 'Symptoms of stresses

Recognize your stress strategies
What is your go-to tactic for calming down? These can be behaviors learned over years and sometimes aren't the healthy option. For example, self-medicating with alcohol or overeating.

Implement healthy stress management strategies
It's good to be mindful of any current unhealthy coping behaviors so you can switch them out for a healthy option. For example, if overeating is your current go to, you could practice meditation instead, or make a decision to phone a friend to chat through your situation. The American Psychological Association suggest that switching out one behavior at a time is most effective in creating positive change.

Make self-care a priority
When we make time for ourselves, we put our well-being before others. While this can feel selfish to start, like the old plane analogy we must put our own oxygen mask on before we can help others. This is also true for effective stress management. The simplest things that promote well-being, such as enough sleep, food, downtime, and exercise are often the ones overlooked. Make time for you.

Ask for support when needed
If you're feeling overwhelmed reach out to a friend or family member you are comfortable talking to. Speaking with a healthcare professional is also an effective way of reducing stress, learning new strategies and preventing burnout.

***Lecture: 9***
***Teaching Methodology***
***Topic: OSCE – Objective Structured Clinical Examination***

Presented by: Ms. M Deepalakshmi, Lecturer, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

OSCE's basic structure is a circuit of assessment stations, where examiners, using previously determined criteria assess range of practical clinical skills on an objective-marking scheme. Such stations could involve several methods of testing, including use of multiple choice or short precise answers, history taking, demonstration of clinical signs, interpretation of clinical data, practical skills and counseling sessions among others. Most OSCEs use "standardized patients (SP)" for accomplishing clinical history, examination and counseling sessions. Standardized patients are individuals who have been trained to exhibit certain signs and symptoms of specific conditions under certain testing conditions.

Features of the Objective Structured Clinical Examination (OSCEs):
- Stations are short – can last for 3 minutes to 20 minutes
- Stations are numerous – 5 to 20

• Stations are highly focused, candidates are given very specific instructions – history collection, procedural skills, counseling, and communication
• A pre-set structured mark scheme is used – no subjectivity and bias

Emphasis on:
• What candidates can do rather than what they know
• The application of knowledge rather than the recall of knowledge

Typically…
• 2 hours for adequate reliability
• Written answer sheets or observer assessed using checklists
• Mix of station types/competences tested
• Examination hall is a hospital ward
• Atmosphere active and busy

Additional options…
• Double or triple length stations
• Linked stations
• Preparatory stations
• "Must pass" stations
• Rest stations

Feasibility/Practicality: OSCEs are very useful to measure specific clinical skills and abilities, but are difficult to create and administer. OSCEs are only cost-effective when many candidates are to be examined at one administration. A separate room or cubical is needed for each station.

Challenges in Developing and administering OSCE: The key to a successful OSCE is careful planning.

Advantages and Disadvantages of OSCE: The advantages of OSCE are its objectivity, reproducibility, and easy recall. All students get examined on predetermined criteria on same or similar clinical scenario or tasks with marks written down against those criteria thus enabling recall, teaching audit and determination of standards. This helps to review the implementation of curricula.

Performance is judged not by two or three examiners but by a team of many examiners in-charge of the various stations of the examination.

OSCE takes much shorter time to execute examining more students in any given time over a broader range of subjects.

OSCE is more difficult to organize and requires more materials and human resources. It is expensive and requires lot of time to prepare and implement the OSCE.

Followed by presentation, participants attended the OSCE practice session and evaluated the students' performance.

**Day: 6 (08th March 2019) [Friday]**

***Lecture: 10***

***Topic: Pharmacoepidemiology models***

Presented by: Mr. Krishna Undela, Lecturer, Dept. of Pharmacy Practice
JSS College of Pharmacy, Mysuru


Pharmacoepidemiology is defined as the study of the use and the effects of drugs in large groups of people. It can be viewed as an epidemiological discipline with particular focus on drugs. Medicines can positively influence public health by their intended therapeutic effect. Medicines can adversely affect public health because of medicine related problems; medicines related problems are an important cause of mortality and most of them can be prevented. There is an important economic burden of medicines on healthcare systems. Medicines are able, via the wastewater, to pollute the environment, including drinking water. Several medicines have endocrine-disrupters or carcinogenic properties. There are wide discrepancies between the countries in licensed medicines and in their price, utilisation and expenditure. Because of these challenges of medicines on public health there is a need:

- to increase awareness and spread knowledge on the impact of medicine utilisation on public health
- to promote harmonised data collection about licensed medicines, their prices, utilisation and expenditure,
- to develop indicators for monitoring price, utilisation and expenditure of medicines at a every country level
- to promote benchmarking exercise on utilisation of medicines at national and regional level
- to assess the outcome of medicine utilisation, linking pharmacoepidemiological data to morbidity-mortality data
- to develop a public health-oriented European database of the licensed medicines with relevant information about their best use

For all these purposes it is essential to have an internationally valid classification system of medicines and a measurement system of their utilisation.

Pharmacoepidemiologic Databases: One of the main methodological developments in pharmacoepidemiology has been the emergence of large databases with more or less complete capture of individual drug use and clinical outcomes for large populations. It makes it possible to gather detailed systematic information on large groups of drug users and to link it to information concerning suspected adverse outcomes in individual users.

Disadvantages:

1. They are not suitable for the study of drug effects where the timing of drug intake is critical, i.e., short-term hyperacute effects.
2. It may be uncertain whether the patient has actually ingested the drug.
3. Cases where the endpoint is poorly described by the coding system.
4. They do not cover medication bought over the counter.

He also narrated about the various models utilized for the study. Pharmacoepidemiology is the study of the use of and the effects of drugs in large groups of people. There are worldwide a number of databases with comprehensive registration of drug use and outcomes for entire populations.

***Lecture: 11***
***Research Manuscript Communication***
***Topic: How to write a world class manuscript***

Presented by: Dr S Ponnusankar, Professor & Head, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

Dr. S. Ponnusankar gave a presentation on how to write a world class research paper emphasizing the timely need for the pharmacy professionals. In his presentation he discussed about why do scientist publish? What is a good manuscript?, How to write a good manuscript? And Revisions and responses to a manuscript?. In his discussion, he narrated that a group of people is investing their time, resource and energy in correcting your article. During his presentation he emphasized that select the appropriate journal for your work and submit once. Wait for the reply from the editor and then decide about submission of article to another journal.

***Lecture: 12***
***Research Manuscript Communication***
***Topic: How to find a good journal***

Presented by: Dr S Ponnusankar, Professor & Head, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

Dr S Ponnusankar gave a presentation on how to find the right journal for the research publication. During his presentation he gave a statistics about the number of journals in various disciplines and its raise in the recent years across the globe. He emphasized that selection of right journal for the publication of research is an art and it should be followed by a rule. He also explained the importance of peer reviewed journal for publication. He added that, what are the factors to be considered for the quality publication.

**<u>Day: 7 (09th March 2019) [Saturday]</u>**
***Clinical Research and Regulatory Requirements – Perspective of CRO***
***Lecture: 13***
***Topic: Clinical Research and Regulatory Requirements***

Presented by:
Mr. Lokesh Chaudhry, Novotech Clinical Research India Private Limited, Bangalore
Mr. Sanjay Kabra, Novotech Clinical Research India Private Limited, Bangalore

This one day talk on clinical research covered various topics in clinical research. It included;

1. Overview of drug development process which covered overall drug development process in detail and where clinical research fits in overall scheme of drug development process. It also covered various phases of clinical research.
2. Why Clinical Research in India covered the need to conduct clinical research in India as well as gave overview of facilities available for clinical research in India.
3. This talk also covered the history of clinical research and how various guidelines on clinical research evolved over the period of last few centuries.
4. ICH – GCP was covered in detail which included responsibilities of responsibilities of various stakeholders in the process of clinical research.
5. Essential Documents such as protocol, informed consent process and Investigator brochure along with many other required documents in the process of conducting clinical research were covered using role play and involving participants.
6. Data Management and Case Report Forms were covered in detail including differences between paper case report form and electronic case report form as well as overall data management process
7. Last but not the least the pharmacovigilance process which has to be followed in not only clinical research but also in overall drug development and post marketing was covered.
8. Finally session was concluded with providing overview of career options in clinical research and gave insight on process followed by organizations in hiring of the potential candidates for employment in clinical research companies.

**Day: 8 (11th March 2019) [Monday]**

***Drug Safety Assessment – Pharmacovigilance, Haemovigilance and Vaccine Vigilance***

***Lecture: 14***

***Topic: Pharmacovigilance***

Presented by: Dr B Dharini, Drug Safety Associate, PvPI, Bangalore

Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. As such, pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological disorder function was excluded with the latest amendment of the applicable legislation). Medication errors such as overdose, and misuse and abuse of a drug as well as drug exposure during pregnancy and breastfeeding, are also of interest, even without an adverse event, because they may result in an adverse drug reaction.

Information received from patients and healthcare providers via pharmacovigilance agreements (PVAs), as well as other sources such as the medical literature, plays a critical role in providing the data necessary for pharmacovigilance to take place. In fact, in order to market or to test a pharmaceutical product in

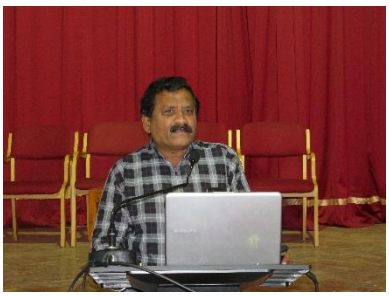
most countries, adverse event data received by the license holder (usually a pharmaceutical company) must be submitted to the local drug regulatory authority.

Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance.

During her presentation, she narrated about the various forms used to report the ADR and how PvPI is collecting the data and documenting the same.

***Lecture: 15***
***Topic: Haemovigilance***

Presented by: Dr Selvaraj, Former Drugs Controller of Tamilnadu, Govt. of Tamilnadu, Chennai



Blood is a “Drug” and legal status: Blood is treated as a `Drugs' under the Drugs and Cosmetics Act, 1940. So it is regulated under the Drugs and Cosmetics Act 1940 and rules, made there under. In 1990, M/s. A.F. Ferguson & Co., a Management Consultancy Firm, was entrusted by the Government of India, Ministry of Health, to study the blood banking system in the country.

The scope of the said study was
(i) To assess the status of Government, Private, Commercial and voluntary blood banks;
(ii) To recommend policy and procedure changes; and
(iii) To prepare a scheme for modernization

The report submitted by the said consultancy firm to the Government in July, 1990. The high-lights the deficiencies with regard to the facilities of testing blood, licensing of blood banks and professional donors and storage of blood. On its recommendation the provisions and Rules governing the licensing and operation of the blood banks and by the Drugs and Cosmetics (First Amendment)Act and Rules, published in the Gazette of India vide notification dated January 22, 1993. Part X-B has been inserted in the Rules and Part XII-B in Schedule F has been substituted.

In part X-B (Rules 122-F to 122-0 ) provisions have been made prescribing the requirements for collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products and for grant and for renewal of licence for the operation of a blood bank/processing of human blood for components/manufacture blood products. Under the said provisions licence can only be granted or renewed with the approval of the Central Licence approving Authority viz. the Drugs Controller of India. Part XII-B in Schedule F contains provisions relating to space equipment and supplies required for a Blood Bank.

Subsequently The Apex Court directed the Union Govt. to improve the blood banking system in 1996 in Common causes Vs Union of India case. Based on that, Schedule F pat XIIB of the Drugs and the Cosmetics Act 1940 is amended in 1996 with various provisions like accommodation, Personnel, equipment, reagents, GMP, various criteria for blood donation, testing of whole blood, records and labels in the interest of Good transfusion free from adverse reaction.

a. At present, India follows a procedure of mandatory licensing under the Drugs and Cosmetics Rules for blood banks.
b. The Supreme Court of India passed an order directing the Government to improve blood-transfusion services.
c. The blood collection from the Professional donor is prohibited

Consequently, the NBTC and SBTCs were created to develop policies and programs for improving blood-transfusion services in India.

Blood Bank Systems in India: According to the World Health Organization, Southeast Asia's estimated blood requirement is about 16 million units per year, but it collects just about 9.4 million units annually, leaving a gap of 6 million units. India with its huge population of over 1.27 billion is lagging behind in blood collection. India has 2760 ( upto Dec 2015) blood banks that can collect 9 million units of blood annually, but collects only 7 million.( The total recorded blood collection in India is 7 million units, which meet only 55% of need against a least requirement of 12 million units) (India's blood requirement is about 11 to 12 million units per year Blood banks in India are able to collect only about 7 to 8 million units per year). They are managed by the public sector (government), Indian Red Cross Society (IRCS), nongovernment organizations (NGOs, on no profit basis), and commercial sectors. Roughly, about 55% blood banks are from the government sector, 5% from the IRCS, about 20-25% from the NGO sector and the rest are from corporate profit-making sectors.

In India, the ratio of usage of blood components to whole blood is 15:75, while globally it is 90:10. According to National AIDS Control Organization (NACO), only 500 blood banks in India can be termed as "big banks" collecting more than 10000 units annually. Nearly 600 of the rest are "small banks" collecting around 1000 units a year. Most of the 2433 blood banks are moderate collecting 3000-5000 units of blood a year.

<u>Reaction types:</u>
Blood is considered to be the living force of our body. Blood is a Tissue. Each unit of blood is single batch. The adverse reactions on blood and its components are:

- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to other allo-antibody
- Non-immunological haemolysis
- Transfusion-transmitted bacterial infection
- Anaphylaxis / hypersensitivity
- Transfusion related acute lung injury (TRALI)
- Transfusion-transmitted viral infection (HBV)
- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted viral infection, other (specify)
- Transfusion-transmitted parasitical infection (Malaria)
- Transfusion-transmitted parasitical infection, other (specify)
- Post-transfusion purpura
- Graft-versus host disease

• Other serious reaction(s) – specify (e.g. transfusion associated circulatory overload (TACO), transfusion associated dyspnoea (TAD), febrile non-haemolytic reactions (FNHTR) and uncategorised unintended responses)

Records:
The Drugs and Cosmetics Act under Schedule F Part XIIB mandates to document the activities by maintaining certain records. Besides the other records the transfusion adverse reactions register should be maintained. Non-maintenance of the records is deemed to punishable under section 27 (d) of the Drugs and cosmetics Act 1940 read with rule 122P(i)a of the rules for not maintaining the records and registers specified in schedule F Part XIIB .

Haemovigilance: Haemovigilance is defined as 'a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence'.
i.e To study and to prevent the transfusion adverse reaction

Reasons for Safe Blood in haemovigilance program
1. It is the fundamental right of the every citizen to get the safe blood under constitution.
2. It is the consumer's right of the consumer (patient) to get the safe blood under the consumer protection Act.
3. It is the responsibility of the State ( Govt) to ascertain that safe blood is being used in the country.
4. It is the duty of the Blood bank for the supply safe blood.
5. It is the responsibility of the regulatory authorities (Drugs Control dept) for the collection and administration of safe blood.
6. It is the moral responsibility of the clinician for the proper administration of blood safely.
Haemovigilance is a tool to improve the quality of the blood transfusion chain, primarily focusing on safety Haemovigilance, as a safety concept, appeared in the beginning of the 1990s. It was initially developed by the French Blood Agency in 1994 as a national system of surveillance and alert, from blood collection to the follow-up of the recipients.

Haemovigilance is now well-recognized as an integral part of quality management system in a blood programme. The goal of Haemovigilance is to identify and prevent occurrence/recurrence of transfusion related unwanted events, in order to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the blood transfusion chain from donors to recipients.

Haemovigilance is an important tool not only to analyze blood transfusion incidents, but also to measure the effects of new processes or corrective actions at a national level. The avoidable transfusion related adverse events remain a serious cause of injury and death. This assessment of transfusion performance thus takes into consideration the safety of the product, the appropriateness of the clinical indication and the effectiveness of the transfusion process.

Haemovigilance system is designed to detect, gather and analyze unexpected or undesirable effects associated with transfusion in order to remedy their causes and prevent their recurrence. The information generated through this system is a key to bring about required changes in the transfusion policies, improve transfusion standards, assist in the formulation of transfusion guidelines and thus to increase the safety and quality of the entire transfusion process.

A system of Haemovigilance is dependent on traceability of blood and blood products from donors to recipients, spontaneous reports of transfusion adverse events/reactions, and rigorous management of information related to the transfusion process.

Haemovigilance Programme in India: A centralized and structured Haemovigilance Programme was launched in India on 10th December 2012. The National Co-coordinating Centre for Haemovigilance is located at NIB and a Core Committee chaired by the Director NIB, co-coordinated this programme. The Core Committee is assisted by a National Advisory Committee which has a varied representation, reflecting key stakeholders. After detailed discussion amongst all the committee members, the Transfusion Reaction Reporting Form (TRRF) and a guidance document for filling the form have been finalized.

Presently reporting is voluntary and limited to information related to adverse transfusion reactions. Awareness about the programme, its objective and its non-punitive implications is being generated through a Haemovigilance Newsletter accessible at haemovigilnce@nib.gov.in

Why Haemovigilance Programme is required in India?

Haemovigilance is required to identify and prevent occurrence or recurrence of transfusion related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient. The information gained from the investigations and analyses facilitate corrective and preventive actions to be taken to minimize the potential risks associated with safety and quality in blood processing and transfusion for donors, patients and staff. Such information is also a key to introduce required changes in the applicable policies, improve standards, systems and processes, assist in the formulation of guidelines, and increase the safety and quality of the entire process from donation to transfusion.

The Haemovigilance system should be organized in efficient national systems, which involve all relevant stakeholders, and should be coordinated and cooperated between the blood transfusion service, hospital clinical staff and transfusion laboratories, hospital transfusion committees, regulatory agency and national health authorities in identification, reporting, investigation and analysis of adverse events near-misses and reactions related to transfusion and manufacturing.

A written procedure should be in place to effectively initiate and coordinate to retrieve and recall blood and product recalls, at all time, with the notification referred to above. The Haemovigilance system in India should be confidential and the identities of patient, reporter and institution should not be disclosed to third parties, with the exception of formal written authorization or when requested by law. Reports should be sent in a standardized format by all the institutions participating in the Haemovigilance scheme. Reports should enable differentiation between adverse events, reactions in recipients and donors, near misses and uneventful transfusion errors. Records should be centrally managed, and the information used to establish trends and maintain systems to minimize recurrence of adverse events and proactively avoid occurrence of near-misses related to safety and quality in blood transfusion. The retention period of documentation and data enabling full traceability should be defined.

Reported events should be analysed in a timely way by experts who understand the clinical procedures involved and who are trained to recognize underlying systems failures. The organization implementing the Haemovigilance system should be capable of making and disseminating recommendations with the full cooperation of participating institutions which should agree to implement these recommendations,

wherever possible. Recommendations for corrective and preventive actions should be rapidly disseminated and acted upon in a timely manner, especially when serious hazards are identified.

Ensuring that blood transfusion is only used in appropriate circumstances is an important way to reduce the risk of adverse events and disease transmission, and to avoid wasting donated blood. Each hospital performing blood transfusion should establish/participate in a Hospital Transfusion Committee to implement national policy and guidelines, to ensure adequate training of staff involved in the transfusion process, and to monitor the use of blood and blood products and transfusion practices at the local level. National Haemovigilance systems can be set up only when effective mechanisms for information collection in hospitals and coordination at national level exist. Such systems are a sign of a well-developed transfusion infrastructure; in such environments, a national Haemovigilance system is essential. For less well-developed transfusion services, the first objective is to ensure that effective hospital transfusion committees are in place and are monitoring clinical transfusion practice at local level. There is a need to strengthen systems for assessment, surveillance and vigilance in blood transfusion. This would require data to be collected using standardized tools from blood centers, hospital blood banks and hospitals practicing transfusion at provincial/regional and district levels to ensure national coverage, quality data and monitoring of progress to identify and implement timely and appropriate actions. Ultimately, the data from national systems may be used for monitoring of blood transfusion safety at the global level.

The Haemovigilance of India is involved all relevant stakeholders and coordinating between the blood transfusion service, hospital clinical staff and transfusion laboratories, hospital transfusion committees, regulatory agency and national health authorities. Extension of the Haemovigilance system to regional and global sharing of information will further enhance the process of learning for improvement. Now India is linked with International Haemovigilance program.

***Lecture: 16***
***Topic: Vaccine Vigilance***
Presented by: Dr Pramod Adusumilli, Senior Drug Safety Associate BioClinica, Mysuru

Vaccines pharmacovigilance is of utmost importance and necessary today, as millions of subjects are being immunized globally in the platinum era of vaccines with the introduction of 13 new vaccines in this century. New vaccines with safety profiles emanating from clinical trials on a small sample size would need active monitoring globally to assess newer reactions post-licensure. Vaccines differ from drugs as they are preventive while drugs are curative.

Vaccine related adverse events are immunologic and indicate immune response while drug reactions are undesirable effects. This has bearing on prevention, analysis, and intervention and data interpretation. The vigilance gap between developed and developing countries needs to be improved. As newer vaccines are produced using sophisticated technologies with novel adjuvants and unique routes of administration (like nasal) for LAIV, new challenges emerge for adverse events detection, analysis and management.

In his presentation, he narrated about the aim and insights about vaccine vigilance, discuss methods for AE detection and management with real time case reports on rare adverse events to commonly administered bacterial and viral vaccines. To make the researchers and managers be better prepared to manage AEs as per international guidelines.

In conclusion, vaccine vigilance is the need of the hour as children are an extremely sensitive young group receiving up to 37 shots from birth to 6years. Clearly, vaccine safety has a narrow margin for error.

**Day: 9 (12th March 2019) [Tuesday]**
***Leadership Management***

***Lecture: 17***
***Topic: Leadership and management skills for young teachers***
Presented by: Dr Praveen Kulkarni, Asst. Professor
Dept. of Community Medicine
JSS Medical College, Mysuru

Teaching is a demanding role that requires incredible organization and time-management skills, as well as the ability to cultivate others' strengths, to persevere in the face of countless obstacles, and to build relationships—the same skills and experiences needed to lead within a variety of contexts.

The leadership practices develop and strengthen as a classroom teacher will transfer to any endeavor the individual might choose to take on. He / she will continue to draw upon these skills and experiences wherever he/she find working for systems change and educational equity—whether leading institution, becoming an attorney, heading up a grassroots community organization, remaining a classroom teacher, or holding a position on the school board. Here are four ways that teaching and leadership go hand-in-hand.

1. Teachers Start by Developing a Strong Vision for Their Classroom
One of the primary aspects of leadership is having a clear vision. As a teacher, you'll start the college year by setting the vision for what student success looks like in your classroom. Great teachers think big and develop a vision for what must be true in order for students to realize their gifts. As with great leaders, great teachers seek tremendous input from stakeholders—students, families, fellow teachers, and the broader community—to decide the direction for their class and what outcomes are most important for students to reach by the end of the school year.

2. Teachers Take Strategic Action to Reach Their Vision Every Day
In addition to setting a vision, a key component of leadership is mapping out the strategy to make that vision come true. This is a major part of your role as a teacher. Teachers set long-term and short-term goals for what you want your students to achieve and determine how you'll work with students, parents, and your school team to help your students reach those goals. Every lesson plan you create and every assignment you prepare is a part of your strategy.

3. Teachers Are Adept at Building Relationships across Lines of Difference
Strong leaders are masters of relationship building. Developing authentic relationships is absolutely crucial to your success as a teacher. You'll constantly work on building trust with your students as you both motivate and challenge them. Teaching also offers you the unique opportunity to build relationships with a diverse group of faculty, staff, and parents, who all bring different backgrounds, experiences, and strengths to the table. Learning how to navigate new contexts and build relationships across lines of difference is perhaps one of the most critical skills that you can develop as a leader right now, as our world becomes more interconnected and diverse.

4. Teachers Continually Push Themselves to Learn and Improve
Learning from mistakes, seeking feedback, and continuing to evolve are among the traits of effective leaders. Teachers by nature are at the center of this kind of culture of learning. As a teacher, your constant effort for learning and evolving—learning how to teach a new concept, learning what motivates each of your students, learning how to navigate the structures within your school to get things done. You are also constantly receiving feedback on what works (and doesn't work) and challenging your own perspective on what your students are capable of achieving.

***Lecture: 18***
***Topic: Team working and team management***
Presented by: Dr Praveen Kulkarni, Asst. Professor
Dept. of Community Medicine
JSS Medical College, Mysuru

It is easy to confuse the terms "team building" and "teamwork," but they are two distinct concepts. Team building focuses on the formation of groups, while teamwork concentrates on the function of groups; both are vital for success. Understanding the basics of team building and teamwork can increase your effectiveness as either a leader or a valued member of a group.

Team-Building Basics: Individual can look at team building in two ways. First, it can refer to the act of putting together a team by either recruiting, interviewing and selecting members from the public or strategically selecting members from within an already-defined group. Second, it can refer to engaging in activities designed to strengthen professional and personal relationships within a team. Team-building activities can increase team members' cohesiveness, productivity and efficiency when working together. Small businesses rely on both aspects of team building to succeed. Small-business entrepreneurs must take extra care to build a high-performance team and should proactively engage team members in team-building exercises to increase teamwork.

Teamwork Essentials: Teamwork is the result of a team effectively working together. It relies on a range of vital factors for success, including good communication skills, mutual respect, complementary skill sets covering all required competencies, defined leadership and defined decision-making procedures. At their best, work teams function like well-oiled machines, with each member knowing exactly what she is responsible for and how her contributions fit into the larger picture of the group's productivity.

Team-Building Strategies: When recruiting or selecting team members, pay close attention to the personality types and skill sets of candidates. Try to build teams where each member's personal weaknesses are covered by the strengths of other team members. Try to bring people together with similar personality types, as well, to increase the chances of team members seeing eye to eye. Team-building exercises designed to strengthen team relationships can take on a variety of forms. The best team-building exercises get employees away from their work areas and out of their personal comfort zones, placing them in situations where they have to trust each other while having fun. Rock-climbing and walking in a charity marathon are examples of effective team-building exercises.

Performance Measurement: Measuring the effectiveness of teams, and monitoring the outcomes of team-building exercises, can help you refine your strategies over time, building high-performance teams in the process. Every team-building initiative should include its own monitoring mechanism. Compare the output levels of teams before and after you send them on a team retreat, for example, to gauge the

tangible impact of the exercise. Use the data as well as direct input from your team to fine-tune future team-building exercises.

***Lecture: 19***
***Topic: Teacher – Student Relationship***
Presented by: Dr Pushpalatha, Professor& Head
Dept. of Community Medicine
JSS Medical College, Mysuru

Successful teachers are those that have the ability to maximize the learning potential of all students in their class. Developing positive relationships between a teacher and student is a fundamental aspect of quality teaching and student learning. Positive teacher-student relationships promote a sense of institution belonging and encourage students to participate cooperatively. Students develop confidence to experiment and succeed in an environment where they are not restricted by the fear of failure. Teachers are able to assist students with motivation and goal setting, and students can turn to them for advice and guidance. As a teacher, it's important to understand how to develop positive teacher-student relationships so to know what to look for at your student. She narrated about various techniques to be used to enhance the teacher – student relationship.

Seven Signs of Positive Teacher-Student Relationships: There are many different ways teachers can build positive relationships with their students. Take some time to reflect on these while you are reading and consider if they are being applied at your son's school.

1. They provide structure
The majority of students respond positively to a structured environment. Teachers should explain clear expectations to their students. Rules and regulations must be sensible and constantly reinforced. In these situations, a student's trust in their teacher will increase and they will understand that their teacher has their best interests at heart.

2. They teach with enthusiasm and passion

3. They display a positive attitude

4. They make learning fun
The creation of an enjoyable learning environment encourages student attendance and participation.

5. They show an interest in your student's lives outside the classroom
Teachers should take a genuine interest in the wellbeing of their students.

6. They treat students with respect.
A teacher who respects their students will experience reciprocal respect from their students.

7. They create a secure and safe environment for students.

Teachers need to set expectations where students do not criticize, bully or intimidate each other.

Developing positive teacher-student relationships takes significant time and effort; however, the benefit on both the teacher and student is immeasurable.

***Lecture: 20***
***Topic: Conflict Management***

Presented by: Dr Pushpalatha, Professor& Head
Dept. of Community Medicine
JSS Medical College, Mysuru

A conflict is a situation when the interests, needs, goals or values of involved parties interfere with one another. In the workplace, conflicts are common and inevitable. Different stakeholders may have different priorities; conflicts may involve team members, departments, projects, organization and client, boss and subordinate, organization needs vs. personal needs. Often, a conflict is a result of perception. Is conflict a bad thing? Not necessarily. Often, a conflict presents opportunities for improvement. Therefore, it is important to understand (and apply) various conflict resolution techniques.

**Forcing**
Also known as competing. An individual firmly pursues his or her own concerns despite resistance from the other person. This may involve pushing one viewpoint at the expense of another or maintaining firm resistance to another person's actions.

*Examples of when forcing may be appropriate:*

- In certain situations when all other, less forceful methods, don't work or are ineffective
- When you need to stand up for your own rights, resist aggression or pressure
- When a quick resolution is required and using force is justified (e.g. in a life-threatening situation, to stop aggression)
- As a last resort to resolve a long-standing conflict

Possible advantages of forcing:

- May provide a quick resolution to a conflict
- Increases self-esteem and draws respect when firm resistance or actions were the response to aggression or hostility

Some caveats of forcing:

- May negatively affect your relationship with the opponent in the long run
- May cause the opponent to react in the same way, even if the opponent did not intend to be forceful originally
- Cannot take advantage of the strong sides of the other side's position
- Taking this approach may require a lot of energy and be exhausting to some individuals

**Win-Win (Collaborating)**
Also known as confronting the problem or problem solving. Collaboration involves an attempt to work with the other person to find a win-win solution to the problem at hand - the one that most satisfies the concerns of both parties. The win-win approach sees conflict resolution as an opportunity to come to a

mutually beneficial result. It includes identifying your opponent's underlying concerns and finding an alternative which meets each party's concerns.

Examples of when collaborating may be appropriate:

- When consensus and commitment of other parties is important
- In a collaborative environment
- When addressing the interests of multiple stakeholders is required
- When a high level of trust is present
- When a long-term relationship is important
- When you need to work through hard feelings, animosity, etc.
- When you don't want to take full responsibility

Possible advantages of collaborating:

- Leads to solving the actual problem
- Leads to a win-win outcome
- Reinforces mutual trust and respect
- Builds a foundation for effective collaboration in the future
- Shared responsibility of the outcome
- You earn a reputation as a good negotiator
- For those involved, the outcome of the conflict resolution is less stressful (however, the process of finding and establishing a win-win solution may be very involved – see the caveats below)

Some caveats of collaborating:

- Requires a commitment from all parties to look for a mutually acceptable solution
- May require more effort and more time than some other methods. A win-win solution may not be evident
- For the same reason, collaborating may not be practical when timing is crucial and a quick solution or fast response is required
- Once one or more parties lose their trust in an opponent, the relationship falls back to other methods of conflict resolution. Therefore, all involved parties must continue collaborative efforts to maintain a collaborative relationship

**Compromising**

Also known as reconciling. Compromising looks for an expedient and mutually acceptable solution which partially satisfies both parties.

Examples of when compromise may be appropriate:

- When the goals are moderately important and not worth the use of more assertive or more involved approaches, such as forcing or collaborating
- To reach temporary settlement on complex issues
- To reach expedient solutions on important issues
- As a first step when the involved parties do not know each other well or haven't yet developed a high level of mutual trust
- When collaborating or forcing do not work

Possible advantages of compromise:

- Faster issue resolution. Compromising may be more practical when time is a factor

- Can provide a temporary solution while still looking for a win-win solution
- Lowers the levels of tension and stress resulting from the conflict

Some caveats of using compromise:

- May result in a situation where both parties are not satisfied with the outcome (a lose-lose situation)
- Does not contribute to building trust in the long run
- May require close monitoring and control to ensure the agreements are met

**Withdrawing**

Also known as avoiding. This is when a person neither pursues their own concerns nor those of their opponent. He or she does not address the conflict but sidesteps, postpones or simply withdraws.

Examples of when withdrawing may be appropriate:

- When the issue is trivial and not worth the effort
- When more important issues are pressing, and you don't have time to deal with it
- In situations where postponing the response is beneficial to you, for example -
- When it is not the right time or place to confront the issue
- When you need time to think and collect information before you act (e.g. if you are unprepared or taken by surprise)
- When you see no chance of getting your concerns met or you would have to put forth unreasonable effort
- When you would have to deal with hostility
- When you are unable to handle the conflict (e.g. if you are too emotionally involved or others can handle it better)

Possible advantages of withdrawing:

- When the opponent is forcing or attempts aggression, you may choose to withdraw and postpone your response until you are in a more favorable circumstance for you to push back
- Withdrawing is a low stress approach when the conflict is short
- Gives the ability/time to focus on more important or more urgent issues instead
- Gives you time to better prepare and collect information before you act

Some caveats of withdrawing:

- May lead to weakening or losing your position; not acting may be interpreted as an agreement. Using withdrawing strategies without negatively affecting your own position requires certain skill and experience
- When multiple parties are involved, withdrawing may negatively affect your relationship with a party that expects your action

**Smoothing**

Also known as accommodating. Smoothing is accommodating the concerns of other people first, rather than prioritizing one’s own concerns.

Examples of when smoothing may be appropriate:

- When it is important to provide a temporary relief from conflict or buy time until you are in a better position to respond or push back

- When the issue is not as important to you as it is to the other person
- When you accept that you are wrong
- When you have no choice or when continued conflict would be detrimental

Possible advantages of smoothing:

- In some cases smoothing will help to protect more important interests while giving up on some less important ones
- Gives an opportunity to reassess the situation from a different angle
- As a rule, does not require much effort

Some caveats of smoothing:

- The risk of being abused is real, i.e. the opponent may try to constantly take advantage of your tendency toward smoothing/accommodating. Therefore, it is important to maintain the right balance and this requires some skill
- May negatively affect your confidence in your ability to respond to an aggressive opponent
- Makes it more difficult to transition to a win-win solution in the future
- Some of your supporters may not like your smoothing response and be turned off

**Day: 10 (13th March 2019) [Wednesday]**

***Teaching Methodology***

***Lecture: 21***

***Topic: Principles of Evaluation, Question paper setting including MCQ's***

Presented by: Dr Madhusudhan Purohit
Deputy Controller of Examinations
JSS Academy of Higher Education & Research, Mysuru

Guidelines for paper setters and line-wise evaluation criteria should be provided to evaluators with centralized paper checking with one question or part of it per evaluator. The question paper setter and evaluator should fulfill their assignment with great honesty, dedication, integrity and seriousness. Before setting a question paper, every paper setter should put himself or herself in the shoes of the examinee and then frame the type, level and duration of the questions.

***Lecture: 22***

***Topic: Pharmacy Practice Research – Designing and Execution of Research Projects***

Presented by: Ms. RS Savitha, Asst. Professor
Dept. of Pharmacy Practice
JSS College of Pharmacy, Mysuru


Pharmacy practice research is a type of health services research that focuses on pharmacist care and its effect on patient outcomes. Although pharmacy practice research also deals with broader issues related to training for, as well as preparation and implementation of,

pharmacist interventions, the focus of this presentation is on the design of trials of pharmacist care (i.e., "interventions").

THE RESEARCH QUESTION: As with other forms of research, a good research project starts with a well-articulated research question.

A good research question should specify the patient population, the intervention (and control, if applicable), and the outcome of interest. The question can be restated in the form of the study objective, for example, "The objective of this study is to determine the effect of pharmacist prescribing, relative to usual physician care, on the proportion of patients with stroke reaching their blood pressure target." The acronym PICO is often used in crafting the research question, where PICO refers to Population, Intervention, Control, and Outcome. Some researchers also like to mention the research design in the research question.

If you do not start with a clear research question, it is unlikely that your proposed study will receive funding or generate interpretable results. In the case of a grant submission, a reviewer who does not understand what you are proposing to study cannot make judgments about the methods you propose and will usually conclude that your methods are unsound. In a situation where you are designing (or helping to design) a study, all of your decisions about methods (as described below) depend upon your research question. As such, an unclear research question will lead to unclear methods.

STUDY DESIGN: The choice of study design is a fundamental first step.

Many pharmacy practice researchers use a "before–after" design, comparing patients' data at enrolment (baseline) with data collected at the end of follow-up. Although a before–after study is simple to conduct, this design suffers from low causal inference, since the researcher cannot say with any degree of certainty that it is the intervention that led to any observed change in outcome. There are always other external factors that might have caused the change.

Randomized designs have the highest level of causal inference. In a patient-level randomized controlled trial, patients are randomly assigned (usually by means of a computer-generated sequence) to one or more treatments (interventions) or control. Each group is followed for a specified period of time, and the outcomes are compared between groups. However, in practice research, it may not be ideal for the same pharmacists to provide care to both the intervention and usual-care groups. That is because doing so can lead to "contamination" (whereby control patients receive some or all of the intervention), which can in turn reduce the difference between the intervention and control groups, leading to a false conclusion that the intervention is ineffective compared with control.

An alternative to randomization by patient is to adopt a clustered design. Cluster randomized trials also have a high level of causal inference. In cluster randomized trials, the unit of randomization is not the patient, but rather an organizational unit (e.g., a pharmacy, a city, or a region). For example, Pharmacy A (and all of its pharmacists) is assigned to provide the intervention to its patients, while Pharmacy B is assigned to provide usual care to its patients. Both pharmacies follow their respective patients, and the researchers compare the outcomes between intervention pharmacies and control (usual-care) pharmacies. This design can mitigate some of the concerns over contamination, since all of Pharmacy A's patients receive the intervention and all of Pharmacy B's patients receive the control. The disadvantages of this design are that it is not as statistically efficient, and larger numbers of patients must be recruited.

Another disadvantage is that pharmacists working for a pharmacy assigned to provide usual care to all of its patients may lose interest and not recruit any patients. If this occurs, then the research design becomes invalid, as there is effectively no control group.

When considering a randomized trial design, ask participating pharmacists if they are willing to provide usual care. You should also ask what constitutes their usual level of care (i.e., what they already do for their patients). For example, if you are planning a diabetes intervention, random assignment of patients to the intervention or usual care might be problematic if one of the pharmacists is a certified diabetes educator and already intervenes in the care of all patients with diabetes. If you discover that certain pharmacists are not willing to provide usual care (as you define it), then it may be best to not have them participate.

POPULATION: The inclusion criteria for the study define the patients who will be recruited. Make these criteria as specific as necessary to ensure you get participants who have the condition of interest and will be responsive to the planned intervention (e.g., "patients with diabetes whose A1C is above the target of 7.0%").

The exclusion criteria define those who will not be studied, because they do not have the condition of interest, are unlikely to respond to the intervention, or are unlikely to provide good data (e.g., cannot communicate in English or French if a survey is involved or unable to participate in follow-up, as may be the case for people with severe alcoholism or psychiatric disorders, those who are homeless, or those who live far away).

Structuring the inclusion criteria too narrowly (i.e., with a lot of restrictions) will limit study generalizability (applicability) to a wider population and will also make it difficult to recruit sufficient numbers of patients. Specifying the inclusion criteria too broadly may lead to inclusion of some patients who do not have the condition of interest or will not be responsive to the intervention.

RECRUITMENT: You must specify how you will recruit patients into your study, a step that is often taken for granted. A well-designed research study includes a recruitment plan that details where and how participants will be recruited.

Pharmacy practice research is particularly susceptible to recruitment problems because pharmacist investigators are busy and do not have the time and/or expertise in conducting research. Pharmacy practice research depends upon pharmacists being able to identify patients who meet the inclusion criteria. It is important that this be done exactly as outlined by the inclusion and exclusion criteria, without any subjective judgment about whether people are likely to benefit or not, as such judgment would introduce bias.

The recruitment plan could be as simple as "Pharmacists will generate a list of all patients receiving metformin (as a marker for type 2 diabetes) from their computer system and will systematically approach all of these patients to invite them to participate in the study." Multiple methods (or sources of participants) may sometimes be needed to reach recruitment targets, but the inclusion and exclusion criteria must be applied consistently.

INTERVENTION GROUP: You will need to describe the intervention being studied in enough detail to allow a pharmacist to apply it to his or her patient. This means specifying all components of the intervention,

such as patient education, additions to or modifications of therapy, interactions with other health care professionals, measurements to be made, and timing and frequency of follow-up visits.

As with a drug intervention, an intervention in practice research should be "strong enough" to affect the condition of interest. Ideally, you will have some preliminary data to suggest that your intervention may be effective.

CONTROL GROUP: In many pharmacy practice trials, the control group is "usual care", i.e., the care that patients would receive had there been no study underway. Of course, you cannot "forbid" any care that a patient would otherwise receive, either from a pharmacist or from a physician or other health care provider, but it is useful to know what the standard of care is among practitioners participating in the study.

In pharmacy practice research, many pharmacists who self-identify as being interested in research participation do so because they are interested in the topic under study. In fact, their usual care may include many components of your intervention. If so, it is important to know this before proceeding.

FOLLOW-UP: You must specify when the follow-up visits will occur, because this also determines when the study outcomes will be measured. You must also decide whether the schedule of follow-up visits will be the same for intervention and control patients. It needn't be, but at the very least, all patients should have a final follow-up visit to ascertain outcomes.

As described below under "Bias and Confounding", losses to follow-up are a major threat to validity and, in my experience, seem to be worse in pharmacy practice research (perhaps because patients feel less inclined to follow through with a pharmacist than with a physician, or because pharmacists may be less diligent in ensuring follow-up with their patients). Your plan to minimize losses to follow-up2 should include procedures to keep study participants and investigators interested and engaged with the study and ways to keep study-related visits (and time) to a minimum. Even if a study participant does withdraw consent, it may be possible to ask for a final follow-up visit to ascertain study outcomes.

OUTCOME MEASURES: Many decisions in the design of a research study relate to the outcome measure (or measures) chosen. Such decisions will affect the study budget, study procedures, and the impact of the trial on clinical practice. It is therefore strongly recommended to choose an outcome that is important in some respect. This could be a clinical outcome (such as mortality, readmission, or relapse) or a validated surrogate outcome (such as blood pressure). Generally, a single outcome should be defined as the primary outcome. The primary outcome is usually the outcome thought to be most responsive to the intervention and the most important. By definition, sample size is calculated on the basis of the primary outcome. Other (secondary) outcomes can also be defined, to provide additional information on the value of the intervention.
As a general rule, outcome measures that are continuous (measures on a known scale, such as weight, blood pressure, or forced expiratory volume in the first second) are more powerful1 and provide more information than dichotomous (yes/no) outcomes. Sometimes, however, a dichotomous outcome, such as readmission to hospital within 30 days (reported as the proportion of patients readmitted), is the most relevant outcome.

For each outcome, indicate how and when it will be measured, and, if necessary, cite relevant literature to show that it is an accepted and valid measure.

The outcome measures chosen for pharmacy practice research are often process-oriented, such as number of drug-related problems identified by the pharmacist. Although these variables do provide some information on the effect of an intervention, they are not well-validated outcome measures, in that they have typically not been shown to correlate with patient outcomes.

SAMPLE SIZE AND ANALYTICAL PLAN: It is beyond the scope of this article to discuss methods of estimating sample size, but suffice it to say here that you must calculate the required sample size.2 Sample size drives the costs of and resources needed for the study; without it, the study will likely be underpowered (i.e., a study that cannot possibly answer your research question, which is both unethical and foolhardy).

As noted above, the sample size is calculated on the basis of the primary outcome. In the sample size calculation, you must justify all of the assumptions made to arrive at that figure, for example, "We assumed a rate of hospital admission in the control group of 20% over 6 months (based upon the work of Smith and others) and a reduction in hospital admission for heart failure with enhanced pharmacist care of 30% (based upon the systematic review of Jones and others).

The analytical plan is an essential part of the study protocol and cannot be developed "after the fact", so you will need to talk with a biostatistician to establish the analytical plan before you begin. Many investigators omit this step because they themselves are uncomfortable with biostatistics, but this is ill advised. Get some help by speaking to a more experienced researcher or a biostatistician. You will not be able to compensate for a missing or inadequate analytical plan once data collection is complete.

BIAS AND CONFOUNDING: Bias and confounding are factors that can affect study outcomes (sometimes even as much as the intervention) and that may "interfere" with assessment of the intervention. It is beyond the scope of this article to address all of the issues related to bias and confounding, but a few are worth mentioning.

Most pharmacy practice research cannot be blinded. Without blinding, patients and providers know the study group to which they have been assigned and can take extra steps. For example, patients assigned to "usual care" in a randomized dyslipidemia study might take some extra steps to see their physician and ask about cholesterol, and participants in the control group may thus receive an intervention that they might not otherwise have received. Some ways to mitigate this problem would be to provide a "sham" (weaker) intervention to the control group (e.g., a pamphlet on heart disease) or to delay delivering the intervention; in the latter situation, the control group eventually receives the intervention, after the comparative period of the trial has been completed. This is known as a waiting group control.

Ideally, outcome information will be collected by an investigator who is blinded to (unaware of) the treatment allocation. For example, a clerk who is not aware of treatment allocation could administer quality-of-life surveys to participants. However, it is sometimes impractical to implement blinded data collection.

Loss to follow-up is a potentially serious source of bias. Losses to follow-up can be minimized by keeping participants engaged with the research and the investigator. Losses to follow-up are especially damaging to a study if more patients are lost from one treatment arm than the other. In practice research done in the community, it is not unusual to lose 15% of patients to follow-up. Large losses to follow-up are a threat to validity, as the patients lost to follow-up are probably different from those who stayed in the trial. Guidance is that at least 80% of patients should have follow-up for a trial to be considered of good quality.

CONCLUSIONS: Pharmacy practice research is vital to the future of the pharmacy profession. Having good evidence is paramount as we strive to improve patient outcomes, expand scopes of practice, and justify new remuneration models.

The foregoing are a few simple guidelines for conducting a randomized controlled trial of a pharmacy intervention. The wise researcher, novice or otherwise, will not be intimidated by these guidelines but rather will consider, apply, and learn from them. If you do decide to undertake a pharmacy practice research study, don't work alone. Get some assistance from an experienced researcher. Most would be happy to help.

***Lecture: 23***

***Topic: SPSS – Hands on Experience***

Presented by: Mr HN Vishwas, Lecturer, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

**SPSS-**Statistical Package for the Social Sciences. It is a software initially developed by SPSS Inc., Earliest version was first released in 1968. SPSS software was acquired by IBM in 2009. Currently used version is Version 25.0 released in 2017. Price of Indian version starting at Rs.6, 370.16 per user per month. SPSS is compatible with the following operating systems-Windows, MacOS, Linux on z Systems, Linux, UNIX.

**How to insert Data in SPSS**

One can directly insert data into SPSS or can insert data from other file formats. SPSS can open all file formats that are commonly used for structured data such as

- Spreadsheets from MS Excel/OpenOffice
- Plain text files/Comma separated (.txt or .csv)
- Relational (SQL) database
- Stata and SAS

The following Statistical tests are possible with SPSS:

- **Descriptive statistics:** Cross tabulation, Frequencies, Descriptives, Explore, Descriptive Ratio statistics
- **Bi-variate Statistics:** Means, t-test, ANOVA, Correlation (bi-variate, partial, distances), Non-parametric tests, Bayesian
- **Prediction for numerical outcomes:** Linear regression
- **Prediction for identifying groups:** Factor analysis, cluster analysis (two-step, K means, hierarchical), Discriminant
- **Geo spatial analysis, simulation**
- **R extension (GUI), Python**

**Importance of Statistics:**

- **Research:** Very important aspect for Scientists.
- Numbers are important in experimentation results (Ex: Medical Sciences/Pharm. sciences)
- Experimental data are vital in generating theories.
- Statistic analysis helps to prove/disprove the theories.
- Statistical tests have become integral part of our Research.

**Variables in SPSS:** SPSS can read and understand only numbers. It will not read and understand alphabets. Major variable in SPSS are: Scale Variable, Nominal Variable, Ordinal Variable.

**Scale Variable:**
In simple terms, Scale variables are Numeric data on an interval or ratio or scale. A variable can be treated as scale when its values represent ordered categories with a meaningful metric.
Ex: Age in years, Weight of a patient, Income in thousands of Rupees, Score of a student in exam

**Ordinal Variable:**
A variable can be treated as ordinal when its values represent categories with some intrinsic ranking.
Ex: Grade-I Employee, Grade-II Employee, Grade-III Employee
First rank, Second rank, Third rank
1=Highly satisfied, 2=satisfied, 3= neutral, 4= dissatisfied, 5= highly dissatisfied

**Nominal Variable:**
A variable can be treated as nominal when its values represent categories with no intrinsic ranking.
Ex: Male/Female, Athletic/Non-athletic
Smoker/Non-smoker
Blood group typing (A/B/O/AB)
Healthy person/Disease patient

**Before Executing any Statistical Test in SPSS:**

- Assign the variables properly. Certain tests are not suitable for all the variables.
  - Ex: Nominal variable should not be assigned as Scale variable
  - Ordinal variable should not be assigned as nominal variable
- During the execution of test, just because you hit the right buttons or combinations of commands, don't believe the Output. (Cross verify once with a Book/Paper)
- SPSS is <u>just a Software</u>, it can do <u>Calculation job</u> for you. It will just give the output. You are going to decide whether test was properly done or not.
- Many Standard journals ask for the data sets before publishing your Research findings. This is kept as open source for any other Scientists for verifying and re-checking your findings. Ex: PLOS ONE (Impact: 3).

**'*p*' Value**

- Probability Value.
- When you perform a hypothesis test in statistics, a p-value helps you determine the significance of your results.
- The p-value is a number between 0 and 1 and interpreted in the following way:
  - A small *p*-value(typically ≤ 0.05) indicates strong evidence against the null hypothesis, so you reject the null hypothesis.
- The **significance** level for a given hypothesis test is a value for which a **P**-value less than or equal to is considered **statistically significant**.
- Typical values for are 0.1, 0.05, and **0.01**.
- These values correspond to the probability of observing such an extreme value by chance
- Hence in **Observational studies**, p value of <0.05 is considered to be Statistically significant.
- In **Experimental studies** (Ex: Pharmacology/ Clinical Research), a p value of <0.01 is considered to be Statistically significant.

**What is magical about 5%? (0.05)**
*p*- value of 0.05 is considered as a 'Practical Benchmark' and standard over many years.
The value has proven to be consistent in various Research disciplines. (Ex: Social Research, Psychological Research, Marketing Research, Observational Studies, etc.,)

**Conclusion:** Careful organization of variables, proper coding and insertion of data can yield result in SPSS. One has to pay attention when executing tests in SPSS, not just click some buttons and note *p-values.*

***Lecture: 24***
***Topic: Modular Teaching (Block Teaching)***
Presented by: Ms. BS Roopa, Lecturer, Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

The block teaching is under taken as a method of delivery of curriculum for V Pharm D students. Block teaching is a style of teaching where the lectures are taught in an intensive block, sometimes as short as 1 to 2 weeks and student learning is compressed, typically with students studying only one course at a time. Test and preferred pedagogies and appropriate to the student profile, with the teaching forming an integrated element of a wider learning strategy enabling students to complete the required learning for a course.

The steps followed to undertake block teaching:

1. Calculate the number of required hours for subject
2. Finalize dates for the subjects
3. Delivery of curriculum of the subject
4. For each subject in the block- Activities are conducted
5. End of the block the sessional examination will be conducted
6. Marks is awarded.

The following advantages of the block teaching was discussed:

• Offers structured learning and activities after the teaching block where students can test their understanding.
• The block teaching sessions will include problem-based learning sessions where students have an opportunity to reflect on their learning.
• Minimum presence on VISION.
• Skills development
• Provision of learning support during the assessment period
• Informative feedback during the course

The following limitations of block teaching was discussed:
• It is almost impossible for a single lecturer to deliver the quality of teaching expected for such a sustained period.
• Both staff and students get tired, and there is little learning by the students at the end of a full day.
• Students who are not able to attend the University for short periods can miss disproportionately large amounts of contact time.

• There is usually no opportunity for students to be given feedback on their learning during the teaching period.

**Day: 11 (14th March 2019) [Thursday]**

***Lecture: 25***

***Topic: Demonstration – Pharm D Info, E-learn and Simulation Lab Practice***

Presented by: Dr GK Sadagoban, Lecturer, Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty

PharmD Info – E Learn

PharmD Info is the Portal, serving as an online forum dedicated for the pharmacy professionals with inbuilt features of an ideal web discussion portal. The goal of this Portal is to create a good communication platform in the web for the pharmacists to make networks within the profession and also with other healthcare professionals and enhance their knowledge, skills and professional relationships. Through this forum, registered members shall form special interest groups and sub-groups on various forum titles (mentioned later in this document) with a designated moderators. The developments of information technology have positively influenced every field and so the education. We, The Faculty of Pharmacy at JSS Ooty realize the evolution of NE(X) T GENERATION LEARNERS and thus committed to exercise ICT enabled teaching-learning methods. Such novel pedagogies will certainly enable the graduates to gain advanced knowledge, skills, motivating them for life-long learning and shape them as a responsible and successful professional in the global society.

Simulation Based Training (SBT)

Simulation Based Training offers an avenue to assess clinical judgment and critical thinking without threatening patient safety. Educators can apply well founded simulation approaches to help student in clinical rotations to attain education goals. On this context, Colleges of Pharmacy has introduced simulation practice settings for IPPE Pharm.D students to practice and understand the core concepts of clinical pharmacy activities and its importance. Simulation activities conducted for IPPE Pharm.D students as a part of their introductory pharmacy practice experience to improve their specific skills and competencies. Medical dispensing Unit, Admixture Lab and Patient Counselling model simulation laboratories are designed and that are equipped with necessary items to give students hands-on clinical experience. At present simulation activities like BP monitoring, Blood Glucose monitoring, Patient Counselling, Medication History Interview, Treatment Chart Review, Drug Dispensing, IV Admixtures, and Medication Reconciliation are conducted in our department.

Feedback session:

After all the presentation, feedback session was organized and the feedback was obtained from all the participants and the same has been analyzed (results are attached herewith).

Dr S Ponnusankar, Organizing Secretary summed up the program and proposed vote of thanks.

DR S Ponnusankar
Professor & Head
Dept. of Pharmacy Practice and
Program Coordinator – QIP 2019

**All India Council for Technical Education (AICTE), New Delhi Sponsored**

**Quality Improvement Program (QIP)**
**On**
**Pharm D Education: Training for the Academic Practitioners**

1st – 14th March 2019
Venue: Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty

# PROGRAM FEEDBACK
# &
# PRE AND POST-TEST ANALYSIS

**All INDIA COUNCIL FOR TECHNICAL EDUCATION, NEW DELHI**
**SPONSORED**
**QUALITY IMPROVEMEN PROGRAM ON**
**PHARM D EDUCATION: TRAINING FOR THE ACADEMIC PRACTITIONERS**
**01 – 14TH MARCH 2019**

# Program Feedback Form

Your feedback is critical for program to ensure we are meeting your educational needs. We would appreciate if you could take a few minutes to share your opinions with us, so we can serve you better.

**Please return this form to the organizer at the end of the program. Thank you.**

Please indicate how much you agree with the following statements by ticking your response using the scale provided.

| | Average | Good | Excellent |
|---|---|---|---|
| The program purpose and objectives were clearly stated. | | | |
| Was the program well organized | | | |
| Speakers subject knowledge | | | |
| Speakers interaction with audience | | | |
| All program participants were actively involved | | | |
| We used our program time effectively | | | |
| I am satisfied and enjoyed with this program | | | |
| Program food | | | |
| Would you recommend the session to others | | | |
| Over all session rating | | | |

Given the topic, was this program: ❑ a) Too short ❑ b) Right length ❑ c) Too Long

In your opinion, was this program: ❑ a) Introductory ❑ b) Intermediate ❑ c) Advanced

Future topics proposed (if any): 1. _____2. _____3. _____

1. What aspects of this program were particularly good?

2. Do you have any suggestions or additional comments about this program?

# QIP Feedback Analysis Report

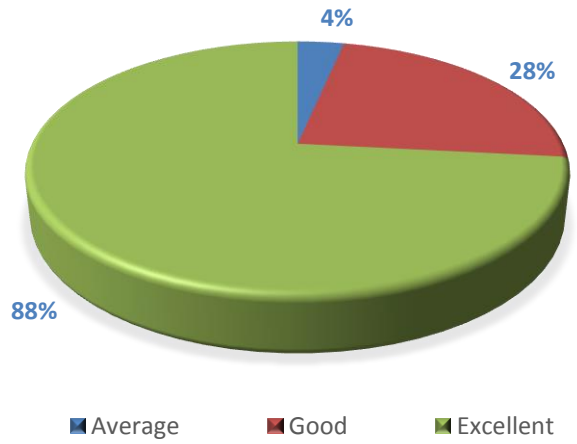
The Quality Improvement Program (QIP) Feedback was collected from thirty delegates individually with the help of a feedback form at the end of the program on their experience attending the workshops which were conducted from 01-14th March, 2019. It focused on:

- purpose and objectives of the program
- organization
- assessment on the speaker's knowledge and interaction with the audience
- active participation of colleagues
- time management
- program food
- remarks on future topics proposed
- other additional suggestions

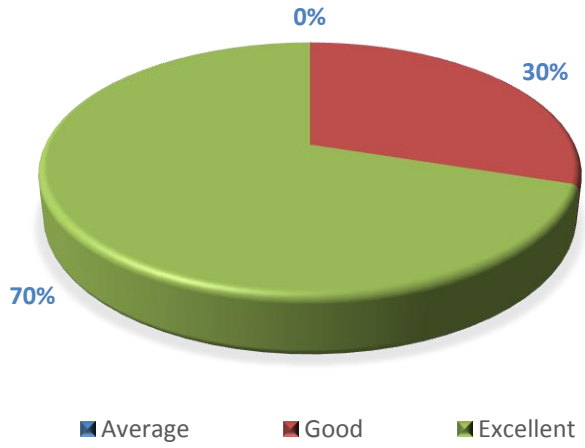
The feedback form gathered information to ensure that the educational needs of the delegates were fulfilled and to understand the changes to be made in the services provided. According to the feedback:

- 73.3% of the delegates understood the purpose and objectives of the program
- 70% stated that the program was well organized
- Majority of the delegates found the speaker's knowledge and their interaction with the audience excellent
- There were mixed opinions regarding the active participation of other delegates with 40% excellent review and 50% average review
- All the delegates stated that they used their program time effectively and is satisfied with the sessions
- Regarding the food provided during the program 50% found it good and 26.6% found it average
- All the delegates stated that they would recommend the session to others and the overall rating of the sessions was 70% excellence
- Majority of the delegates found the program interactive and found the sessions of pharmacokinetics, OSCE, SPSS, ICT, Teaching methodology, Evaluation and assessment of question paper particularly good and informative. The also commented on the hospitality and co-operation by the faculty and students of the college.
- The most common suggestion on topics for future workshops were statistical analysis, OSCE, SPSS and pharmacoeconomics

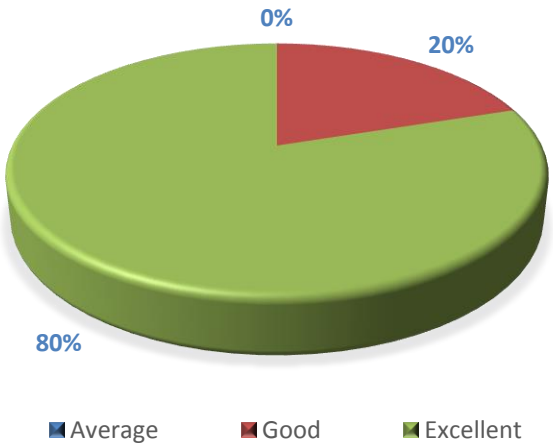
1. The program purpose and objectives were clearly stated



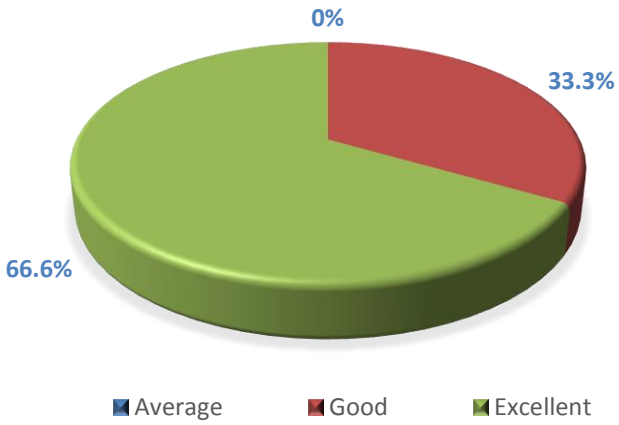

2. Was the program well organized?



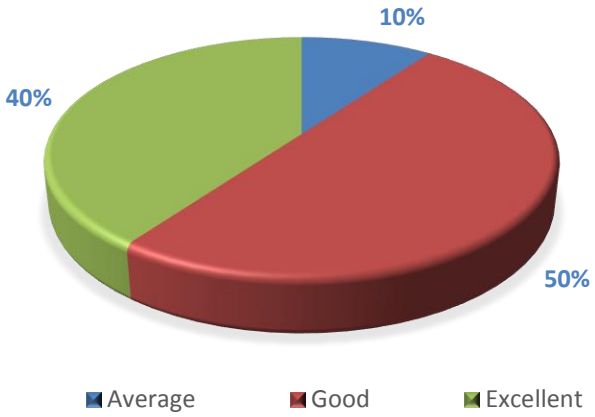

3. The speaker's subject knowledge



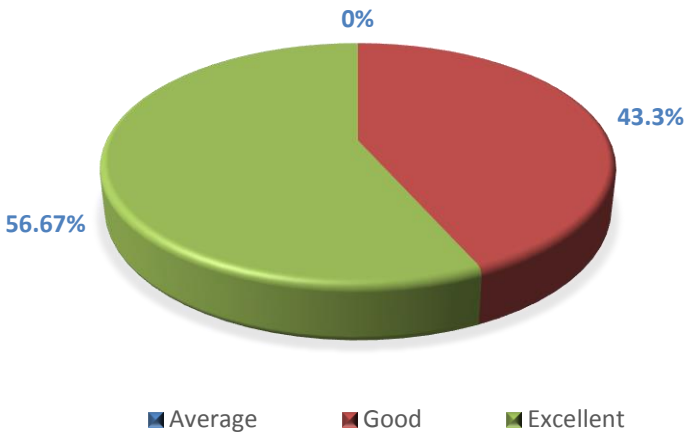
4. The speaker's interaction with audience



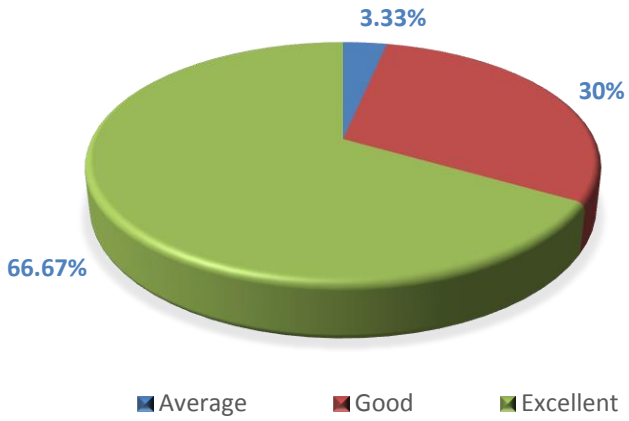

5. All program participants were actively involved



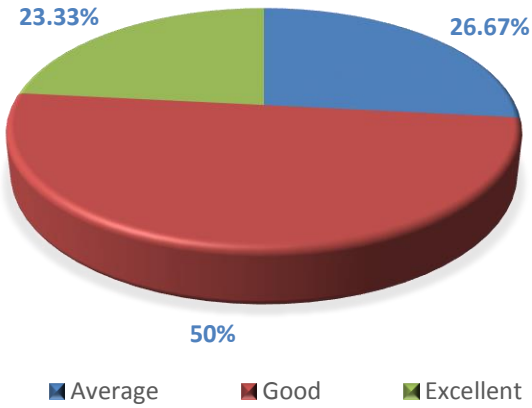

6. Used our program time effectively



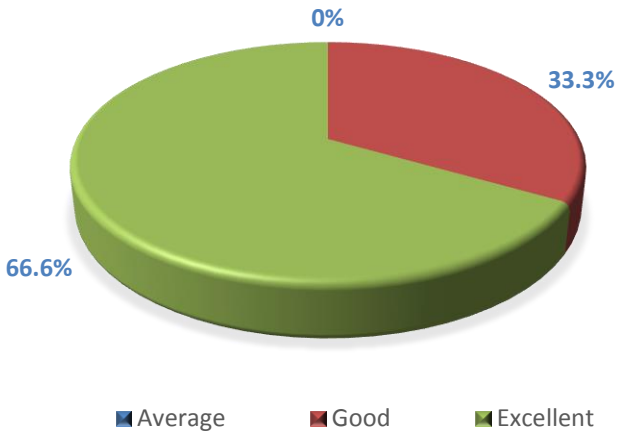
7. Satisfied and enjoyed the program



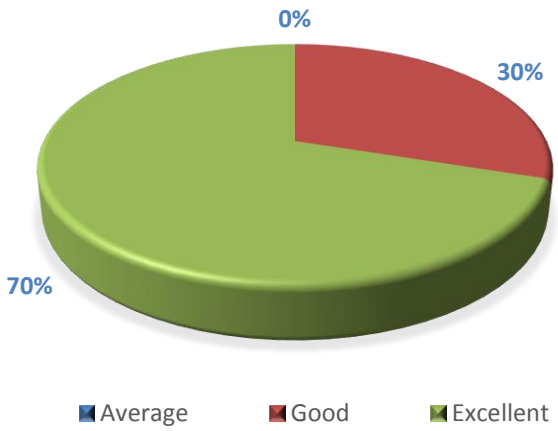

8. Program food



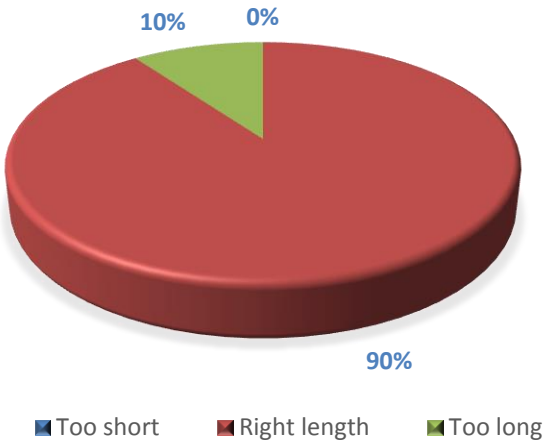

9. Recommend the session to others



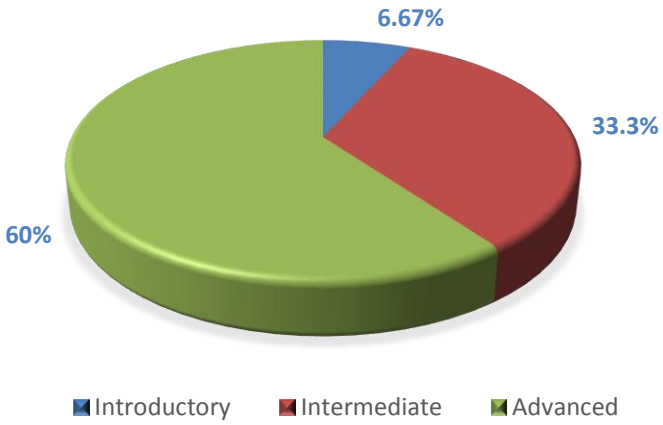
10. Over all session rating




11. Given the topic, was the program




12. Future topics, if proposed (if any)



# JSS Academy of Higher Education & Research, Mysuru

**(Deemed to be University – Accredited 'A+' Grade by NAAC)**

## JSS College of Pharmacy, Ooty

**(An ISO 9001:2015 Certified Institution)**

## Department of Pharmacy Practice


## AICTE Sponsored Quality Improvement Program on Pharm D Education: Training for the Academic Practitioners

## 1st -14th March 2019

**Pre-test & Post-test Questionnaire**

**I. Teaching Methodology:**

1. Evidence based medicine includes which of the following:
a) Best available evidence b) Individual clinical experience
c) Patient values d) All of the above

2. What is the first step in applying EBM concepts to answer a clinical question?
a) Acquire evidence b) Appraise evidence
c) Ask question d) Apply evidence e) Assess whole process

3. What is the best design to study the prevalence of a disease?
a) Cross sectional study b) Case control study
c) Randomized controlled study d) Cohort study

4. What is the best design to study the prognosis of a disease?
a) Cross sectional study b) Case control study
c) Randomized controlled study d) Cohort study

5. What is the best design to study the efficacy of an intervention?
a) Cross sectional study b) Case control study
c) Randomized controlled study d) Cohort study

6. Gen Z students born
a) Before year 1995 b) after year 1995 c) before year 2010 d) after year2010

7. Open source software
a) Cannot be shared b) cannot be modified c) can be modified and shared d) None of the above

8. With the software audacity
a) You can edit video b) You can edit audio
(c) You can edit both audio and video d) You can record audio but cannot edit

9. Light board is a
a) Computer screen b) Teaching tool c) Whiteboard for teaching d) Video recording software

10. With screen capture software you can
a) Record audio only b) Record video only
c) Record both audio and video d) Capture only still image

**II. EXPERIENTIAL LEARNING:**

1. How many cases a student need to document in one rotation?
a) 08 b) 06 c) 10 d) 12

2. How many informal case discussions should be done per rotation?
a) 05 b) 05 c) 04 d) 02

3. How many hours of hospital posting is prescribed per week?
a) 20 b) 15 c) 18 d) 24

4. Whom to report the observed ADR?
a) PvPi b) Nurse c) Patient d) Hospital superintendent

5. Elaborate SOAP:
a) Subjective, observation, analysis, plan b) Source, objective, assessment, pharmacotherapy
c) Subjective, objective, assessment, plan d) Subjective, observation, adhere to plan, pharmaceutical plan

6. Internship posting includes which of the following rotations?
a) 6 months in general medicine & 2 months specialty departments
b) 6 months in general medicine & 3 months specialty departments
c) 6 months in general medicine & 6 months specialty departments
d) 6 months in general medicine & 4 months specialty departments

7. The specific objectives of internship is to
a) Provide patient care b) Promote health improvement
c) Develop leadership qualities d) All of the above

8. The satisfactory completion of internship is assessed by
a) Proficiency of knowledge b) Communication skill
c) Time management d) Evidence based approach

9. OSCE is the standard mode of assessment of
a) Competency b) Clinical skills c) Cognitive knowledge d) All the above

10. Curriculum organization used for different concepts at the same class is?
a) Vertical b) Horizontal c) Logical d) None

**III. CLINICAL PHARMACOKINETICS**

1. Therapeutic Index is a golden rule for assessing the efficacy and safety of the drugs
a) True b) False

2. The Clearance value of a drug is a useful parameter to calculate _____ of a drug
a) Loading dose b) Maintenance dose c) Empirical dose d) Toxic dose

3. Which of the following pharmacokinetic parameter is NOT useful for assessing the bioavailability/bioequivalence of a drug dosage form

a) Half Life b) Area Under the Curve c) Peak concentration d) Peak time

4. The extent of plasma protein binding of the drug will determine the following EXCEPT

a) Absorption b) Distribution c) Elimination d) Therapeutic outcomes

5. For any drug, minimum how many half-lives are required to attain the steady state concentration?

a) 3 b) 5 c) 7 d) 9

**IV. CLINICAL RESEARCH**

1. Which of the following characterizes phase III drug testing?

a) It usually requires small patient numbers
b) It can be done without approval.
c) It usually involves a comparison between different treatments.
d) It always demonstrates superiority of the new approach.

2. For what purpose does the IRB review the informed consent?

a) Protect the Institution
b) Protect the subject
c) Provide the Institution with information about proposed research trials
d) Protect the Sponsor

3. Prior to subject's participation in the trial, the _____should be signed and personally dates by the subject or by the subject's LAR.

a) Protocol b) Clinical Trial Agreement
c) IRB Approval Report d) Written Informed Consent Form

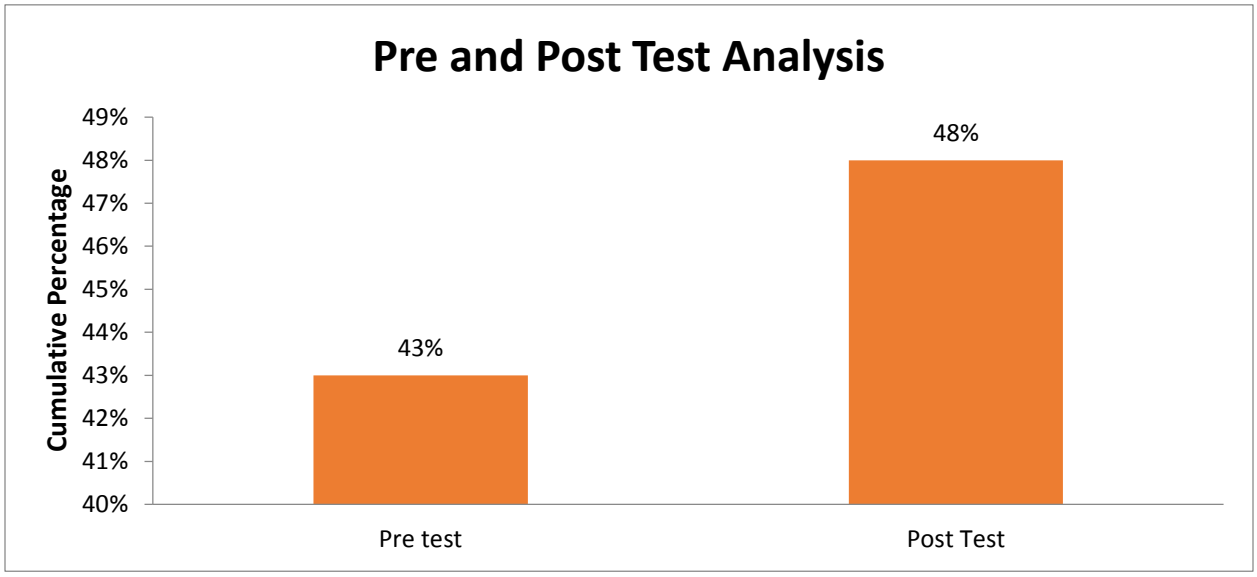
4. Factual data are objectively verifiable.

a) True b) False

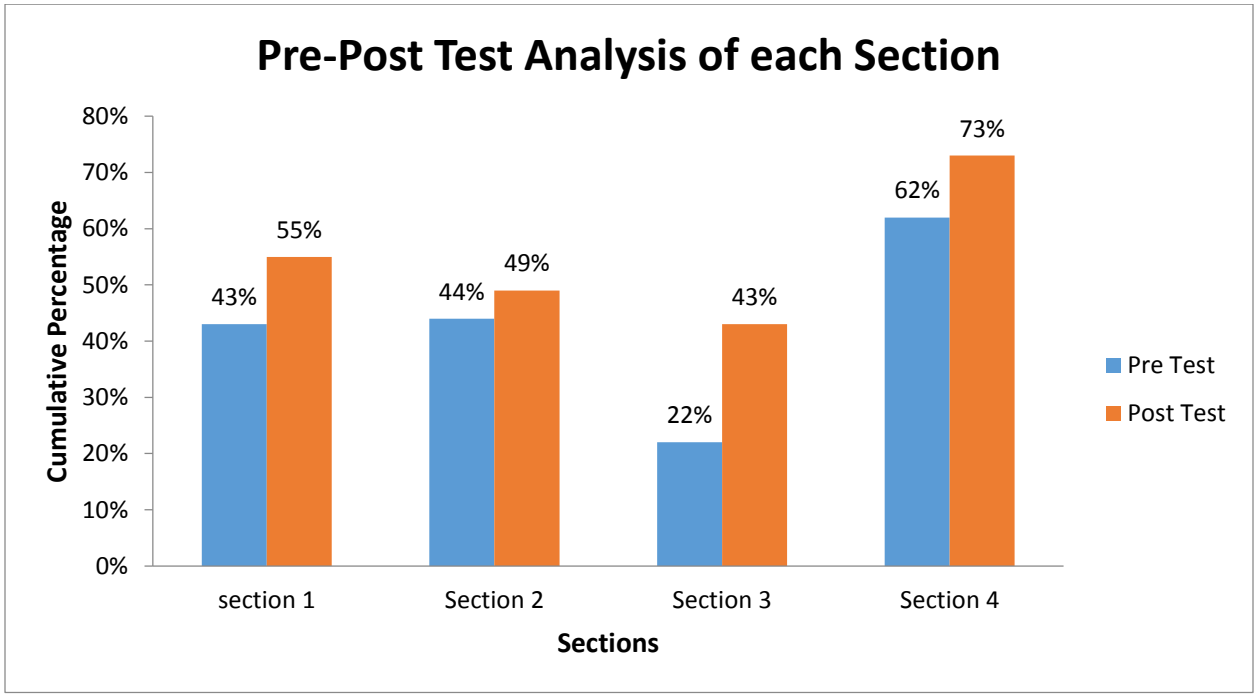
5. An event that prolongs a hospitalization for a patient in a clinical trial is considered a serious adverse event:

a) True b) False

Pre and post-test analysis of the program




Pre and post-test analysis of the program organized (section wise)



Pre and post-test analysis of the each participant