

Pharmaco-Economics



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Week 1 Contents

- Introduction to Economics
- The Ant Philosophy
- Define Economy
- Clarification of Scarcity
- The Wants and Needs of economy
- Economic Factors of Production
 - Land
 - Labor
 - Capital

Introduction of Economics

- **Economics** is the **social science** that studies the **production, distribution, and consumption** of **goods and services**.
- It is the study of how we satisfy our wants and needs with the limited resources we have.
- **Scarcity**- all resources are limited and therefore are scarce. Everyone cannot have everything they want. There is not enough stuff to go around.

“The Ant Philosophy”

An amazing Four-Part Philosophy for Success

- Ants are the amazing creation that resembles the **unity** and a philosophy in which sets the tone for managers and the leaders of any type of organizations.
- **Mr. Rohn** states that everybody should study ants. They have an amazing **four-part philosophy**.



“The Ant Philosophy”

An amazing Four-Part Philosophy for Success

▣ **Wow, what a great philosophy to have, the ant philosophy.**

1. Never give up
2. Look a head
3. Stay positive
4. Do all you can



“The Ant Philosophy”

An amazing Four-Part Philosophy for Success

- **Here is the first part: ants never quit.**
- That's a good philosophy. If they are headed somewhere and you try to stop them, they'll look for another way. They'll climb over, they'll climb under, and they will climb around. They keep looking for another way. What a neat philosophy, to never quit looking for a way to get where you're supposed to go.



“The Ant Philosophy”

An amazing Four-Part Philosophy for Success

- **Second, Look a head**
- **ants think winter all summer.**
- That’s an important perspective. You can’t be so judgmental as to think summer will last forever. So ants are gathering their winter food in the middle of summer.

“The Ant Philosophy”

An amazing Four-Part Philosophy for Success

- **The third part of the ant philosophy is that Stay positive.**
- **ants think summer all winter.**
- That is so important. During the winter, ants remind themselves, “ this won’t last long – we’ll soon be out of here.” And the first warm day, the ants are out. If it turns cold again, they’ll drive back down, but then they come out the first warm day. They can’t wait to get out.

“The Ant Philosophy”

An amazing Four-Part Philosophy for Success

- **Here's the last part of the ant philosophy. Do all you can**
- How much will an ant gather during the summer to prepare for the winter ? All the possibly can.
- What an incredible philosophy, the “all-you-possibly-can” philosophy.

Wants & Needs

- To decide how funds get allocated we need to look at our **wants** and **needs**.
- **Needs** are our basic needs to survive, food, clothes, and shelter.
- **Wants**, put simply, are everything else and they are unlimited. I want a new car, new mp3 player, or a new house. I don't need any of them to survive.

Factors of Production

- Finally, what are the resources that we have to use to satisfy our wants and needs?
- There are three basic resources known as **the factors of production: Land; Labor and Capital**

The factors of production:

1. Land
2. Labor
3. Capital



Land



- this refers to all natural resources used to produce **goods** and **services**.
- This includes crops that are grown on a land, minerals that are mined from land and rent that is paid to an owner of land for its use.
- A **good** is a physical thing you can hold
- A **service** is some thing that gets used up right after it is purchased.

Labor



- this is the effort that an individual person puts into making a good or service.
- For this effort the person is paid a wage or salary.
- Labor includes factory workers, medical personal, and teachers. They all provide their labor for a wage.

Capital



- this is anything that is used to produce other goods and services.
- If you make cars you need machines to make the metal that is used in the cars. It is also the truck that drives the cars to the dealer who sells them, and it is the building that the cars are made in. All of these are the resource known as capital.

Micro and Macro Economics

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Outline

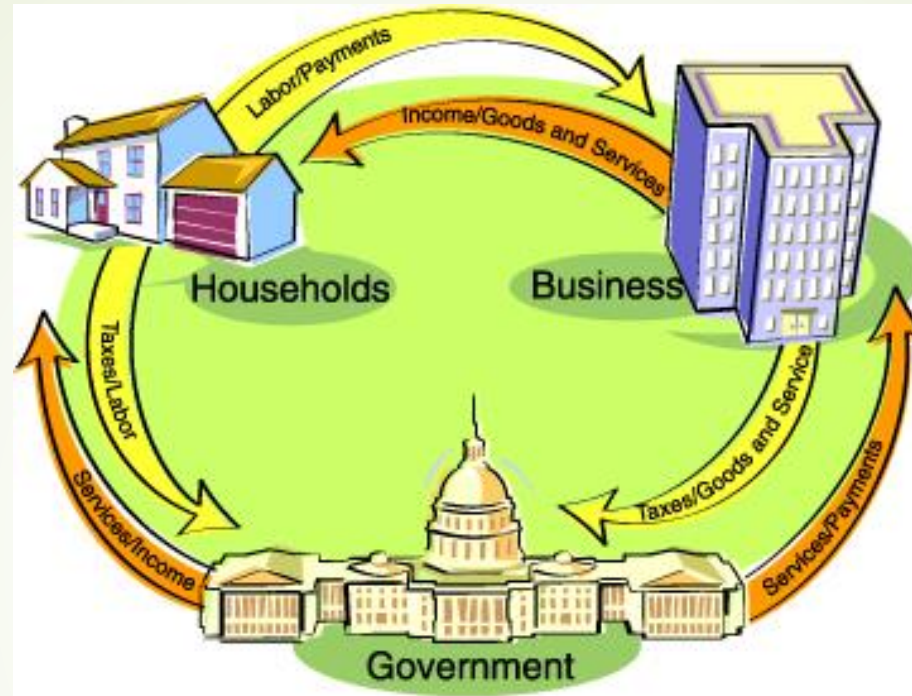
- Microeconomics VS Macroeconomics
- Demand and Supply Curve
- Four stages of business cycle
 - Prosperity
 - Recession
 - Depression
 - Recovery



Microeconomics: The forces of demand and supply

- ▶ is the study of economic behavior among individual consumers, families, and business whose collective behavior in marketplace determines the quantity of goods and services demanded and supplied at different prices.

Macroeconomics: Issues for the entire economy



is the study of the broader economic picture and how an economic system maintains and allocates its resources. It focuses on how a government's monetary and fiscal policies affect the overall operation of an economic system and the standard of living of its citizens.

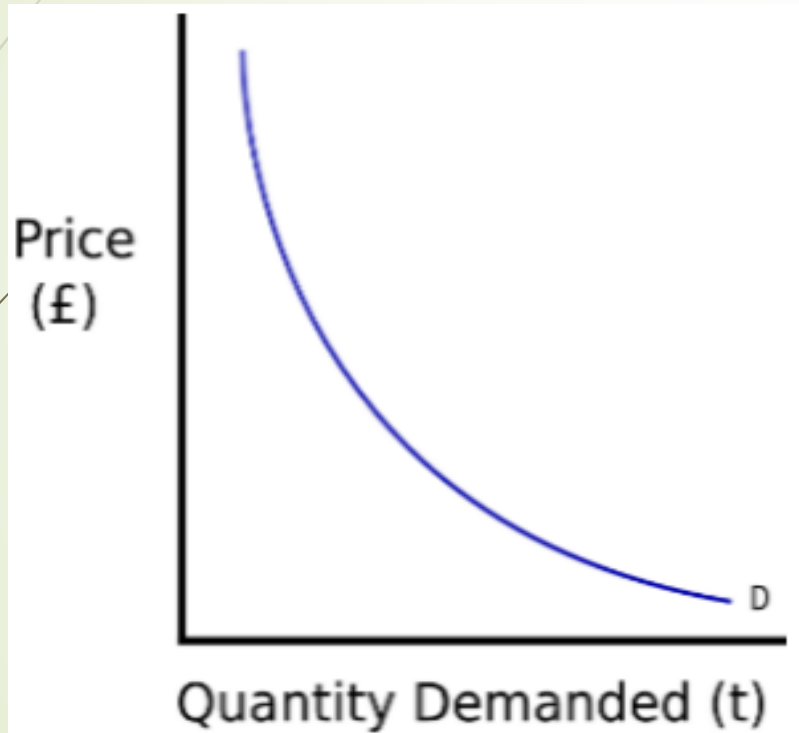
The factors that drive demand and supply:

- **Demand:** is the willingness and ability of buyers to purchase goods and services at different prices.

Demand Curve

- A demand curve is a graph of the amount of a product that buyers will purchase at different prices.
- **The price of a good and the quantity demanded usually have an inverse relationship; if one increase the other decreases.**
- In general, as the price of a good or service goes up, people buy smaller amounts. In other words, as price rises, the quantity demanded declines.
- At **lower prices**, consumers are willing to buy **more of a good**.

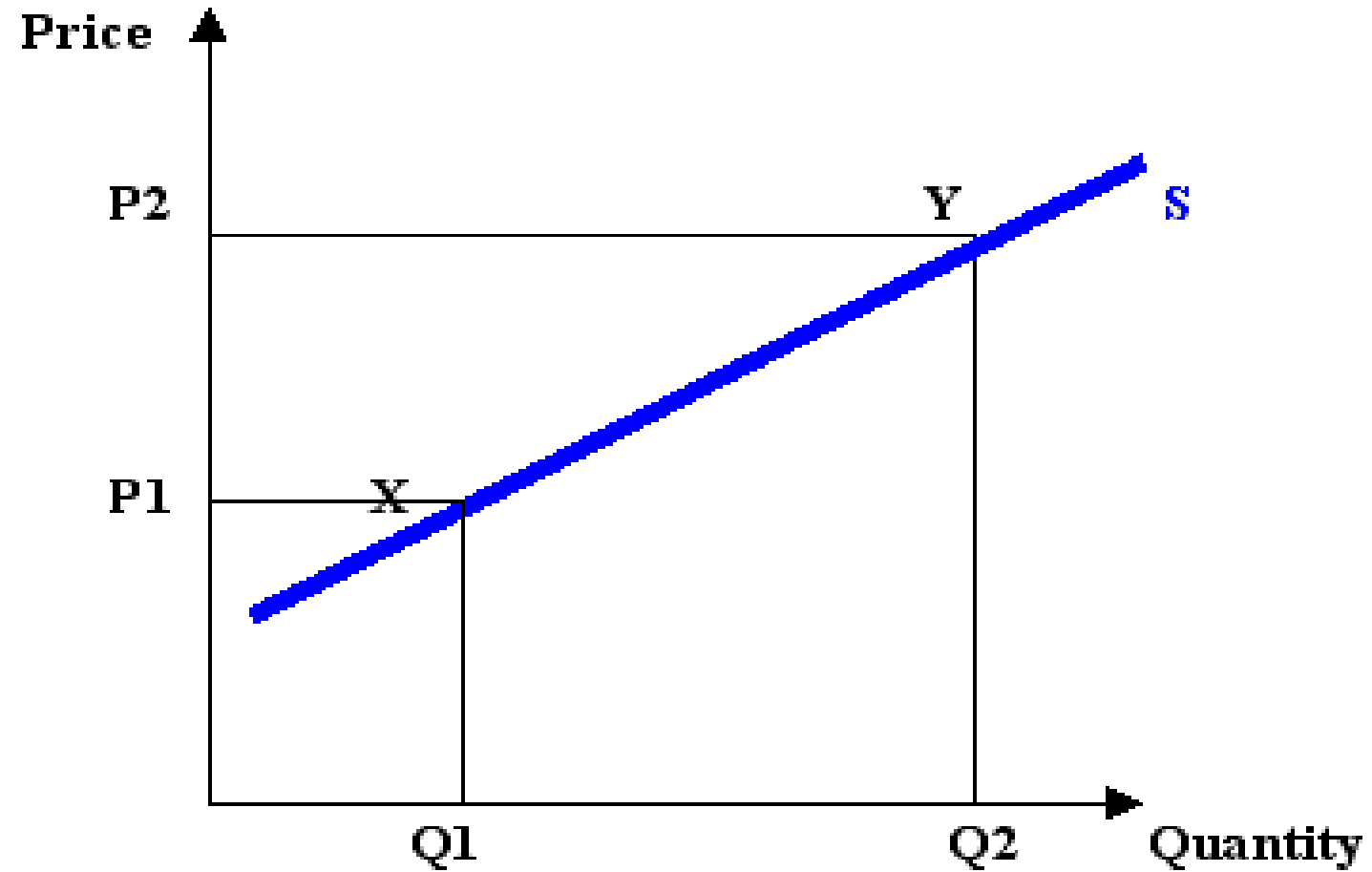
Demand Curve



Supply curve

- ▶ A supply curve shows the relationship between different prices and the quantities that sellers will offer for sale, regardless of demand.
- ▶ **As the price rises, the quantity that sellers are willing to supply also rises.**
- ▶ **At the lower prices, the quantity supplied decreases.**

Supply curve



Four stages of the business cycle:

- 1.-Prosperity
- 2.-Recession
- 3.-Depression
- 4.-Recovery

Prosperity stage of business cycle

- Prosperity is characterized by low unemployment and strong consumer confidence. Businesses expand by hiring more employees, investing in new technology, and making similar purchases to take advantage of new opportunities.

Recession stage of business cycle

- A cyclical economic contraction that lasts for six months or longer.
- Consumers often postpone major purchases, layoffs may occur, and household savings maybe depleted have sold cars, jewelry, and stocks to make ends meet.
- When this economic slowdown continues it falls into the next cycle, depression.

Depression stage of business cycle

- ▶ A depression occurs when an economic slowdown continues in a downward spiral over a long period of time. In this cycle food and other basic necessities were scarce and jobs are rare and precious.
- ▶ Example is the great depression of 1930s in US history: unemployment was at 25% and more than 5,000 banks had gone out of business.

Recovery stage of business cycle

- ▶ During recovery, consumer spending begins to increase and business activity accelerates, leading to an increased number of jobs.

Downturn in the economy

- The two stages of the business cycle that indicates a downturn in the economy are **recession** and **depression**.

Upward in the economy

- The two stages of the business cycle that indicates an upward in the economy are **prosperity** and **recovery**.

The stability of the Nation's Economy

Outline

- Stability of nation's economy
 - 1. Productivity
 - 2. Price level changes
 - Inflation and Deflation
 - 3. Employment level

The stability of the nation's economy is affected by:

- 1. Productivity
- 2. Price level changes
- 3. Employment level

1. Productivity

- ▶ is the relationship between the goods and services produced in a nation each year and the inputs that produce them.
- ▶ As productivity rises, so do an economy's growth and the wealth of its citizens.
- ▶ In recession, productivity stalls or possibly declines.

2. Price-level changes

- ▶ is another indicator of an economic stability.
- ▶ **Inflation** and **deflation** are important indicators of an economy's general stability.

Inflation

- **Inflation** is the rising prices caused by a combination of excess consumer demand and increase in the costs of raw materials, component parts, human resources, and other factors of production.
- Inflation **devalues** money as persistent price increases reduce the amount of goods and services people can purchase with a given amount of money.

Deflation

- ▶ **Deflation** is the opposite situation, occurs when prices continue to fall. In Japan, where deflation has been a reality for several years, shoppers pay less for variety of products ranging from Big Macs to apartments. While this situation may sound ideal to consumers, it can weaken the economy.
- ▶ U.S. government measures price level changes by the Consumer Price Index which measures the monthly average change in price of goods and services

3. Employment level

- ▶ a nation's unemployment rate is an indicator of both overall stability and growth.
- ▶ The unemployment rate shows the number of people actively seeking employment who are **unable to find jobs** as a percentage of the total labor force.

WEEK 4-5

Pharmacoeconomics INTRODUCTION



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OUTLINE

- Introduction
 - Goals & objectives of Pharmacoeconomics
 - History of Pharmacoeconomics
 - Perspectives of Pharmacoeconomics
 - Costs and types
 - Consequences or Outcomes
 - Applications
- 

INTRODUCTION

- The term Pharmacoeconomics was coined by Ray Townsend in 1986.
- It is a branch of health economics:
 - ✓ Making choices between options, when there is scarcity of resources, and
 - ✓ Fundamentally comparative, weighing the costs and benefits of 2 options.

PHARMACOECONOMICS

- The description & analysis of the costs of drug therapy to health care system & society.
- Pharmacoeconomics research identifies, measures & compares the costs (i.e. resources consumed) & consequences (i.e. clinical, economic, humanistic) of pharmaceutical products & services.
- *Pharmacoeconomics analysis:*
 - Efficient allocation of limited resources among competing alternative medications and services
 - Biggest bang for your buck (**More value for your money**), using a quantitative measure.
- **To make the best use of limited resources.**

Why we need pharmacoeconomics

- In the US, the average per capita spending on medication (Rx drugs) is about \$ 858 vs \$ 400 for other industrialized countries.
- Median cost of branded cancer drugs is estimated to be around \$ 9,000/ month.
- **Repatha** (Evolocumab) for high cholesterol: \$ 15,000/ year.
- **Tecfidera** (Dimethyl fumarate) for multiple sclerosis (MS): \$ 54,000/ year.
- **Daklinza** (Daclatasvir) for hepatitis C: \$ 63,000 for 12 week regimen.

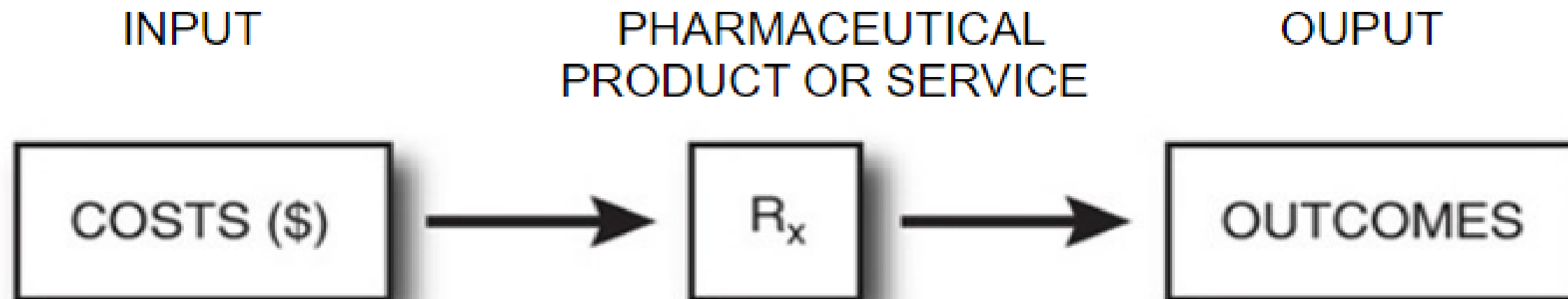
Why we Need pharmacoeconomics

- **Orkambi** (Ivacaftor/ lumacftor) for cystic fibrosis: \$ 259,000/ year
- **Spinraza** (Nusinersen) for spinal muscular atrophy: \$ 750,000 for 1st year and then \$ 375,000/ year for life.
- **Luxturna** (Voretigene neparvovec) for blindness due to specific inherited retinal disease: \$ 850,000 one-time treatment (gene therapy).
- Even cost of common generic drugs increased by 20 to 85 % in recent years.

Pharmacoeconomics

- **Goal:** To identify, measure and compare costs and consequences (outcomes) of pharmaceutical interventions.
- **Objective:** To allocate health care resources, assuring that each patient receives the most suitable treatment.
- **Composition:** It includes ideas and methods from a variety of domains including statistics, clinical epidemiology, decision analysis, and psychometrics (it is multidisciplinary).

Pharmacoeconomics



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Cost Analysis
(a partial pharmacoeconomic study)

Clinical or Outcome Study
(not an economic study)

Pharmacoeconomic Analysis

Pharmacoeconomics

Pharmacoeconomics is a set of methods to evaluate the:

1. Economic (**Cost efficient**),
2. Clinical (**Effectiveness**),
3. Humanistic (**Impact on Healthcare system, Individual and the society**) **Outcomes** (ECHO) of pharmaceutical products and services (*or any health care service*)

PHARMACOECONOMICS

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History of Pharmacoeconomics

- ✓ In the early 1960s pharmacy as a clinical discipline gained the recognition within the healthcare system.
- ✓ At this point, some subjects became part of pharmacy education such as clinical pharmacy, drug information, and pharmacokinetics.
- ✓ Pharmacoeconomics rooted in 1970s.
- ✓ The first book on health economics published in 1973, and 1978, in the University of Minnesota, the concept of cost-benefit and cost-effectiveness analysis introduced through the works of McGhan, Rowland, and Bootman.

History of Pharmacoeconomics

- Make use of the complicated pharmacokinetic procedure, Bootman et al., published an early pharmacy research editorial in 1979 displaying cost-benefit analysis of aminoglycoside dosages.
- In 1983, the University of Ohio, College of Pharmacy, initiated a particular pharmacy educational curriculum.
- The intent of the University was to provide the idea of the utilization of cost-effective and cost-benefit analysis in the healthcare system, with emphasis on their application to the delivery of pharmaceutical care.
- The term pharmacoeconomics was used for the first time by **Ray Townsend** from the Upjohn company in a public forum at meeting of the pharmacist in Toronto, Canada in **1986**.

History of Pharmacoeconomics

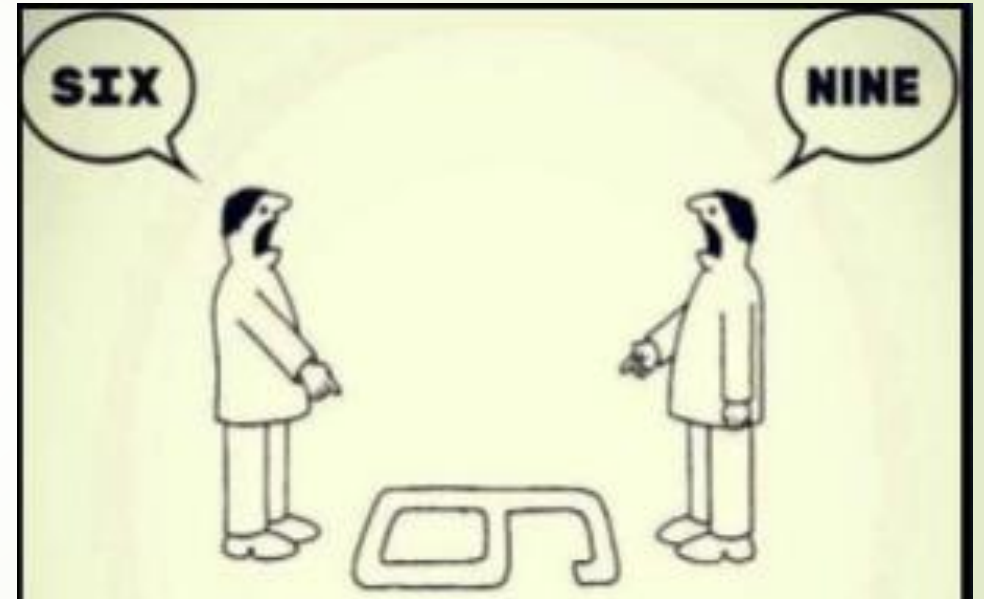
- ✓ Currently, pharmacoeconomics research is a prosperous industry with numerous practitioners, an outsized study, and an application program.
- ✓ Additionally, there are a number of journals and successful professional societies including the International Society for Pharmacoeconomics and Outcomes Research.

PERSPECTIVES OF PHARMACOECONOMICS

- Assessing costs and consequences-the value of a pharmaceutical product or service-depends heavily on the perspective of the evaluation.
- Common perspectives include those of the patient, provider, payer, and society.
- A pharmacoeconomic evaluation can assess the value of a product or service from single or multiple perspectives.
- Once the perspective is clear, a full evaluation of the relevant costs and consequences can begin.

PERSPECTIVES OF PHARMACOECONOMICS

- Patient perspective
- Provider perspective
- Payer perspective
- Societal perspective



After selection of perspective next step cost related measurements

PATIENT PERSPECTIVE

- ▶ Patient perspective is paramount because patients are the ultimate consumers of healthcare services.
- ▶ Costs from the perspective of patients are essentially what patients pay for a product or service-that is, the portion not covered by insurance.
- ▶ Consequences, from a patient's perspective, are the clinical effects, both positive and negative, of a program or treatment alternative.

PATIENT PERSPECTIVE

All the relevant cost and consequences experienced by the patient

Included costs:

- ✓ Direct costs
- ✓ Indirect costs
- ✓ Intangible costs



PROVIDER PERSPECTIVE



- Costs from the provider's perspective are the actual expense of providing a product or service, regardless of what the provider charges.
- Providers can be hospitals, managed-care organizations (MCOs), or private-practice physicians.
- Concerned with the expenses of providing products or services
- From this perspective, direct costs such as drugs, hospitalization, laboratory tests, supplies, and salaries of healthcare professionals can be identified, measured, and compared.

PAYER PERSPECTIVE

- Social Security/Government, third party payers eg. private insurance companies and employers.
- Included costs:
 - ✓ Direct costs
 - ✓ Indirect costs:
 - ❑ relevant to employers,
 - ❑ lost workdays,
 - ❑ lost productivity at work



SOCIETAL PERSPECTIVE



- The broadest of all perspectives that comprehensively evaluates all costs and consequences
- Considers the benefits to society as a whole Included costs:
 - ✓ Direct: overall cost of providing care.
 - ✓ Indirect: loss of productivity

COSTS

- Cost involves all the resources that are used to produce and deliver a particular drug therapy.
- **Types of Costs**
 - ✓ Direct costs:
 - Medical vs Nonmedical
 - ✓ Indirect costs
 - ✓ Intangible costs
 - ✓ Opportunity costs

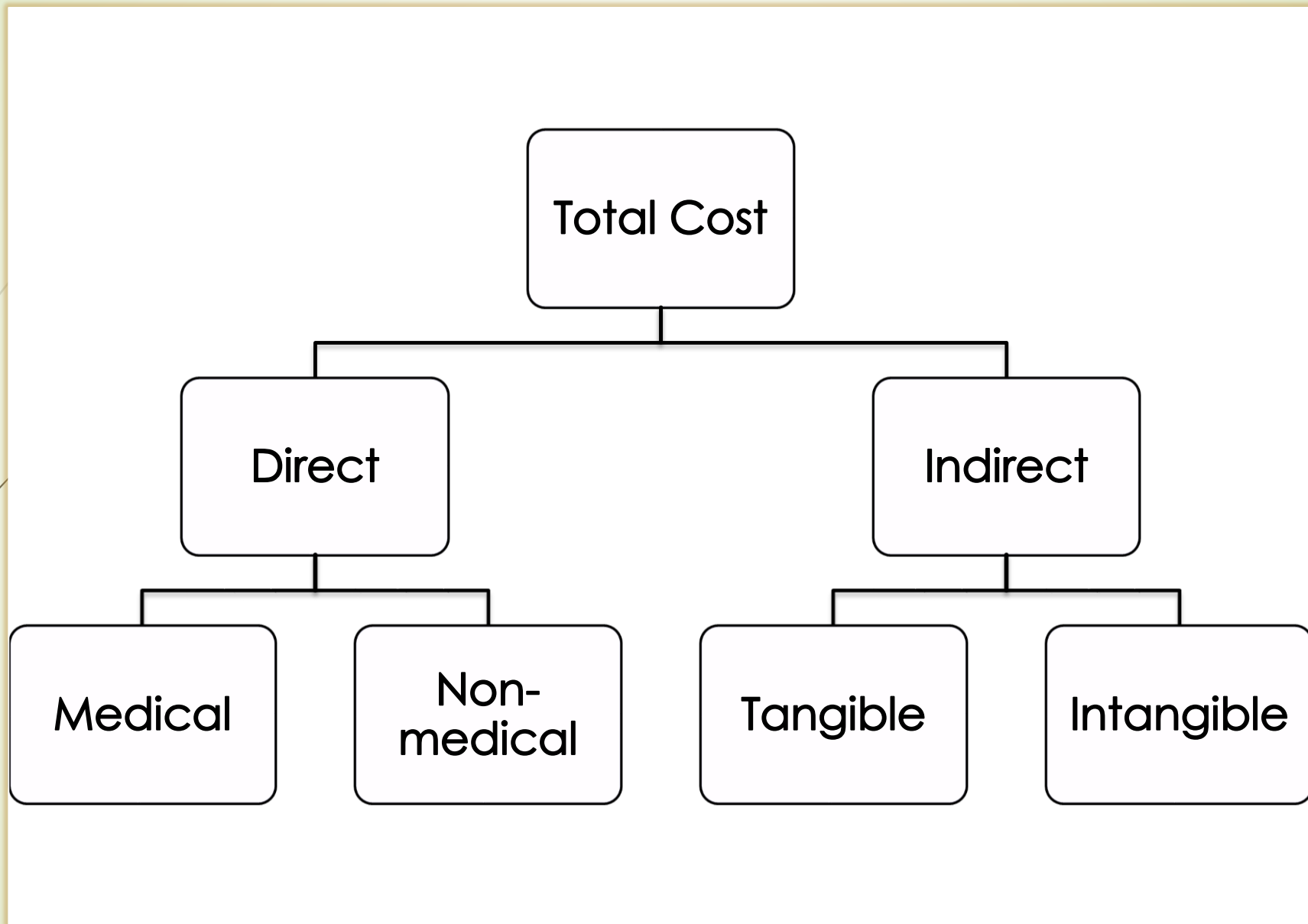


Table 1. Example of Healthcare Cost Categories

S. No.	Cost Category	Cost
1	Direct medical costs	Medications Supplies Laboratory tests Healthcare professionals' time Hospitalization
2	Direct nonmedical costs	Transportation Food & Family care Home aides
3	Indirect costs	Lost wages (morbidity) Income forgone because of premature death (mortality)
4	Intangible costs	Pain & Suffering Inconvenience Grief
5	Opportunity costs	Lost opportunity Revenue forgone

Direct costs:

Direct Medical Costs: Direct medical costs are the costs incurred for medical products and services used to prevent, detect, and/or treat a disease.

➤ **These include:**

➤ **Fixed costs** or costs that do not vary immediately with the number of patients treated. E.g. capital costs of hospital building or equipment etc.

➤ **Variable costs** or costs that vary immediately with number of patients treated. E.g. costs of drugs, syringes, needles etc.

➤ **Direct non-medical costs:**

Costs incurred by the patient in receiving medical care. E.g. transportation to and from hospital.

Indirect nonmedical cost:

- Indirect nonmedical costs are the costs of reduced productivity (e.g., morbidity and mortality costs).
- Indirect costs are costs that result from morbidity and mortality and are an important source of resource consumption, especially from the perspective of the patient.
- **Morbidity** costs are costs incurred from missing work (i.e., lost productivity), whereas **mortality** costs represent the years lost as a result of **premature death**.



➤ **Intangible costs:**

- Intangible costs are those of other nonfinancial outcomes of disease and medical care.
- E.g. Costs of pain, worry and other suffering which a patient or his family might suffer.

➤ **Opportunity costs:**

- Opportunity costs represent the economic benefit forgone when using one therapy instead of the next best alternative therapy.
- The amount lost by not using economic resources in its best alternative use (labour, capital, building, management etc.)
- Resources invested in one area will be at expense of loss of another opportunity.

Incremental Costs

- Incremental costs represent the additional cost that a service or treatment alternative imposes over another compared with the additional effect, benefit, or outcome it provides.
- As medical interventions become increasingly intense, costs generally increase.
- However, the additional outcome gained per additional dollar spent generally decreases. At some point of increasing expenditures, there may be no additional benefits or even a reduction in outcome.
- Thus incremental costs are the extra costs required to purchase an additional unit of effect and provide another way to assess the pharmacoeconomic impact of a service or treatment option on a population.

Consequences or OUTCOMES

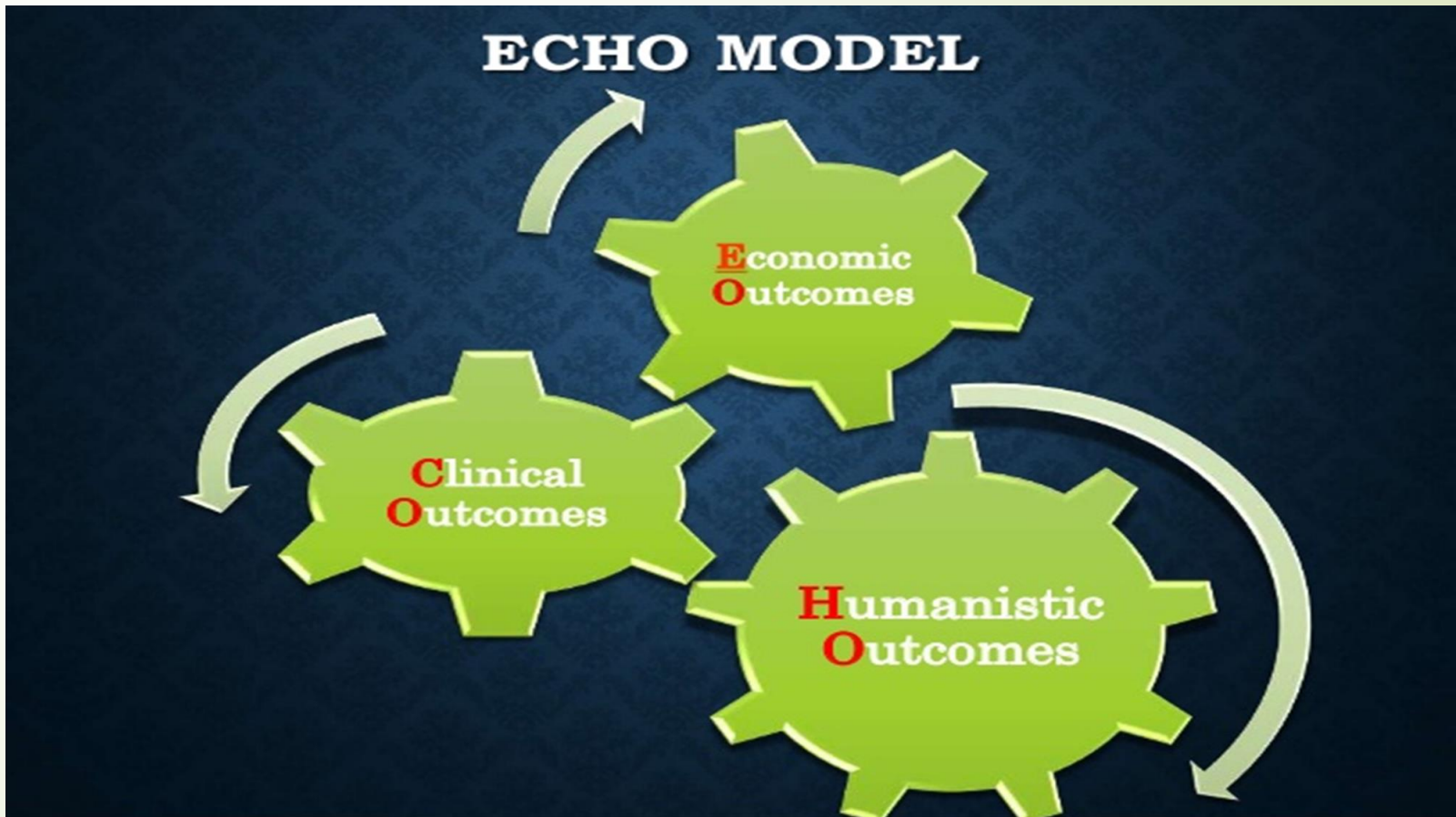
- ▶ Similar to costs, the outcomes or consequences of a disease and its treatment are an equally important component of pharmacoeconomic analyses.
- ▶ The manner in which consequences are quantified is a key distinction among pharmacoeconomic methods because the assessment of costs is relatively standard.

Consequences or OUTCOMES

- ▶ Like costs, the consequences (or outcomes) of medical care also can be categorized. One approach is to separate outcomes into three categories:
 - A. Economic,
 - B. Clinical, and
 - C. Humanistic.

ECHO Model

- Economic
- Clinical
- Humanistic
- Outcomes



Consequences or OUTCOME PARAMETERS

- **Economic:** Economic outcomes are the direct, indirect, and intangible costs compared with the consequences of medical treatment alternatives.
 - ✓ Direct, indirect and intangible costs
- **Clinical:** Clinical outcomes are the medical events that occur as a result of disease or treatment (e.g., safety and efficacy end points).
 - ✓ As a result of disease or treatment -survival / mortality -morbidity

➤ **Humanistic:** Humanistic outcomes are the consequences of disease or treatment on patient functional status or quality of life along several dimensions (e.g., physical function, social function, general health and well-being, and life satisfaction).

✓ Patient preferences / Utilities.

✓ Quality of life.

➤ Assessing the economic, clinical, and humanistic outcomes (**ECHO**) associated with a treatment alternative provides a complete model for decision making.

Positive versus Negative Consequences

- An example of a positive outcome is a desired effect of a drug (efficacy or effectiveness measure), possibly manifested as cases cured, reductions in hemoglobin A1c, life-years gained, or improved health-related quality of life (HRQOL).
- Because all drugs have adverse effects, negative consequences also can occur with their use.
- A negative outcome is an undesired or adverse effect of a drug, possibly manifested as a treatment failure, an adverse drug reaction (ADR), a drug toxicity, or even death.

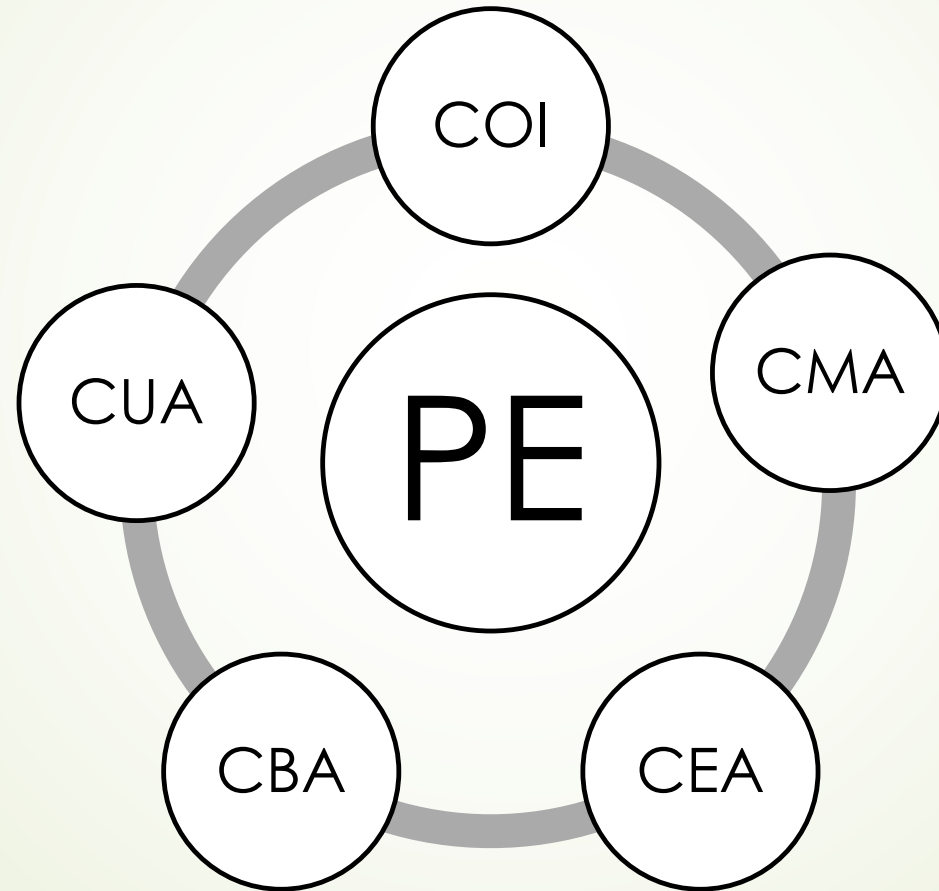
Intermediate and Final Consequences

- Consequences also can be discussed in terms of intermediate and final outcomes.
- Intermediate outcomes can serve as a proxy for more relevant final outcomes.
- For example, achieving a decrease in low-density lipoprotein cholesterol levels with a lipid-lowering agent is an intermediate consequence that can serve as a proxy for a more final outcome such as a decrease in myocardial infarction rate.

PHARMACOECONOMIC ANALYSIS

1. **Cost of Illness (COI):** Evaluation of overall economic impact of a disease on a population
2. **Cost minimization analysis (CMA):** assumes equal outcomes
3. **Cost effectiveness analysis (CEA):** measures outcome in natural or physical units
4. **Cost Benefit analysis (CBA):** measures both benefit and cost in monetary terms
5. **Cost Utility analysis (CUA):** measures outcomes in QALY

PHARMACOECONOMIC ANALYSIS



Applications of Pharmacoeconomics

- ▶ Assist in decision making and allocating scarce resources
- ▶ Assessing the value of a new agent
- ▶ Formulary decision making
- ▶ Drug policy decisions, treatment guidelines & Justify the addition of new clinical service
- ▶ Pricing in pharmaceutical industry
- ▶ Decision on reimbursement
- ▶ Third-party; payers use such information to decide whether to pay for a particular treatment, or to determine what price they are willing to pay.

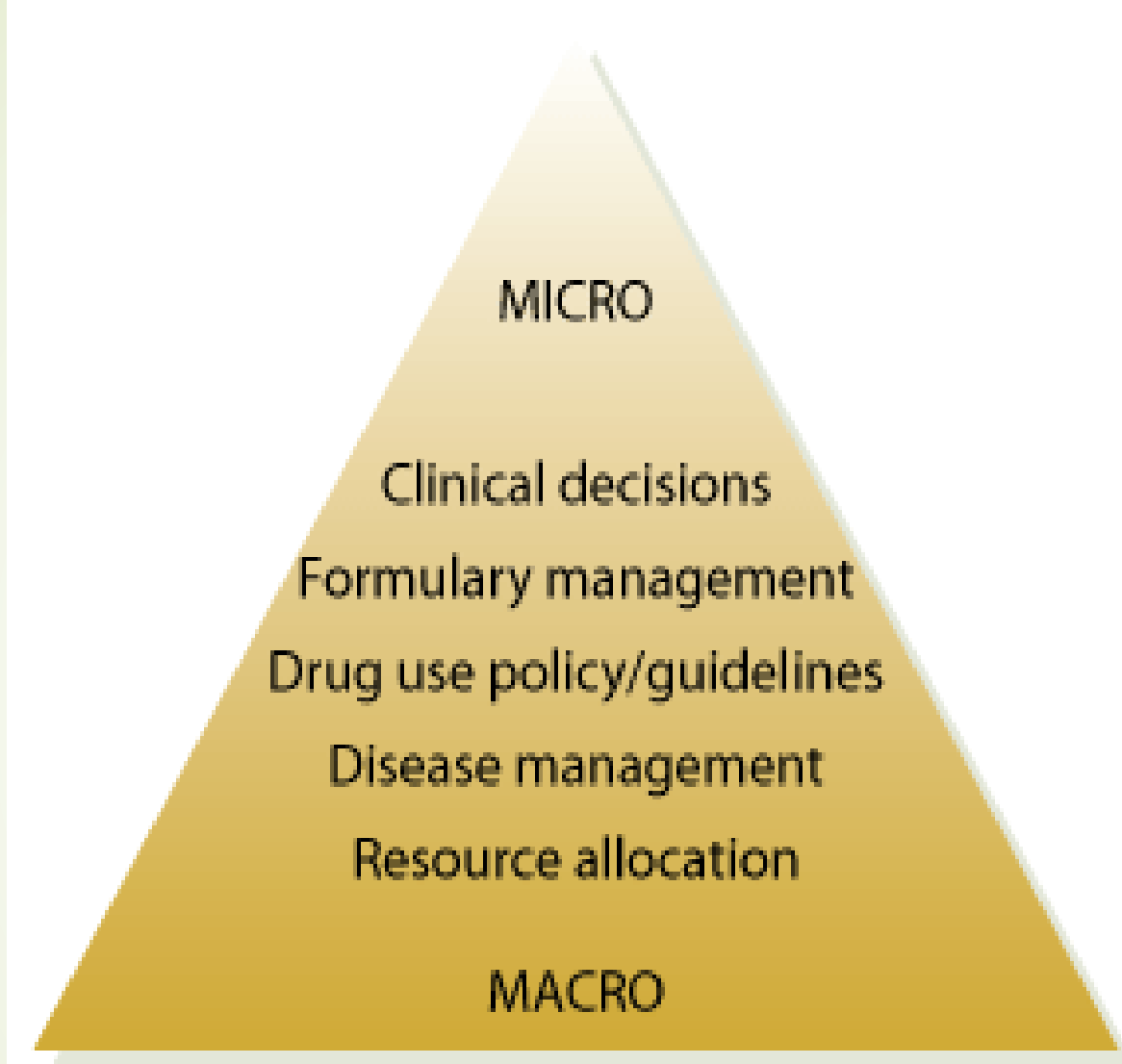


Figure 2. Decisions that can be supported using Pharmacoeconomics

Drug Therapy Evaluation

- Historically, pharmacoeconomic principles and methods have been applied commonly to assist clinicians and practitioners in making more informed and complete decisions regarding drug therapy.
- For example, pharmacoeconomics can provide critical cost-effectiveness data to support the addition or deletion of a drug to or from a hospital or MCO formulary, with or without restriction.
- In fact, the pharmacoeconomic assessment of formulary actions is becoming a standardized part of many pharmacy and therapeutic committees.
- The application of pharmacoeconomics also can be useful for making a decision about an individual patient's therapy.

Clinical Pharmacy Service Evaluation

- The most recent application of pharmacoeconomic principles and methods has been for justifying the value of various healthcare services, particularly pharmacy services.
- When a specific service is competing for hospital or MCO resources, pharmacoeconomics can provide the data necessary to show that the service maximizes the resources allocated by healthcare system administrators.
- Pharmacoeconomics can be useful in determining the value of an existing service, estimating the potential worth of implementing a new service, or capturing the value of a “cognitive” clinical intervention.
- Practitioners and administrators can then use these data to make more informed resource-allocation decisions.

Methods of Pharmacoeconomic Evaluation



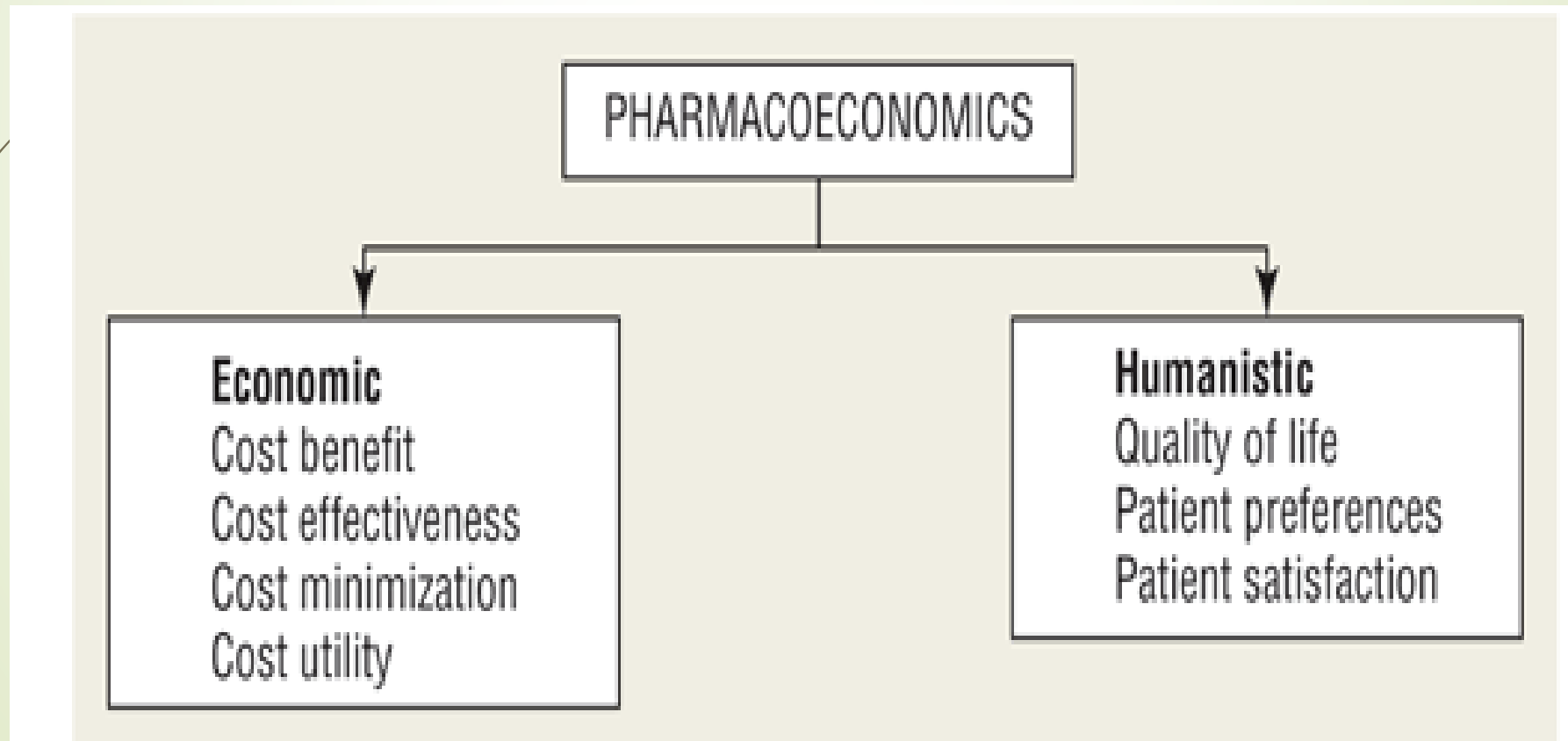
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Methods of Pharmacoeconomics



Economic Evaluation Methods

- The basic task of economic evaluation is to identify, measure, value, and compare the costs and consequences of the alternatives being considered.
- The two distinguishing characteristics of economic evaluation are as follows:
 - (1) Is there a comparison of two or more alternatives ? and
 - (2) Are both costs and consequences of the alternatives examined ?

1. Partial economic evaluations

- **Partial economic evaluations** can include simple descriptive tabulations of outcomes or resources consumed and thus require a minimum of time and effort.
- If only the consequences or only the costs of a program, service, or treatment are described, the evaluation illustrates an outcome or cost description.
- A **cost-outcome or cost-consequence analysis (CCA)** describes the costs and consequences of an alternative but does not provide a comparison with other treatment options.
- Another partial evaluation is a cost analysis that compares the costs of two or more alternatives without regard to outcome.

Full economic evaluations

- Full economic evaluations include:
 - 1. cost-minimization,**
 - 2. cost-benefit,**
 - 3. cost-effectiveness, and**
 - 4. cost-utility analyses.**
- Each method is used to compare competing programs or treatment alternatives.
- The methods are all similar in the way they measure costs (in dollars) and different in their measurement of outcomes.
- Although a full economic evaluation generally provides higher quality and more useful information, the time, resources, and effort employed are also great.

Basically five types of Pharmacoeconomic Analysis methods are used:

1. Cost of Illness (COI)
2. Cost-minimization (CMA)
3. Cost-benefit (CBA)
4. Cost-effectiveness (CEA)
5. Cost-utility (CUA)

Table 2. Summary of Pharmacoeconomic Methodologies

S. No.	Method	Description	Application
1	Cost-of illness evaluation (COI)	Estimates the cost of a disease on a defined population	Use to provide baseline to compare prevention/treatment options against
2	Cost-minimization analysis (CMA)	Finds the least expensive cost alternative	Use when benefits are the same
3	Cost-benefit analysis (CBA)	Measures benefit in monetary units and computes a net gain	Can compare programs with different objectives
4	Cost-effectiveness analysis (CEA)	Compares alternatives with therapeutic effects measured in physical units; computes a cost-effectiveness ratio	Can compare drugs/programs that differ in clinical outcomes and use the same unit of benefit

Table 2. Summary of Pharmacoeconomic Methodologies

S. No.	Method	Description	Application
5	Cost-utility analysis (CUA)	Measures therapeutic consequences in utility units rather than physical units; computes a cost-utility ratio	Use to compare drugs/programs that are life extending with serious side effects or those producing reductions in morbidity
6	Quality of life (QOL)	Physical, social, and emotional aspects of patient's well-being that are relevant and important to the patient	Examines drug effects in areas not covered by laboratory or physiologic measurements

Cost of Illness (COI)

1. Cost of Illness

- Evaluation of overall economic impact of a disease on a population.
- Measures the economic burden of a disease.
- Sum of all costs and all consequences of the disease.
- Has the advantage of defining the disease, its epidemiology, outcomes and consequences.
- COI evaluation is not used to compare competing treatment alternatives but to provide an estimation of the financial burden of a disease.
- Thus the value of prevention and treatment strategies can be measured against this illness cost.

Example: *Costs attributable to Type II diabetes in adults.*

Cost of Illness

- An illness consumes resources and, thus, it has a cost. The cost of an illness is the sum of three broad components:
 - (1) medical resources used to treat the illness,
 - (2) the nonmedical resources associated with it, housekeeping, meal preparation, hygiene assistance, transportation.
 - (3) lost productivity due to illness or disability.

WEEK-7

Cost Minimization Analysis (CMA)



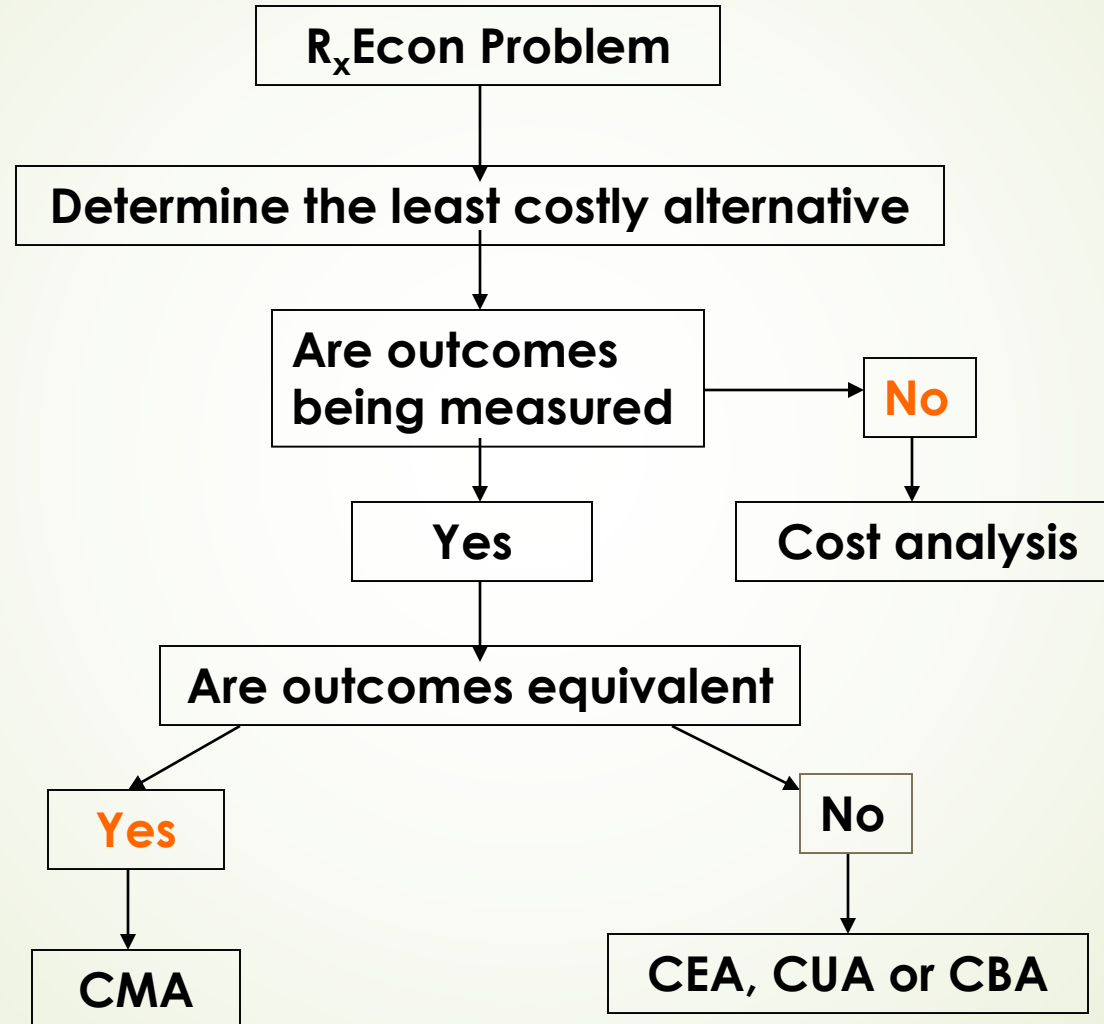
2. Cost-Minimization Analysis (CMA)

- This type of evaluation compares two or more alternative treatments that produce clinically equivalent outcomes.
- In CMA, the alternatives must have an assumed or demonstrated equivalency in safety and efficacy.
- Once equivalency is demonstrated, the focus is on choosing the one with the smallest total costs.

- *Example* – treating patient with same therapy in hospital vs home.

- CMA is a relatively straightforward and simple method for comparing competing programs or treatment alternatives as long as the therapeutic equivalence of the alternatives being compared has been established.
- Remember, CMA shows only a “**cost savings**” of one program or treatment over another.
- Employing CMA is appropriate when comparing two or more therapeutically equivalent agents or alternate dosing regimens of the same agent.
- This method has been used frequently, and its application could expand given the increasing number of “**me too**” products and **generic competition** in the pharmaceutical marketplace.

Cost Minimization Analysis



Cost-Minimization Analysis:

Example 1:

➤ Problem:

- Compare the costs of eardrops in treating patients with impacted earwax using CMA.

➤ Outcome measurements desired:

- Cost minimization for common eardrops used for the removal of impacted earwax for 500 outpatients.

- **Assumptions and conditions:**

1. Treatment is for patients with impacted earwax, with no history perforated eardrums.
2. Adverse outcome is averted; i.e., impacted earwax was removed successfully without problems .
3. Number of outpatients treated is 500.
4. Duration for treatment is less than 5 days.
5. No compliance and failure problems are found.

- **Medication alternatives compared:**

Rx a: polypeptide oleate mixture (6 ml)

Rx b: carbamide peroxide (15 ml)

Rx c: mineral oil and hydrogen peroxide USP
(15 ml of each prepackaged separately)

	Rx a	Rx b	Rx c*
Acquisition cost:	\$21.26	\$1.25	\$0.06
Dispensing costs (parts & labor)	\$6.00	\$6.00	\$7.00

*Note: *: (Rx c requires filling the liquids in two containers; thus we assign an extra cost.)*

Calculations:

	Rx a	Rx b	Rx c
Total cost per Rx	\$27.26	\$7.25	\$7.06

Outcome measurements:

	Rx a	Rx b	Rx c
Total cost:	\$13,630.00	\$3,625.00	\$3,530.00
(500 Rx's)			

Outcome findings:

Rx C leads to cost minimization.

Rx A is 386% of the cost of Rx C.



Week 8

Mid-Term

Exam

100

WEEK 9

Cost-Effectiveness Analysis (CEA)

Cost-Effectiveness Analysis (CEA)

- It is an approach used for identifying, measuring, and comparing the significant costs and consequences of **alternative** interventions.
- If you can measure the therapeutic effect in “natural units” (i.e. drop in blood pressure, lives saved, cases cured, FBG reduction, blood cholesterol level reduction) you compare the Cost per gain in therapeutic effect.
- CEA is particularly useful in balancing cost with patient outcome, determining which treatment alternatives represent the best health outcome per dollar spent, and deciding when it is appropriate to measure outcome in terms of obtaining a specific therapeutic objective.
- In addition, CEA can provide valuable data to support drug policy, formulary management, and individual patient treatment decisions.

Cost-effective Therapies

- ▶ are those with outcomes worth their corresponding costs relative to competing alternatives
 - ▶ Therapies that are less expensive and at least as effective as other alternatives
 - ▶ Therapies that are more expensive than alternative therapies with an additional benefit worth the additional cost
 - ▶ Therapies that are less expensive and less effective in instances where the extra benefits provided by the competing therapy is not worth the additional expense

Examples where CEA is best technique

- ▶ Compare the costs and outcomes of two or more antihypertensive
 - ▶ Cost per decrease in blood pressure
- ▶ Compare two programs designed to prevent excess mortality
 - ▶ Cost per life saved

Note: Cost-utility analysis is a special form of cost-effectiveness analysis

Types of CEA methods

1. Average cost-effectiveness ratio (ACER)
 2. Incremental cost-effectiveness ratio (ICER).
- An **ACER** represents the total cost of a program or treatment alternative divided by its clinical outcome to yield a ratio representing the dollar cost per specific clinical outcome gained, independent of comparators.

$$\text{ACER} = \frac{\text{health care costs (\$)}}{\text{clinical outcome (not in \$)}}$$

- This allows the costs and outcomes to be reduced to a single value to allow for comparison. Using this ratio, the clinician would choose the alternative with the least cost per outcome gained.
- The most cost-effective alternative is not always the least costly alternative for obtaining a specific therapeutic objective.
- In this regard, cost-effectiveness need not be cost reduction but rather **cost optimization**.

- **Incremental CEA** can be used to determine the additional cost and effectiveness gained when one treatment alternative is compared with the next best treatment alternative.
- Thus, instead of comparing the ACERs of each treatment alternative, the additional cost that a treatment alternative imposes over another treatment is compared with the additional effect, benefit, or outcome it provides.

$$\text{ICER} = \frac{\text{cost}_A (\$) - \text{cost}_B (\$)}{\text{effect}_A (\%) - \text{effect}_B (\%)}$$

This formula yields the additional cost required to obtain the additional effect gained by switching from drug A to drug B.

Cost-Effectiveness Analysis

➤ Problem:

➤ To determine the lowest cost per unit of effectiveness of eardrops treatments for patients with impacted earwax using CEA

➤ *Operational definitions :*

➤ Cost-effectiveness = net cost/net effectiveness

➤ Net effectiveness \equiv adverse outcomes averted

➤ Net cost = sum of the cost of drugs and cost due to side effects and noncompliance treatments

- **Outcome measurements desired:**

Estimating cost-effectiveness for three common eardrops used for the resolution of impacted earwax in 500 outpatients in our organization

Rx a: polypeptide oleate mixture (6ml)

Rx b: carbamide peroxide (15ml)

Rx c: mineral oil and hydrogen peroxide USP

(15ml of each prepackaged separately)

- **Assumptions and conditions:**

Medications and packaged costs are the same as in CMA Example

	Rx a	Rx b	Rx c*
Acquisition cost:	\$21.26	\$1.25	\$0.06
Dispensing costs (parts & labor)	\$6.00	\$6.00	\$7.00

*Note: *: (Rx c requires filling the liquids in two containers; thus we assign an cost.)*

Assumptions:

1. Treatment is for patients with impacted earwax, with no history perforated eardrums
2. Adverse outcome is averted; i.e., impacted earwax was removed successfully without problems.
3. Number of outpatients treated is 500
4. Costs of treatment depends on the effectiveness of each choice-direct side-effect costs and noncompliance costs are to be included as follows:

Notes → *Side effects* Side effects require extra visits

- Costs are \$70 per visit:

Visits caused by local irritation:

	Rx a*	Rx b	Rx c
Per 500 patients:	30	5	5

**Rx a has been reported to cause more irritations*

Compliance failures Compliance failures require extra prescriptions to re- treat. Repeat prescriptions for re-treating non-adherence are:

	Rx a*	Rx b	Rx c
Per 500 patients:	25	50	100

(Note: Mineral Oil and Peroxide Rx c are used p.m. and a.m. respectively; i.e., more difficult to comply. Polypeptide oleate (Rx a) requires the least applications

Calculations

	Rx a	Rx b	Rx c
<i>Side effect costs:</i>			
Extra visits/500 patients	30	5	5
Cost of visits @ \$70	\$2,100	\$350	\$350
<i>Compliance failure costs:</i>			
Repeat Rx's/500 patients	25	50	100
Cost per Rx (from Example 1)	\$27.26	\$7.25	\$7.06
Cost of repeat Rx's	\$681.50	\$362.50	\$706.00
<i>Net costs</i>			
Drug costs for 500 patients	\$13,630.00	\$3,625.00	\$3,530.00
+ side effect costs	\$2,100.00	\$350.00	\$350.00
+ compliance failure costs	\$681.50	\$362.50	\$706.00
Total	\$16,411.50	\$4,337.50	\$4,586.00

Outcomes measured:

Cost-effectiveness or net costs for resolving impacted earwax for 500 patients in our organization are

Rx a	Rx b	Rx c
\$16,411.50	\$4,337.50	\$4,586.00

Note: Based on a cost of illness (untreated) was \$47,000.00, so the medication intervention gave us cost savings of (subtracting from above)

Rx a	Rx b	Rx c
\$30,588.50	\$42,662.50	\$42,414.00

Outcome findings Cost-effectiveness of the three eardrops by ratio

Rx a	Rx b	Rx c
\$16,411.50	\$4,337.50	\$4,586.00
3.78	1.00	1.06

- Rx b is the most cost-effective; Rx a is the least cost-effective. However, it is still saving \$30,588.50 compared with cost of illness
- Note: Rx c, the cost-minimization champion in Example 1, is not the most cost-effective
 - We should now appreciate how outcomes differ with the use of different models for drug impact analysis

WEEK 10

Cost-Benefit Analysis (CBA)

4. Cost-Benefit Analysis

- Evaluation technique for comparing the value of all resources consumed (**costs**) in implementing a program or intervention against the value of the outcome (**benefits**) from that program or intervention.
- Outcomes of alternative interventions is valued in monetary units (\$) thus you can compare alternatives with different outcomes.
- Scope of analysis is usually broad, addressing large societal issues.

4. Cost-Benefit Analysis

Two methods are used for CBA.

All costs and benefits are expressed in dollars.

There are two ways to express the results:

1. Calculate the **Benefit to Cost ratio (B:C)** for each action

$$\frac{\text{Benefit (\$)}}{\text{Cost (\$)}}$$

2. Or calculate the **Net Benefit**
= Benefit (\$) – Cost (\$)

➤ Choose alternative with the largest value.

Guidelines for the interpretation of this ratio are indicated:

- ▶ If the **B:C ratio is greater than 1**, the program or treatment is of value. The benefits realized by the program or treatment alternative outweigh the cost of providing it.
- ▶ If the **B:C ratio equals 1**, the benefits equal the cost. The benefits realized by the program or treatment alternative are equivalent to the cost of providing it.
- ▶ If the **B:C ratio is less than 1**, the program or treatment is **not economically beneficial**. The cost of providing the program or treatment alternative outweighs the benefits realized by it.

Examples of questions CBA may address

- AIDS prevention and awareness programs
- Smoking cessation intervention
- Diabetes drug adherence
- Breast cancer screening

Steps in Conducting a Cost-Benefit Analysis

Step 1

- to identify clearly the intervention(s), program(s), or therapeutic regimen(s) to be evaluated

Step 2

- to identify and value all of the resources consumed or costs of providing each intervention, program, or regimen. Different types of resources should be recognized

Step 3

- Benefits are identified and valued in the third step.
- If the benefit of an intervention is lives saved, a monetary value must be assigned to those lives

Step 4

- ▶ to sum the value of all the cost and then sum all the benefits of each program, intervention, or regimen. Total costs then may be subtracted from total benefits to determine net benefits:

Net Benefits = Total Benefits – Total Costs

- ▶ Some investigators prefer to compute a cost-to-cost ratio. Although the analytic approach is commonly called CBA, calculation a benefit-to-cost ratio frequently is appropriate because the total benefits are usually expected to exceed total costs, producing a ration of greater than 1:1

Benefit-to-Cost Ratio = Total Benefits/Total Cost

Table 1. Simplified Cost-Benefit Analysis Applied to Drug Therapy

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Variable	Cost	
	Drug A	Drug B
Cost		
acquisition cost	300	400
administration	50	0
monitoring	50	0
adverse effects	100	0
Subtotal	500	400
Benefit		
Days at work	1000	1000
Extra months of life	2000	3000
Subtotal	3000	4000
Benefit-to-cost ratio	3000/500 = 6:1	4000/400 = 10:1

Cost Benefit Analysis

➤ **Problem:**

- Comparison of two medication regimens for resolving an infection by means of CBA

➤ **Outcome measurement:**

- To compare the costs/benefits of two regimens of antibacterials in resolving an infectious disease in a 30-bed unit of our hospital
 - One regimen uses parenteral antibacterials only; the other regimen uses a combined regimen of parenteral and oral antibacterial.

Assumptions:

1. This was in a hospital with 30 beds in a unit fully used for each regimen
2. Total hospital costs per bed-day were: (a) \$700 for combination therapy & (b) \$720 for parenteral therapy
3. The combination therapy resulted in an average hospital stay of 8 days, and parenteral therapy resulted in an average hospital stay of 12 days.
4. The combination regimen was found to produce a cure rate of 88%, a failure rate of 5%, and partial resolutions of 7%. The parenteral regimen had a cure rate of 90%, a failure rate of 7%, and partial resolutions of 3%.

Calculations:

– The benefits (cure rate or problem resolution) of the two regimens were so close that, for the purpose of our discussion, we consider them equal without going into statistical discussions. Thus, the denominators in the equations that follow are equal:

- Cost-benefit ratio for combination therapy=
 $8 \text{ days} \times 30 \text{ beds} \times \$700/\text{bed-day} = \$168,000/\text{benefit}$
- Cost-benefit ratio for parenteral therapy=
 $12 \text{ days} \times 30 \text{ beds} \times \$720/\text{bed-day} = \$259,200/\text{benefit}$

Comparing the cost-benefit ratios of the two regimens
combination: parenteral = 168,000: 259,200

Outcome measurements:

Our cost-benefit analysis shows that combination therapy compares favorably to parenteral therapy in the ratio of 168,000/ 259,200, or 0.648 to 1.00, in our service unit for treating 30 patients.

Note: that if the benefits (outcome of treatment for the two regimens) were not equal, we would need to calculate the benefits in each denominator for each regimen to allow us to express them as ratios.

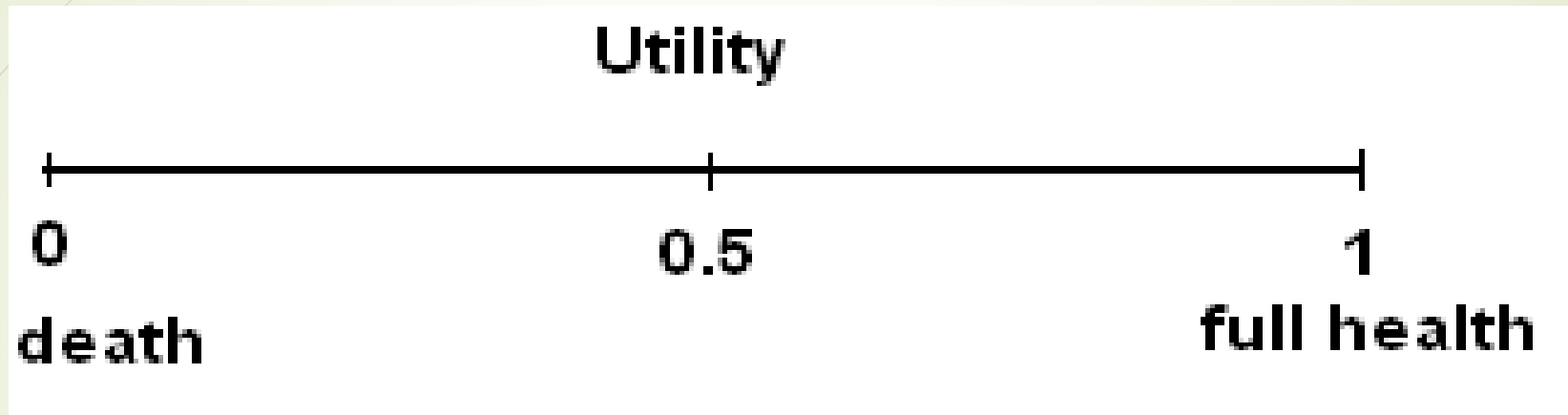
WEEK 11

Cost-Utility Analysis (CUA)

Cost-Utility Analysis (CUA)

- CUA is a formal economic technique for assessing the efficiency of healthcare interventions
 - It is considered by some to be a specific type of CEA in which the measure of effectiveness is a utility- or preference adjusted outcome
 - Utility is the value or worth placed on a level of health status, or improvement in health status, as measured by the preferences of individuals or society
- CUA, incorporates the quality of (or preference for) the health outcome achieved
 - CUA, using QALYs gained as the outcome measure, is the most common approach to combining quantity and quality-of-life outcomes in economic evaluations

Quality Adjusted Life Years



- $\text{QALY} = \text{Utility} \times \# \text{ years in health state}$
- One year at full health $\text{QALY} = 1.0$
- Death $\text{QALY} = 0.0$
- 3 years disabled ($U = 0.5$) = 1.5 QALYs

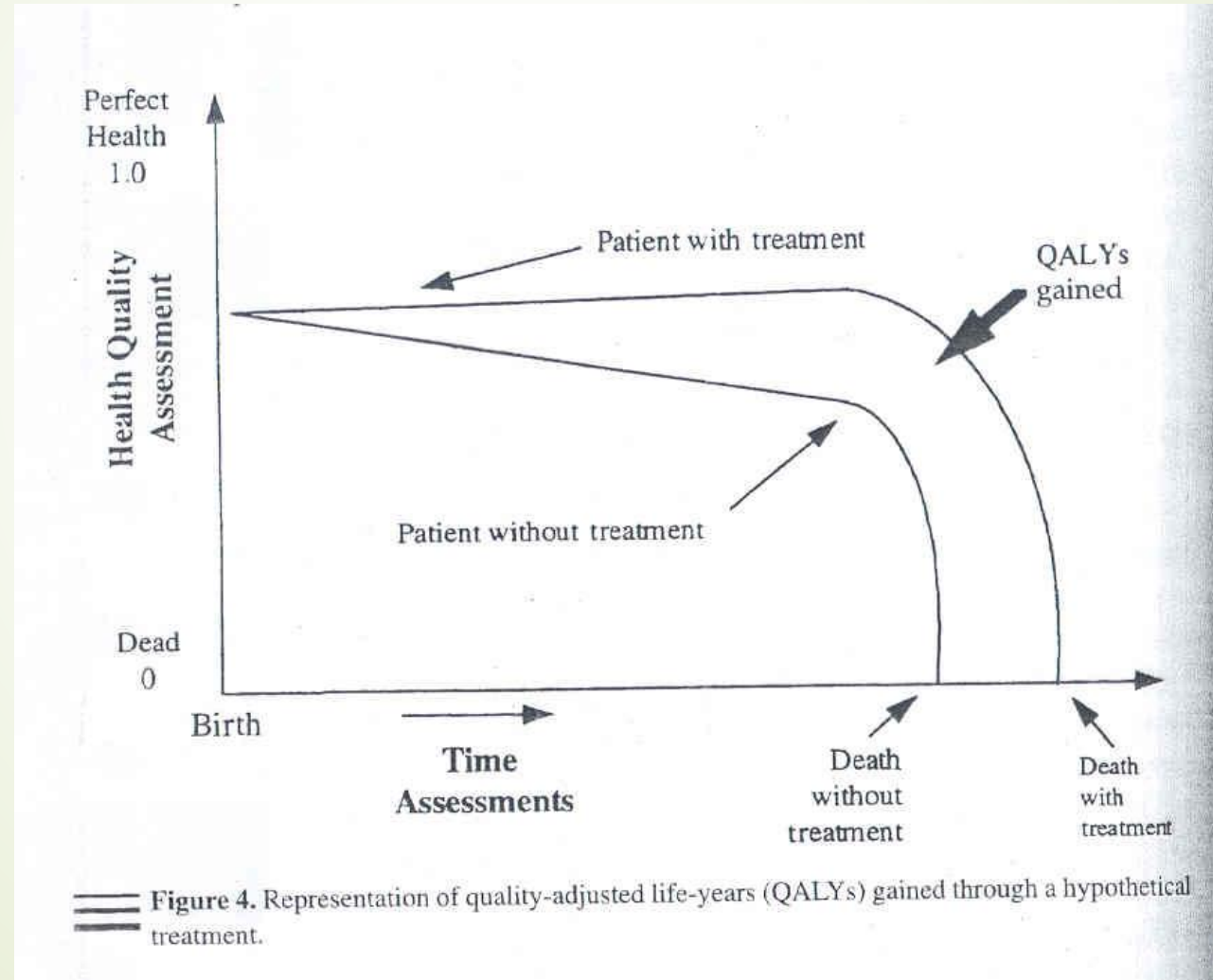
Application of CUA

- CUA is the most difficult and expensive economic evaluation method to use
- CUA should be used when QoL is the important outcome:
 - Psychological well-being, physical and social function are important in the treatment of arthritis
 - Chemotherapy may increase survival but decrease well-being, both quality and quantity of life are important

Impact of Pharmaceutical Interventions

- Pharmaceutical interventions are critical components of health care
 - Pharmaceuticals can produce QALYs by lengthening life, improving the quality of life, or both

Cost-Utility Analysis and Healthcare Interventions



Humanistic Evaluation Methods

- Pharmacoeconomic evaluations also may focus on humanistic concerns.
- Methods for evaluating the impact of disease and treatment of disease on a patient's *health-related quality of life (HRQOL)*, patient preferences, and patient satisfaction are all growing in popularity and application to pharmacotherapy decisions.
- These methods also can assist clinicians in quantifying the value of pharmaceuticals.

- **HRQOL** has been defined as the assessment of the functional effects of illness and its consequent therapy as perceived by the patient.
- These effects often are displayed as physical, emotional, and social effects on the patient.
- Measurement of **HRQOL** usually is achieved through the use of patient-completed questionnaires.
- Many questionnaires are available, and most are either disease-specific or generic measures of health status.

WEEK 12-15

Criteria for selecting Pharmaco-Economics study methods



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Criteria for selecting pharmaco-economic study methods

Research Question for Comparing Therapies	Appropriate method
<ul style="list-style-type: none">• Similar therapies producing essentially identical outcomes	<ul style="list-style-type: none">• Cost minimization analysis (CMA)
<ul style="list-style-type: none">• Different therapies resulting in clinically different patient outcomes	<ul style="list-style-type: none">• Cost-effectiveness analysis (CEA)
<ul style="list-style-type: none">• Similar therapies affecting quality of life or patient preference for treatment	<ul style="list-style-type: none">• Cost utility analysis (CUA)
<ul style="list-style-type: none">• Comparison of different programs with different outcomes (for resource allocation decisions)	<ul style="list-style-type: none">• Cost-benefit analysis (CBA)

Comparison of Pharmacoeconomic Methods

Method	Cost unit	Outcomes measure	Interpreting study results
CMA	dollar	<ul style="list-style-type: none"> Assumed to be equal 	<ul style="list-style-type: none"> Choose product with lowest cost
CEA	dollar	<ul style="list-style-type: none"> Natural clinical units 	<ul style="list-style-type: none"> Lowest cost per unit of effectiveness
CUA	dollar	<ul style="list-style-type: none"> QALYs 	<ul style="list-style-type: none"> Cost per QALY relative to other treatments
CBA	dollar	<ul style="list-style-type: none"> dollar 	<ul style="list-style-type: none"> Ratios of greater than 1.0

		COSTS		
		Higher	Same	Lower
BENEFITS	Higher	<i>Evaluate</i>	Accept	Accept
	Same	Reject	<i>Indifferent</i>	Accept
	Lower	Reject	Reject	<i>Evaluate</i>

FIGURE 2.1. Pharmacoeconomic outcomes. *Source: S. Salek, Pharmacoeconomics and Outcome Assessment: A Global Issue* (Haslemere, UK: Euromed Communications Ltd., 1999) p. 110.

Strategies to Incorporate Pharmacoeconomics into Pharmacotherapy


- Various strategies are available to incorporate pharmacoeconomics into pharmacotherapy.
- Following three strategies are used for assessing the pharmaceutical products and services:
 1. Published pharmacoeconomic studies,
 2. Building economic models, and
 3. Conducting pharmacoeconomic research.

Table 3. Advantages and Disadvantages of Pharmacoeconomic Application Strategies

S. No	Strategy	Advantage	Disadvantage
1	Use published literature	<ul style="list-style-type: none"> • Quick • Inexpensive • Subject to peer review • Results can be from RCT (Randomized Controlled Trial) • Variety of results can be examined 	<ul style="list-style-type: none"> • Results from RCT • Difficult to generalize results • May not be comparative • Misuse of pharmacoeconomic terms • Variations in rigor/quality
2	Build an economic model	<ul style="list-style-type: none"> • Quick • Relatively inexpensive • Yields organization-specific results • Bridges efficacy and effectiveness • Data collection is unobtrusive 	<ul style="list-style-type: none"> • Results dependent on assumptions • Potential for researcher bias • Controversial • Reluctance of decision makers to accept results
3	Conduct a Pharmacoeconomic study	<ul style="list-style-type: none"> • Flexible • Usually comparative • Yields organization-specific data • Reflects “usual care” or effectiveness • Data from multiple sources can be 	<ul style="list-style-type: none"> • Expensive • Time consuming • Difficult to control and randomize • Potential for patient selection bias • Potential for small sample size

1. Use the Pharmacoeconomic Literature

- ▶ Quantifying the value of pharmaceuticals through pharmacoeconomics has increased in popularity.
- ▶ Many pharmacoeconomic analyses are published in primary medical and pharmacy literature sources.
- ▶ Over the past 30 or more years, the actual number of pharmacoeconomic studies published exceeded 35,000 in 1993.

- 
- However, the eagerness to conduct pharmacoeconomic evaluations of drugs often exceeds the quality of these evaluations. Variations in quality and indiscriminate use of pharmacoeconomic terminology are documented in medical and pharmacy literature sources.
 - To use this literature as an aid in clinical decision making, it must be
 - (1) Critically evaluated for quality and rigor and
 - (2) Interpreted correctly.
 - Therefore, prior to using pharmacoeconomic data to make clinical and policy decisions, decision makers should recognize the potential limitations of those data.


- 
- To enhance the ability to use pharmacoeconomic results published in the literature, consider the following points:
- What is the technical merit of the study?
 - Are the results applicable to local decision making?
 - Do the results apply generally in different jurisdictions with different perspectives?
-
- These guidelines and criteria have been combined and summarized into 11 categories most pertinent to pharmacotherapy.
 - A summary of these 11 criteria and pertinent questions for each category are given in **Table 4**.

Table 4. Basic Criteria for Evaluation of Pharmacoeconomic Literature

S. No.	Criteria	Parameters
1	Objective	<ul style="list-style-type: none">• What is the question(s) being considered?• Is the question clear, defined, and measurable?
2	Perspective	<ul style="list-style-type: none">• What is/are the perspective(s) of the analysis?• Is the perspective appropriate given the scope of the problem?
3	Pharmaco-economic method	<ul style="list-style-type: none">• What pharmacoeconomic tool was used?• Is it appropriate given the problem?• Is it actually what was conducted?
4	Study design	<ul style="list-style-type: none">• Were all appropriate alternatives considered and described?• Were any appropriate alternatives omitted?• Are the alternatives relevant to the perspective and clinical nature of the study?• Is there evidence that the alternatives' effectiveness has been established?

Continued..... Table 4. Basic Criteria for Evaluation of Pharmacoeconomic Literature

5	Choice of interventions	<ul style="list-style-type: none">• Were all appropriate alternatives considered and described?• Were any appropriate alternatives omitted?• Are the alternatives relevant to the perspective and clinical nature of the study?• Is there evidence that the alternatives' effectiveness has been established?
6	Costs and consequences	<ul style="list-style-type: none">• What are the costs and consequences (outcomes) included?• Are the costs and outcomes relevant to the perspective chosen?• Do they include negative outcomes (failures, ADRs)?• How were they valued?• Were costs and consequences measured in the appropriate physical units?
7	Discounting	<ul style="list-style-type: none">• Was the study performed over time?• Were costs and consequences that occur in the future discounted to their present value?• Was any justification given for the discount rate used?

Continued.....Table 4. Basic Criteria for Evaluation of Pharmacoeconomic Literature


8	Results	<ul style="list-style-type: none">• Are the results accurate and practical for medical decision makers?• Were the appropriate statistical analyses performed?• Was an incremental analysis performed?
9	Sensitivity analysis	<ul style="list-style-type: none">• Are the cost ranges for significant variables tested for sensitivity?• Are the appropriate and relevant variables varied?• Do the findings follow the anticipated trend?
10	Conclusions	<ul style="list-style-type: none">• Are the conclusions of the study justified?• Is it possible to extrapolate the conclusions to daily clinical practice?
11	Sponsorship	<ul style="list-style-type: none">• Was there any bias due to the sponsorship of the study?

2. Build an Economic Model

- ▶ Modeling studies use *existing clinical and/or epidemiologic data* to project future outcomes.
- ▶ Use of economic models can provide support for various clinical decisions, especially those which are *time-contingent*.
- ▶ Identifying assumptions regarding the *treatment alternatives being compared*, the *patient outcomes under study*, and the probability of those outcomes occurring can provide the basis for an economic simulation to *assist in the medication decision-making process*.
- ▶ Using an economic model can help the clinician to forecast the impact of medication-use decisions on a patient, institution, or healthcare system.

3. Conduct a Pharmacoeconomic Evaluation

- Clinicians may need to conduct a pharmacoeconomic evaluation if there is:
 - Insufficient literature,
 - Published results cannot be extrapolated to clinical practice, or
 - Building a model is not appropriate.
- Thus this strategy should be reserved for pharmacy decisions that may have a significant impact on cost and/or quality of care.

- 
- The resources necessary and the type of evaluation conducted will vary depending on the research question and on whether one is conducting a **prospective** outcomes analysis or a **retrospective** database analysis.

Prospective analysis

- A prospective study watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor(s).

Retrospective analysis

- A retrospective study looks backwards and examines exposures to suspected risk or protection factors in relation to an outcome that is established at the start of the study.

Table 5. Advantages and Disadvantages of Retrospective and Prospective Analyses

Analysis Type	Advantages	Disadvantages
Prospective observational analysis	<ul style="list-style-type: none"> • Flexible • Yields provider-specific data • Reflects “usual care” or effectiveness • Usually offer comparative data • Data from multiple sources can be used • Less expensive than randomized controlled trials • Prospective 	<ul style="list-style-type: none"> • Prospective • Expensive (time and money) • Difficult to control and randomize • Potential for patient selection bias • Small sample size • Difficulty generalizing results to other providers • Longer timeframe
Retrospective database analysis	<ul style="list-style-type: none"> • Has potential for large sample size • Can provide data quickly • Is customer specific • Reflects ‘usual care’ or effectiveness • Relatively inexpensive • Shorter timeframe • Data collection is unobtrusive 	<ul style="list-style-type: none"> • Retrospective • Inconsistent coding/upcoding • Variations in database quality among managed care plans • Inconsistent access to pharmacy versus medical claims • Inability to randomize patients to treatment



➤ Limitations of pharmacoeconomic research:

- Lack of institutional resources,
- Small sample sizes,
- Difficulty randomizing,
- Inability to compare with placebo, and
- Difficulty generalizing results all may be limitations.

Steps for conducting a Pharmacoeconomic Analysis

Step 1: Define the Pharmacoeconomic Problem

- Identify the disease state and what aspect you want to deal with.
- i.e. What is the most cost effective method for controlling glucose in the treatment of type II diabetes?



Step 2: Assemble a Cross-Functional Study Team

- ▶ The study team can provide early buy-in and additional resources for a pharmacoeconomic evaluation.
- ▶ Team members vary depending on the analysis but can include representatives from medicine, nursing, pharmacy, hospital administration, and information systems.




Step 3: Define the Appropriate Study Perspective

- ▶ Choose a study perspective(s) most relevant to the problem.
- ▶ For example, if the problem is as listed in step 1, then the perspective of the institution or healthcare system may be most appropriate.



Step 4: Identify Treatment Alternatives and Outcomes

- ▶ Treatment alternatives can include pharmacologic and nonpharmacologic options but should include all clinically relevant alternatives. The outcomes identified should include both positive and negative clinical outcomes.



Step 5: Identify the Appropriate Pharmacoeconomic Method to Employ

- Pharmacoeconomic methods to choose from include CMA, CBA, CEA, and CUA.
- Employing the incorrect method can adversely affect medication decisions influencing both cost and quality of care.



Step 6: Place a Monetary Value on Treatment Alternatives and Outcomes

- ▶ Placing a monetary value on treatment alternatives and outcomes includes not only drug administration and acquisition costs but also the cost of positive and negative clinical outcomes (e.g., determining the cost of ADRs and treatment failures).
- ▶ This can be measured prospectively or retrospectively or estimated using comprehensive databases or expert panels.



Step 7: Identify Resources to Conduct Study in an Efficient Manner

- Resources necessary will vary by study but can include access to medical or computerized records, average medical personnel wages, and specialty medical staff.

Step 8: Identify Probabilities that Outcomes May Occur in the Study Population

- What are the probabilities of the outcomes identified in step 4 actually occurring in clinical practice ?
- Using primary literature and expert opinion, these probabilities can be obtained and may be manifested as efficacy rates and incidence of ADRs.
- **Typical outcomes used include:**
 - cure rate (percent cured of illness)
 - improved quality of life
 - decreased incidence of morbidity
 - years of extended life
 - relief or reduction in symptoms
 - no effect
 - Adverse events (drug interactions and side-effects)
 - mortality



Step 9: Employ Decision Analysis

- The use of decision analysis can assist in conducting various economic evaluations, including CEA, CBA, CUA etc.

Step 10: Discount Costs or Perform a Sensitivity or Incremental Cost Analysis

- Costs and consequences that occur in the future must be discounted back to their present value.
- Sensitive variables must be tested over a clinically relevant range and results recalculated.
- If appropriate, an incremental analysis of the costs and consequences should be performed.

Discounting

- ▶ If the analysis spans more than a year, then the dollar values must be adjusted to a common point in time.
- ▶ Discounting adjusts future costs or benefits using an expected interest or **discount rate**.
- ▶ **Present Value = Future value**

$$(1+r)^n$$

where r = discount rate (typically ranges from 0.03 to 0.06)

and n = the number of years in the future.



Sensitivity Analysis

- ▶ When estimating costs and outcomes, you typically have a range of possible values.
- ▶ **Sensitivity analysis** requires that the results be recalculated at the different values to see if the conclusions change.



Step 11: Present Study Results

- Results should be presented to the cross-functional team and the appropriate committees at an institution or MCO.
- Presentation style and content can vary depending on the audience.

Step 12: Develop a Policy or an Intervention

- Take the study results and develop a policy or an intervention that can improve or maintain quality of care, possibly at a cost savings.



Step 13: Implement Policy and Educate Professionals

- Spend adequate time and resources strategically implementing the policy or intervention.
- Educate the healthcare professionals most likely to be affected by this policy using various strategies, including verbal, written, and online communication.

Step 14: Follow-Up Documentation

- Once the intervention or policy has been implemented for a reasonable period of time, collect follow-up data.
- These data will provide feedback on the success and quality of the policy or intervention.

Thank You