SRI LAKSHMI NARAYANA INSTITUE OF MEDICAL SCIENCES AND HOSPITAL, PUDUCHERRY

Date: 13/01/2019

From
Dr. Somasundaram,
Professor and Head,
Dept. of Pharmacology,
Sri lakshmi narayana institue of medical sciences and hospital, Puducherry

To
The Dean,
Sri lakshmi narayana institue of medical sciences and hospital, Puducherry

Sub: Permission to conduct value-added course: Research methodology in Pharmacoeconomics

Dear Sir,

With reference to the subject mentioned above, the department proposes to conduct a value-added course titled: **Research methodology in Pharmacoeconomics** from Feb 2019 to August 2019. We solicit your kind permission for the same.

Kind Regards

Dr. Somasundaram,

FOR THE USE OF DEANS OFFICE

Names of Committee members for evaluating the course:

The Dean: Dr.Balagurunathan   HOD: Dr.Somasundaram   Expert: Dr.Somasundaram   Dr.Jayasheel

The committee has discussed about the course and is approved.

Dean   Subject Expert   HOD

Sri Lakshmi Narayana Institute of Medical Sciences

OSUDU, AGARAM VILLAGE, VILLIANUR COMMUNE, KUDAPAKKAM POST,
PUDUCHERRY - 605 502.

[Recognised by Medical Council of India, Ministry of Health letter No. U/12012/249/2005-ME (P -II) dt. 11/07/2011]
[Affliated to Bharath University, Chennai - TN]

Circular

17/01/2019

Sub: Organising Value-added Course: Research methodology in Pharmacoeconomics.

With reference to the above mentioned subject, it is to bring to your notice that Dept. of Pharmacology from Sri Lakshmi Narayana institue of medical sciences and hospital, Puducherry is organising **"Research methodology in Pharmacoeconomics** The course content is enclosed below."

The application must reach the institution along with all the necessary documents as mentioned. The hard copy of the application should be sent to the institution by registered/ speed post only so as to reach on or before 31/01/2019. Applications received after the mentioned date shall not be entertained under any circumstances.

Dean

Encl: Copy of Course content

Course Title: Research Methodology in Pharmacoeconomics

CourseObjective:
Overview of Pharmacoeconomics
Types of P_E studies
Introduction to the concept of costs
Health economic in economic evaluations
Pharmacoeconomic models for conducting economic analysis
Cost effective analysis
Cost utility analysis
Cost minimization concept
Health technology assessment in India
Decision tree models for conducting cost- effective analysis
Designing a P-E model in excel
Real world evidence in health care
Mankov model in P-E
Mankov model in excel
Protocol discussion – P/E studies

CourseOutcome:
An attempt to identify, measure, and evaluate the end results of health care services. It may include not only clinical and economic consequences, but also outcomes, such as patient health status and satisfaction with their health care.

Course Audience: IInd year MBBS students

Course Coordinator: Dr. Jaikumar

Course Faculties with Qualification and Designation:

1. Dr. Somasundaram, Hod and Professor, Dept. of Pharmacology
2. Dr.J.Jayasheela, Assistant professor, Dept. of Pharmacology

Course Curriculum/Topics with schedule (Min of 30 hours)

SlNo	Date	Topic	Time	Hours	Faculty
1	05/02/19	Overview of Pharmacoeconomics	4-6 pm	2 hrs	**Dr. Somasundaram**
2	12/02/19	Types of P_E studies	4-6 pm	2 hrs	
3	19/02/19	Introduction to the concept of costs	4-6 pm	2 hrs	
4	26/02/19	Health economic in economic evaluations	4-6 pm	2 hrs	
5	23/10/18	Pharmacoeconomic models for conducting economic analysis	4-6 pm	2 hrs	
6	05/03/19	Cost effective analysis	4-6 pm	2 hrs	
7	12/03/19	Cost utility analysis	4-6 pm	2 hrs	**Dr.J.Jayasheela**
8	19/03/19	Cost minimization concept	4-6 pm	2 hrs	
9	26/03/19	Health technology assessment in India	4-6 pm	2 hrs	
10	09/04/19	Decision tree models for conducting cost- effective analysis	4-6 pm	2 hrs	
11	23/04/19	Designing a P-E model in excel	4-6 pm	2 hrs	
12	14/05/19	Real world evidence in health care	4-6 pm	2 hrs	
13	11/06/19	Mankov model in P-E	4-6 pm	2 hrs	
14	16/07/19	Mankov model in excel	4-6 pm	2 hrs	
15	06/08/19	Protocol discussion – P/E studies	4-6 pm	2 hrs	
			Total Hours	30	

REFERENCE BOOKS: i). **A concise book on Pharmacoeconomics**

ii). **Research Methodology in Pharmacoeconomics**

VALUE ADDED COURSE

1. Name of the programme & Code

Research Methodology in Pharmacoeconomics

2. Duration & Period

30 hrs & Feb 2019 – August 2019

3. Information Brochure and Course Content of Value Added Courses

Enclosed as Annexure- 1

4. List of students enrolled

Enclosed as Annexure- 1I

5. Assessment procedures:

Short answers *Enclosed as Annexure- 1II*

6. Certificate model

Enclosed as Annexure- IV

7. No. of times offered during the same year:

& Feb 2019 – August 2019

8. Year of discontinuation: 2019
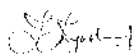
9. Summary report of each program year-wise

Value Added Course- Feb 2019 – August 2019					
Sl. No	Course Code	Course Name	Resource Persons	Target Students	Strength & Year
1	PH08	Research Methodology in Pharmacoeconomics	Dr.G.Somasundaram Dr.Jayasheela	2nd MBBS	20 (Feb 2019 – August 2019)
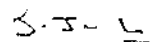
10. Course Feed Back

Enclosed as Annexure- V
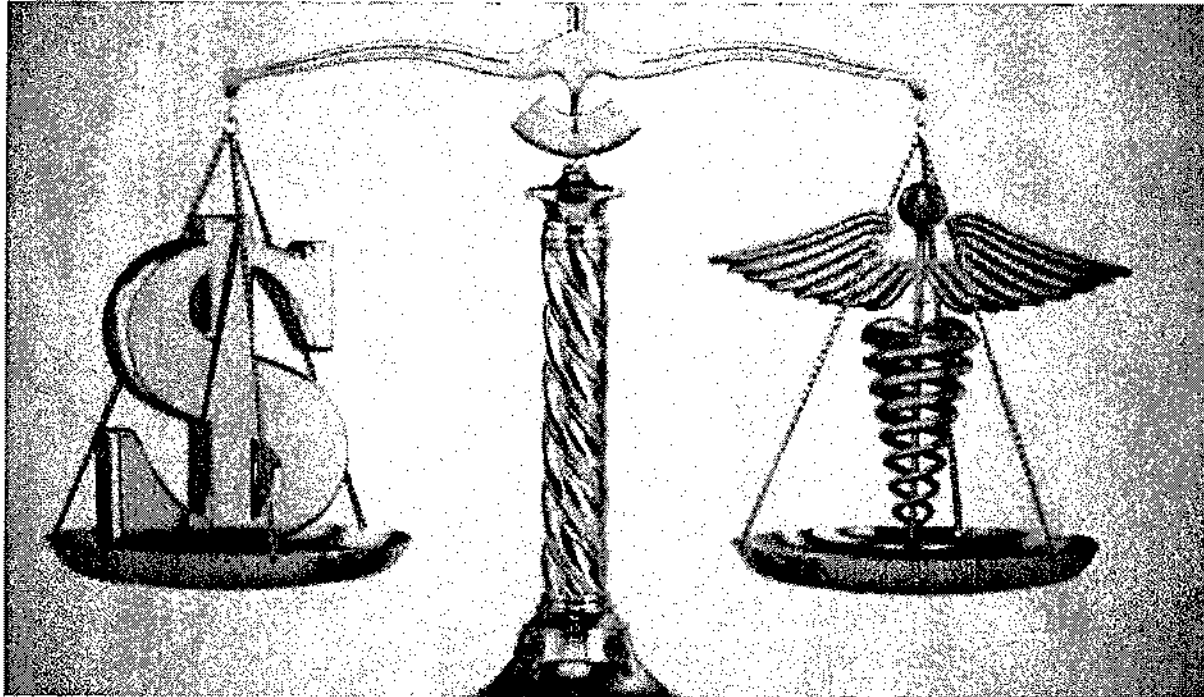
RESOURCE PERSON   **COORDINATOR**

RESEARCH METHODOLOGY IN PHARMACOECONOMICS
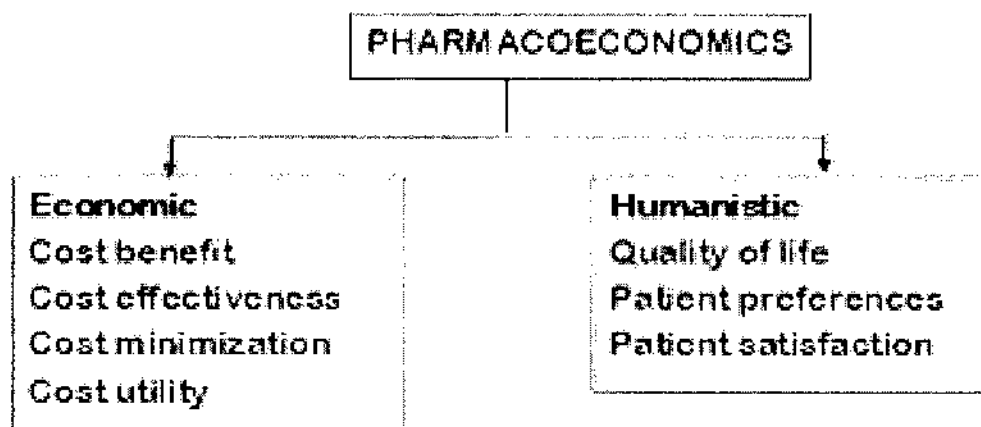
PARTICIPANT HAND BOOK

COURSE DETAILS

BIHER

SLIMS

Particulars	Description
Course Title	Research methodology in Pharmacoeconomics
Course Code	PH08
Objective	Overview of Pharmacoeconomics
	Types of P-E studies
	Introduction to the concept of costs
	Health economic in economic evaluations
	Pharmacoeconomic models for conducting economic analysis
	Cost effective analysis
	Cost utility analysis
	Cost minimization concept
	Health technology assessment in India
	Decision tree models for conducting cost-effective analysis
	Designing a P-E model in excel
	Real world evidence in health care
	Mankov model in P-E Protocol designing in P-E studies
Further learning opportunities	Health economics and outcomes research
Key Competencies	On successful completion of the course the students will have knowledge in the branch of Pharmacoeconomics
Target Student	2nd MBBS Students
Duration	30hrs Feb 2019 – Aug 2019
Theory Session	18hrs
Practical Session	12hrs
Assessment Procedure	Multiple choice questions

Introduction:

Pharmacoeconomics can be defined as the branch of economics that uses cost-benefit, cost-effectiveness, cost minimization, cost-of-illness and cost-utility analyses to compare pharmaceutical products and treatment strategies (Brinsmead 2003). Pharmacoeconomics and health outcomes research are playing an increasingly important role in informing clinical development and market access decisions of new innovative medicines. It mainly works on the health economics which particularly focuses upon the costs and benefits of drug therapy

PHARMACOECONOMICS

Economic
Cost benefit
Cost effectiveness
Cost minimization
Cost utility

Humanistic
Quality of life
Patient preferences
Patient satisfaction

Pharmacoeconomics: Needs and Challenges

Multi-factorial Variability of Drug Pricing

Enumerable factors affect the prices of drug; some of them are as follows:

i. The sector in which medicines are purchased: The price is often higher in the private sector due to distilentor's costs and profiteering.

ii. The types of procurement agent: e.g. different prices may be paid for the same product by a public sector purchaser, such as Ministry of Health

iii. The distribution route. A patient who purchases a medicine at a hospital pharmacy may have to pay more if the hospital pharmacy purchased the product from a local wholesaler than if it has been purchased by tender and supplied through public health sector distribution system10. Many times hospital pharmacy may have limited stock of the generic drugs which one is cheaper than the branded drugs prescribed to the patient on routine basis and patient has to purchase the branded drugs in the emergency condition.
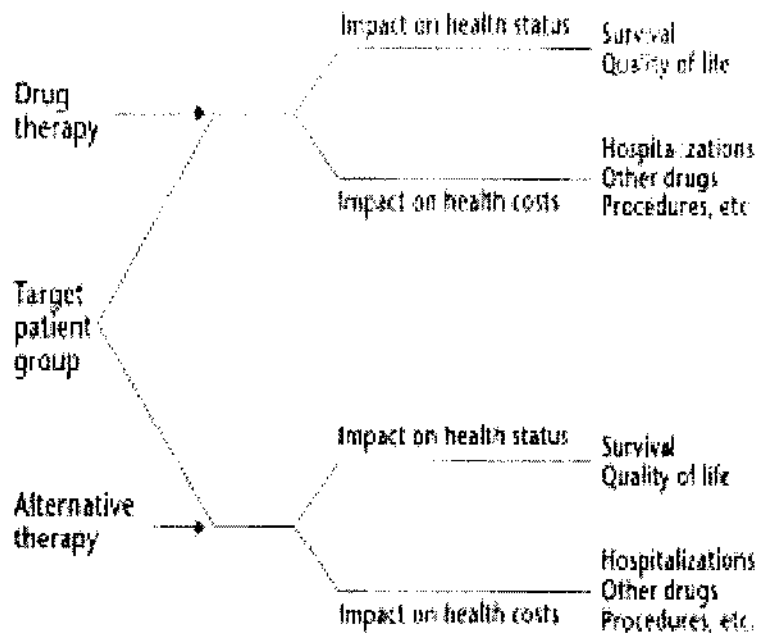
Need of Pharmacoeconomics

Pharmacoeconomics identifies measures and compares the cost and consequences of pharmaceutical products and services and describe the economic relationship involving drug research, drug production distribution, storage, pricing and used by the people. It runs through the thread of our socioeconomic system, which regulates and influences all the sectors involved in pharmaceuticals. The demand for and the cost of health care are increasing in all countries as the improvement of health technologies. All over the world, patients are affected by high price of medicines. In a developing country like India, 85% of total health expenditure is financed by house-hold out of pocket expenditure. Many poor people frequently face a choice between buying medicines or buying food or other necessities due to limited resources and high pricing of drug. So medicine prices do matter. Pharmacoeconomics has become more important over the past 20 years, due to an increases emphasis on efficient drug therapies for disease, which increase health cost etc. Pharmacoeconomics is a subdivision of health economics and results from that discipline coming of age through consolidation to diversification. Health economics, as a branch of economics is itself relatively young. Basically the pharmacoeconomics is needful in following manner:

• In Industry- Deciding among specific research and development alternatives.

• In Government- Determining program benefits and prices paid.

• In Private Sector- Designing insurance benefit coverage

Aims and Objectives of Pharmacoeconomic Evaluation

Implementation of pharmacoeconomic evaluation will help to reduce monetary burden on the consumers (by insuring global pricing strategy) for the effective management of health care system as the principle of pharmacoeconomic evaluation is to make more efficient use of limited resources for maximization of health care benefit at lower cost . In this way, it can be applied in practice to take decisions about drug therapies.

Drug therapy — Impact on health status → Survival, Quality of life

Impact on health costs → Hospitalizations, Other drugs, Procedures, etc

Target patient group

Alternative therapy — Impact on health status → Survival, Quality of life

Impact on health costs → Hospitalizations, Other drugs, Procedures, etc.

The Fundamentals

Types of Cost

Costs involved in pharmacoeconomic evaluation can be mainly divided into financial cost (mandatory cost) and economic cost (resource for which no mandatory payment is made) opportunity cost is the benefit foregone when selecting one therapy alternative over the next best alternative. Several costs can be measured when weighing up the cost of any invention. The first step in any cost analysis is identification of the various costs. These can be direct, indirect and intangible. Direct i.e. costs from the perspective of the healthcare funder: including staff costs, capital costs, drug acquisition costs. It includes physicians' fees, cost of administering the medication, costs of treating an adverse drug reaction, etc. Indirect i.e. costs from the perspective of society as a whole: for example, these might include loss of earnings, loss of productivity, loss of leisure time, due to the illness, and cost of travel to hospital etc. This would include not just the patient themselves but also their family and society as a whole. Intangible i.e. the pain, worry or other distress; which a patient or their family might suffer. These may be impossible to measure in monetary terms, but are sometimes captured in measures of quality of life.

The cost can be measured in following ways:

• Cost / unit

• Cost / treatment

• Cost / person

- Cost / person / year

- Cost / case prevented

- Cost / life saved

- Cost / DALY (disability-adjusted life year)

Outcomes

The second fundamental component of a pharmacoeconomic study is outcomes or benefits. A cost-benefit analysis compares the costs and outcomes of alternative therapies and the outcome is then expressed in monetary terms (Brien et al 1997). Cost-benefit analysis allows researchers to make comparisons across a wide variety of alternatives. It compares the costs involved in implementing a programme with the value of the outcome. Since the endpoints are measured in monetary terms, different endpoints can be studied, such as a surgical procedure compared with a pharmaceutical intervention

Methods of Pharmacoeconomic

Evaluation Pharmacoeconomic evaluations include any study designed to assess the costs (resources consumed) and consequences (clinical, humanistic) of alternative therapies The evaluation mechanisms delineated were often helpful in demonstrating the cost impact of innovative treatments, therefore granting them greater acceptance by healthcare providers, administrators, and the public.

There are basically four types of pharmacoeconomic studies.

- Cost-minimization analysis (CMA)

- Cost-effectiveness analysis (CEA)

- Cost-utility analysis (CUA)

- Cost-benefit analysis (CBA)

Cost Effective Analysis (CEA) CEA is a technique designed to assist a decision-maker in identifying a preferred choice among possible alternatives. Generally, cost-effectiveness is defined as a series of analytical and mathematical procedure that aid in the selection of a course of action from various alternative approaches. CEA evaluates multiple drug treatments for the same condition. The cost of the drug treatments are weighed against the effectiveness of the drug (Thwaits et al 1998). The costs

of drug treatments include acquisition costs, physician involvement, and nursing costs for administration of the drug. The effectiveness of drug treatment is measured in tangible measures such as length of hospital stay, duration of treatment required, and mortality rate. The results of a CEA are expressed as cost/outcome for both therapies. Pharmacoeconomic analysis should be incorporated in the clinical trial itself. However, for the majority of drugs, CEA is done on the basis of pre-existing data available in the medical literature. CEA is the most commonly applied form of economic analysis in the literature, and especially in drug therapy (Lee et al 1991). It does not allow comparisons to be made between two totally different areas of medicine with different outcomes. The key measure of these evaluations is the incremental cost effectiveness ratio (ICER), which can be determined as follows:

Incremental cost effectiveness ratio= Cost of drug A - Cost of drug B Benefits of drug A - Benefits of drug B

Cost Utility Analysis (CUA) CUA is a type of evaluation in which drugs/interventions with different outcomes can be compared. CUA is the most appropriate method to use when comparing programs and treatment alternatives that are life extending with serious side effects (e.g., cancer chemotherapy), those which produce reductions in morbidity rather than mortality (e.g., medical treatment of arthritis), and when HRQOL is the most important health outcome being examined (Bootman 1995). CUA is employed less frequently than other economic evaluation methods because of a lack of agreement on measuring utilities, difficulty comparing QALYs (quality adjusted life years) across patients and populations, and difficulty quantifying patient preferences.

Applications of Pharmacoeconomics

I.   One of the primary applications of pharmacoeconomics in clinical practice today is to aid clinical and policy decision making. Through the appropriate application of pharmacoeconomics, practitioners and administrators can make better, more informed decisions regarding the products and services they provide. Complete pharmacotherapy decisions should contain assessments of three basic outcome areas whenever appropriate: economic, clinical, and humanistic outcomes (ECHO). Traditionally, most drug therapy decisions were based solely on the clinical outcomes (e.g., safety and efficacy) associated with a treatment alternative

II.   II. Pharmacoeconomic data can be a powerful tool to support various clinical decisions, ranging from the level of the patient to the level of an entire healthcare system. Fig. 8

shows various decisions that can be supported using pharmacoeconomics, including effective formulary management, individual patient treatment, medication policy, and resource allocation. For discussion purposes, the application of pharmacoeconomics to decision making is divided into two basic areas: drug therapy evaluation and clinical pharmacy service evaluation.
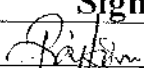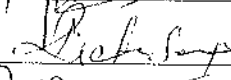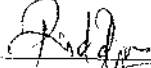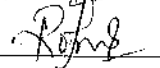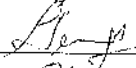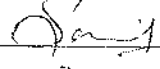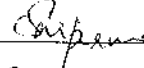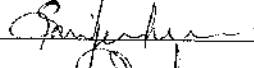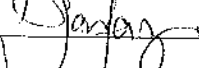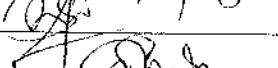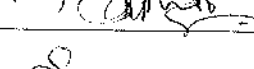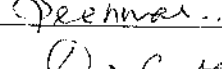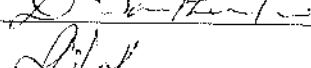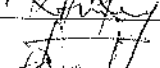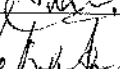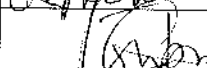
Conclusion

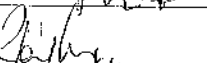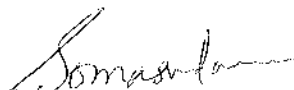The perspective of a pharmacoeconomic evaluation is paramount because the study results will be highly dependent on the perspective selected. When evaluating published pharmacoeconomic studies, factors should to be considered are study objective, study perspective, pharmacoeconomic method, study design, choice of interventions, costs and consequences, discounting, study results, sensitivity analysis and study conclusions. Majority of pharmacoeconomic guidelines provide only general and vague recommendation in many areas may be because of no consensus among the developers and challenge of sustenance for relatively young science of pharmacoeconomics. Therefore strict guidelines having uniform global standards should be formulated by an independent body comprising of people from academia, industry and health authorities. Upon implementation it would be helpful towards prescribing a rational drug therapy and pharmacist, the bridge between patients and doctors, will dispense as well as help in purchasing drugs for hospital pharmacies. This would also help in reducing the monetary burden on institutions and public.
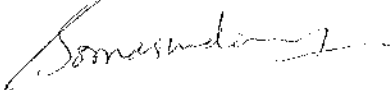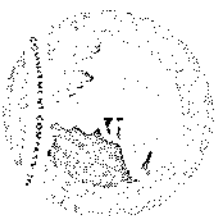
ANNEXURE -II
VALUE ADDED COURSE

Participant list of Value added course: **Research Methodology in Pharmacoeconomics**

Feb 2019 to Aug 2019

Sl. No	Name of the Student	Register No	Signature
1	RAJKUMAR R	U18MB331	
2	RAJU .S	U18MB332	
3	RICHAL SAWIN	U18MB333	
4	RIDDHI RAJESH PRASAD	U18MB334	
5	ROHINI V	U18MB335	
6	S.R.HEENA FEEMISHNEE	U18MB336	
7	SABARISH K S	U18MB337	
8	SAI SRI MUTYALA	U18MB338	
9	SAIPURNNIMA R.K	U18MB339	
10	SANJEEV KUMAR G.S	U18MB340	
11	SARFARAZ ISLAM	U18MB341	
12	SAURABH SINGH	U18MB342	
13	SEENUVAS .P	U18MB343	
14	SHANTHALAKSHMI D	U18MB344	
15	SHASHANK RITU RAJ	U18MB345	
16	SHEETAL SHRIVASTAVA	U18MB346	
17	SHLOKA SHAW	U18MB347	
18	SHRABASTI CHATTOPADHYAY	U18MB348	
19	SHREYA GUMBER	U18MB349	
20	RAJKUMAR R	U18MB350	

PROFESSOR & HOD
DEPARTMENT OF PHARMACOLOGY
Sri Lakshmi Narayana Institute Of Medical Sciences
PONDICHERRY - 605 502.

Topic- Research Methodology in Pharmacoeconomics Code: PH08

1. Which of the following statements represents the *best* definition of pharmacoeconomics?

   a) Description and analysis of the costs of drug therapy to health care systems and to society

   b) Process of identifying, measuring and comparing the costs, risks, and benefits of programs, services, or therapies and determining which alternative produces the best health outcomes for the resources invested

   c) Putting principles, methods, and theories into practice to quantify the value of pharmacy products and services used in the real world

   d) Studies that attempt to identify, measure, and evaluate the results of health care services in general

2. Which of the following statements is *true* regarding the perspective (point of view) of a pharmacoeconomic analysis?

3. There are various categories of health care costs. Which of the following *best* represents a direct medical cost and an indirect nonmedical cost, respectively?

    a. Pain and transportation
    b. Drugs and suffering
    c. Mortality and morbidity
    d. Medical professional time and lost productivity

4. Which of the following statements *best* describes economic outcomes?

    a) Medical events that occur as a result of a disease or treatment
    b) Direct, indirect, and intangible costs compared with the consequences of medical treatment alternatives
    c) Consequences of disease or treatment on patient functional status or quality of life
    d) Cost savings associated with a disease or treatment alternative

5. Which of the following are distinguishing characteristics of a full economic evaluation?

    a) Comparison of two or more treatment options
    b) Determination of the least expensive treatment alternative
    c) Examination of both the costs and consequences of the treatment alternatives
    d) a and c
    e) a and b

a)Should be conducted from a single perspective.
b)Should be conducted from multiple perspectives.
c)Costs and consequences should be identified and measured relative to the perspective(s) selected.
d)Societal perspective is the only relevant and valid perspective for a local pharmacoeconomic analysis.

6. When quantifying the value of a clinical pharmacy service, your goal is to express the benefits associated with this service in a dollar value. Which economic evaluation method would you employ?

a) Cost-benefit analysis
b) Cost-effectiveness analysis
c) Cost-minimization analysis
d) Cost-utility analysis

7. The economic evaluation method known as cost-effectiveness analysis would be best applied in which of the following cases?

a) When comparing two or more treatment alternatives that differ in humanistic outcome
b) When comparing two or more treatment alternatives that are equal in clinical outcome
c) When comparing two or more treatment alternatives that differ in clinical outcome
d) When comparing two or more treatment alternatives that differ in cost

8. The appropriate use of cost-minimization analysis requires which of the following to be *true*?

a) Costs must include measures of lost productivity.
b) Outcomes must be adjusted for quality of life.
c) Data must be obtained from similar sources.
d) Consequences for each alternative must be equivalent.

9. Which of the following statements provides the *best* description of an incremental cost-effectiveness ratio?

a) A summary measurement of efficiency
b) The cost per benefit of a new strategy, independent of other treatment alternatives
c) The extra cost to obtain an extra benefit realized from switching from one alternative to another
d) The cost per quality-adjusted life year gained

10. Which of the following statements about the application of pharmacoeconomics to pharmacy decision making is *false*?

a) Pharmacoeconomics can be a powerful tool for determining the value of drug use guidelines.
b) Pharmacoeconomics should be the only consideration when making a drug therapy decision.

c) Pharmacoeconomics can assist P&T committees in incorporating clinical, economic, and humanistic outcomes of drug therapy into formulary management decisions.

d) Pharmacoeconomics can provide data to support resource allocation decisions.
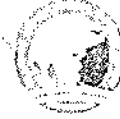
Answers

1-A

2-B

3-C

4-A

5-C

6-A

7-C

8-A

9-B

10-B

Sri Lakshmi Narayana Institute of Medical Sciences

This is to certify that Rajkumar R has actively participated in the Value Added Course on "RESEARCH METHODOLOGY IN PHARMACOECONOMICS" held during February 2019 to August 2019 Organized by Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry- 605 502, India

Dr. G.Somasundaram
Dr.Jayasheela.J

RESOURCE PERSON

Dr.Jaikumar

COORDINATOR

Student Feedback Form

Course Name: Research methodology in Pharmacogenomics

Subject Code: PHC8

Name of Student: Rohini V   Roll No.: U18MB335

We are constantly looking to improve our classes and deliver the best training to you. Your evaluations, comments and suggestions will help us to improve our performance

Sl. NO	Particulars	1	2	3	4	5
1	Objective of the course is clear					✓
2	Course contents met with your expectations				✓	
3	Lecturer sequence was well planned					✓
4	Lectures were clear and easy to understand					✓
5	Teaching aids were effective				✓	
6	Instructors encourage interaction and were helpful					✓
7	The level of the course					✓
8	Overall rating of the course	1	2	3	4	5

*Rating: 5 – Outstanding; 4 - Excellent; 3 – Good; 2 – Satisfactory; 1 - Not-Satisfactory

Suggestions if any:

SRI LAKSHMI NARAYANA INSTITUE OF MEDICAL SCIENCES AND HOSPITAL, PUDUCHERRY

From

Date:07.08.2019

Dr.G.Somasundaram
Professor and Head,
Department of Pharmacology
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry

To
The Dean,
Sri Lakshmi Narayana Institute of Medical sciences
Pondicherry.

Sub: Completion of value-added course: Research methodology in pharmacoeconomics

Dear Sir,

With reference to the subject mentioned above, the department has conducted the value-added course titled: **Research methodology in pharmacoeconomics** on **Feb 2019 to August 2019**. We solicit your kind action to send certificates for the participants, which is attached with this letter. Also, I am attaching the photographs captured during the conduct of the course.

Kind Regards

Dr.G.Somasundaram

Encl: Certificates

Photographs