• The criteria for PE study are needed to know for evaluating, conducting and reporting PE literature and data.

□ Uses of the literature:

It is useful in:

• As an aid in clinical decision making
• In understanding the potential effect of therapy
• In understanding the transition from efficacy to efficiency in clinical practice
• To evaluate, interpret and transfer the results to other health care setting and countries.

The important criteria for pharmacoeconomics study are as follows: OPMOI CD RS CSC

1. Study objective
2. Study perspective
3. Pharmacoeconomics method
4. Study design
5. Choice of intervention

6 Costs and consequences
7. Discounting
8. Study results
9. Sensitivity analysis
10. Study conclusion
11 Sponsorship and bias
12 Use of comparator

1. Study objectives:

- A clear statement of the purpose of study should be given. This objective should be clear, concise, well defined and measurable.

2. Study perspective.

- The researcher must select one or more perspective (patient, provider, payer or society) This perspective should be appropriate given the scope of the Pharmacoeconomics problem identified.
- Based on the perspective there can be variation in the cost.

Eg. In the study of cost-of-illness

Pts of payer and Pts provider (company/insurance agency)

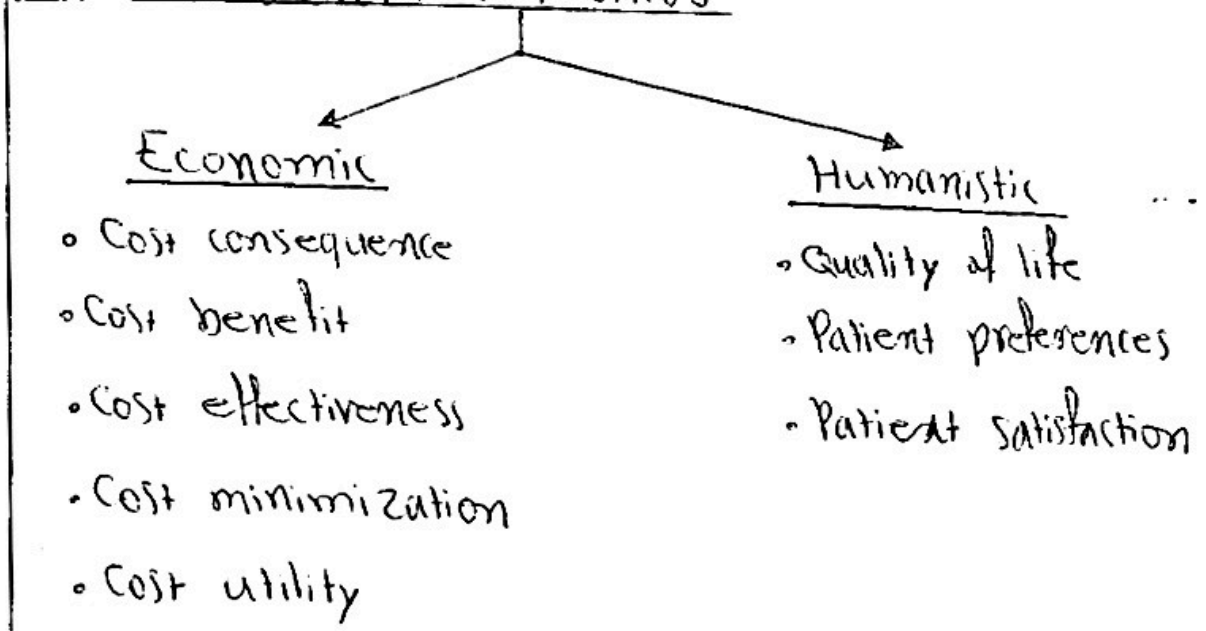
↓

Choice of drug and service varies

↓

Variation in the cost

3. Pharmacoeconomic Method:



• The method selected for the study should be clearly specified (e.g. CEA, CMA, CBA, COI, CUA). The method should be appropriate to the given the problem. If the alternatives differ in therapeutic outcome,

method like CMA cannot be selected.

4. Study Design:

- Pharmacoeconomic evaluations can be retrospective or prospective. Retrospective are capable of reflecting the usual care and can be rich in information. However, prospective studies are usually preferred.
- In the case of pharmacoeconomic studies conducted as part of clinical trials, care should be taken in interpreting the data. In clinical trials, costs need not be reflective of the general practice situation as costs are often protocol driven.

5. Choice of interventions:

- All relevant treatment options that are available should be described completely. The treatment alternatives and dosages being compared should be those used in common practice and evidence of their effectiveness should be established.

6. Costs and Consequences: مناسب وواضح

All the important and relevant cost and consequences for each program or treatment alternatives should be identified. The cost and consequences identified must be relevant to the study prospective and measured in the suitable terms using the appropriate physical units.

7. Discounting:

- The comparison of treatment alternatives should be made at one point in the time. Cost and consequences that may occur in the future should be discounted to their present value.
- Discounting is the adjusting for differential timing, it is the process of reducing any costs and consequences that may occur in the future, back to their present value.

8. Study results:

A detailed discussion of the study assumption

and limitations of the study should be specified. How to interpret the result in the context of different practice settings should be mentioned.
- The result should show that the appropriate statistical analyses were performed.

9. Sensitivity analysis: 2M

- It is imperative that researchers test the sensitivity of study results using sensitivity analysis.
- Sensitivity analysis is the process of testing the robustness of an economic evaluation by examining changes in results
- SA is of paramount importance because of the very common need for investigators to use assumptions and estimates for unknown variables.

10. Study conclusion:

- The conclusions of the study should be justified properly Researchers study conclusions to clinical

practice, both internal variation and external validation should be performed.

Internal validation involves justification of the conclusion from the study.

- External validation involves the generalization of the conclusions.

11- Sponsorship and bias:

- At the time of evaluating the quality and usefulness of a study, the aspect of sponsorship should be considered properly.
- Many studies are conducted or sponsored by companies or organizations

12. Use of comparator (مقایسه‌کننده):

- A comparator becomes essential for certain pharmacoeconomics studies which compare the new drug or procedure or program with an older drug or existing intervention.
- The comparator can either be the gold standard

drug / intervention in that condition or the most commonly used drug, dosage of procedure.