

IE 485

Decision Making in Health Care

Decision making process

Decision making:

The study of **identifying** and **choosing** alternatives based on the **values** and **preferences** of the decision maker.

Making a decision implies that there are alternative choices to be considered, and in such a case we want not only to identify as many of these alternatives as possible but to choose the one that best fits with our goals, objectives, desires, values, and so on.

Decision making in health care

Healthcare related decisions

1. Large-scope decisions

- Made by policy-makers and concern all citizens
- Require considerable effort and a long process

Example: The health regulations that are made and implemented by ministry of health

2. Medium scope decisions

- Concern only a part of society

Example: Decision for a specific province or a hospital is an example for medium scope decisions.

3. Small scope decisions (Medical Decision Making)

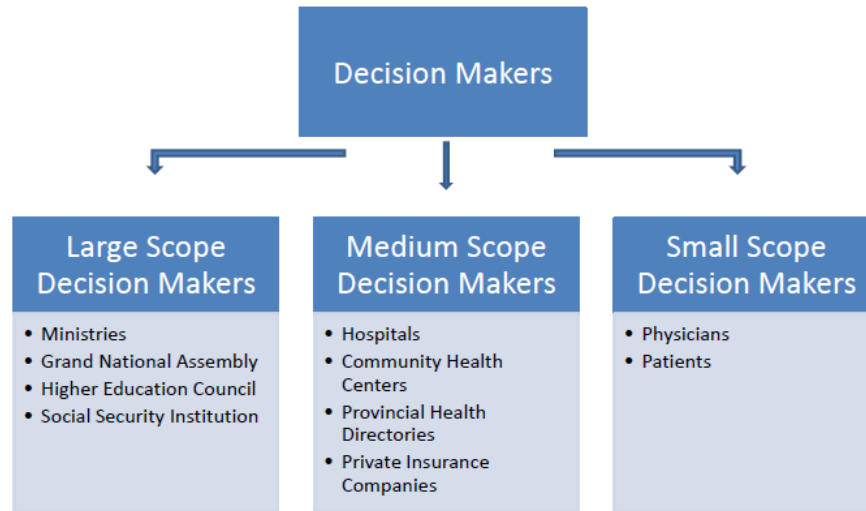
- Concern individuals and usually arise from personal choices.

Example: A treatment method that a physician decides to administer his patient

The choice of the patient among alternative treatment options can be considered as small scope decisions.

Decision making in health care

The decision makers in health care services: those who plan, provide, receive, or pay for it



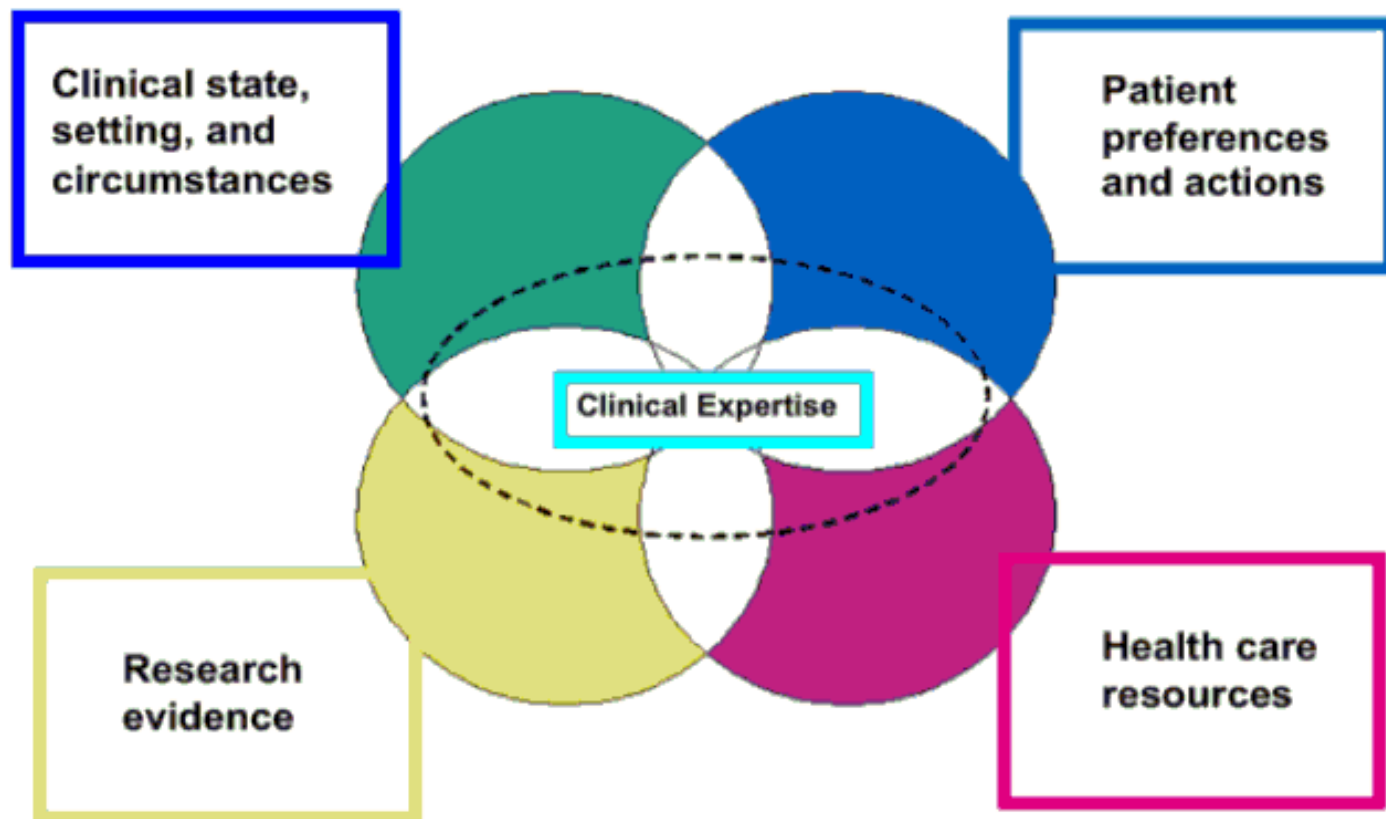
Health care policy making: MoH, SSI



Medical decision making:

Physicians must frequently choose treatment long before they know which disease is present

Even when the illness is known one must usually select from **among several treatment options** the consequences of each cannot be foretold with certainty.



Decision making in health care

Some example decision settings:

- Should clinicians check the blood pressure of each adult who walks into their offices?
- Should health care planners start a breast cancer screening programme?
- Should local health departments free scarce resources used for cancer treatments to increase the care for new-borns?

Trade-off questions

Economic evaluation in healthcare

Economic evaluation in healthcare

- There is a vast amount of literature on economic evaluation in health care
- Studies have been conducted by economists, medical researchers, clinicians, decision analysts and multidisciplinary teams

Economic evaluation in healthcare

These are examples of general, recurring questions about:

- Who should do what to whom?
- With what health care resources?
- With what relation to other health care services?

To answer these questions one should have an idea on the **relative merit or value** of the alternative courses of action they pose

Economic evaluation (efficiency evaluation) is one of the strategies whereby these estimates of relative value can be ascertained and interpreted

Economic evaluation in healthcare

Economic evaluation asks questions such as:

- Is this health procedure, service or programme worth doing compared with other things we could do with the same resources?
- Are we satisfied that the health care resources required by the procedure, service or programme should be spent in this way rather than some other way?

Economic evaluation in healthcare

Economic evaluation is necessary but **not sufficient**. Other types of evaluation that should be considered are

- Efficacy: Can it work?
- Effectiveness: Does it work?
- Availability: Is it reaching those who need it?

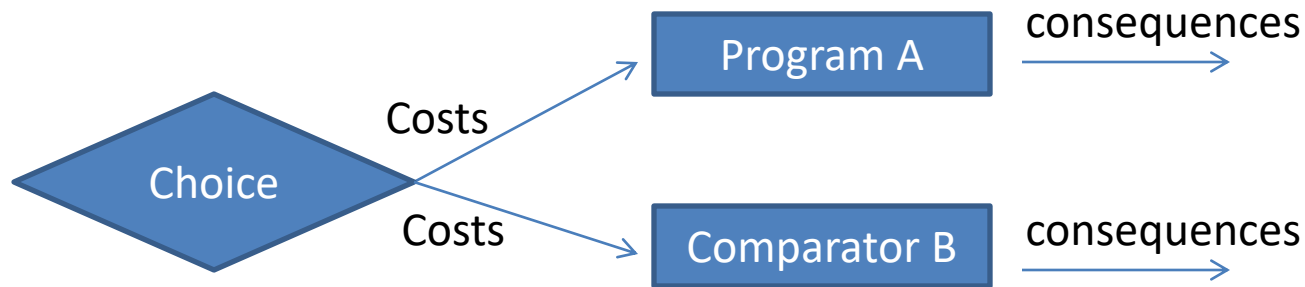
Economic Evaluation

Economic evaluation is important because it leads to organized consideration of the factors involved in a decision to commit resources to one use instead of another

- Without a systematic analysis, it is difficult to identify the relevant alternatives
- The viewpoint is important
- Some attempt at measurement is necessary to reduce the uncertainty surrounding orders of magnitude

Economic evaluation

- It is involved with **inputs** and **outputs** of activities and concerns itself with *choices*



Comparative analysis of alternative courses of action in terms of both their costs and consequences

A: Programme of interest

B: Comparator (could be doing nothing)

Difference in costs is compared with the difference in consequences, in an incremental analysis

Different forms of economic evaluation are used such as

- Cost minimization
- Cost-effectiveness analysis
- Cost-utility analysis
- Cost-benefit analysis

One should use the appropriate method for the problem at hand

Forms of economic evaluation

Type of Study	Measurement/ valuation of costs in both alts.	Identification of consequences	Measurement/ valuation of consequences
Cost-minimization analysis	Monetary value (e.g. Dollars)	Identical on all relevant respects	None
Cost-effectiveness analysis	Monetary value	Single effect of interest <i>common to both alts</i> , achieved in different degrees	Natural units (e.g. Life years gained, disability days saved, number of cases detected)
Cost-utility analysis	Monetary value	Single or multiple effects, <i>not necessarily common</i> to both alts.	Healthy years (QALYs)
Cost-benefit analysis	Monetary value	Single or multiple effects, <i>not necessarily common</i> to both alts.	Monetary value

An introduction to the basic methods

Cost Minimisation

Example 1: Two programmes involving minor surgery for adults

Both accomplish *the same outcome of interest*

One requires hospital administration for one day, one does not

Both programmes achieve the same outcome of interest (operations successfully completed) *to the same degree* (identical number of surgeries), presumably at *different costs*

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Cost Minimisation

Example 2 (Lowson et al. (1981)) Comparative analysis of three methods of providing long-term oxygen therapy in the home:



Figure 1 Sources of oxygen (gas cylinder, oxygen concentrator, and liquid oxygen).

Cost analysis is used on the grounds that effectiveness of the three methods **was not a contentious issue**.

http://www.scielo.br/scielo.php?pid=S0021-75572013000100003&script=sci_arttext&tlng=en

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Cost-Effectiveness Analysis

Example 1: Renal Failure

- Comparing the costs and consequences of two programs:

Hospital dialysis

Kidney transplantation

- Outcome of interest (***common to both programmes***): Life years gained
- The programmes may have differential success in achieving this outcome as well as differential costs.

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Cost-Effectiveness Analysis

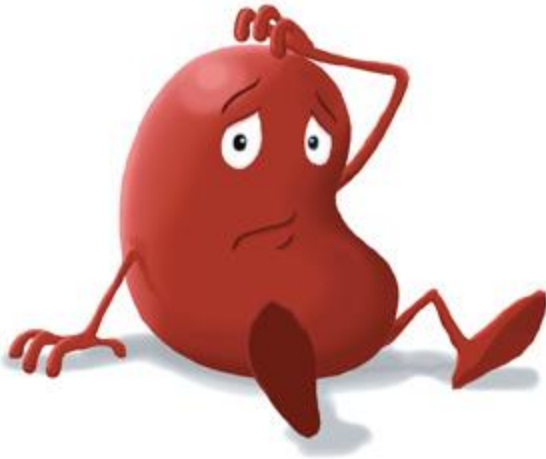
- There is usually a trade-off between success amounts and cost values (otherwise, the choice is obvious)
- Outcome: Prolongation of life
- The results may be stated in terms of :
 - Cost per unit effect (cost per life-year-gained)
 - Effect per unit cost (life years gained per dollar spent)

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Cost-Effectiveness Analysis

Note that cost-effectiveness can be used to compare any alternatives as long as they have a **common effect**

Kidney transplantation vs heart surgery if the common effect of interest is life-years saved



<http://www.beaumont.ie/kidneycentre-forpatients-kidneytransplant>

<https://www.pinterest.com/pin/467459636293838951/>

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Cost-benefit analysis

Example 1:

Suppose that the renal failure example is extended as follows:

Alternative programs

- Home dialysis

- Hospital dialysis

- Kidney transplantation

Consequences of interest

- Prolongation of life

- Quality of life

- Medical complications

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Cost-benefit analysis

Example 1:

Now we have three alternatives and also **three effects to consider**
Cost-effectiveness analysis would involve the following steps:

- Calculate cost effectiveness ratios for the three effects
- Either choose one of them as primary effect, and base comparison on this effect or find a way to combine multiple effects into a common denominator
- Attach a measure of value to the set of effects (often in terms of dollar benefits).
- Not always easy!

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Cost-benefit analysis

Example 2: Comparing the following programmes

A hypertension screening programme, aimed at preventing premature death



An influenza immunization programme, aimed at preventing disability days



The outcome of interest **differs** between alternatives

Again, attach a measure of value to the set of effects (often in terms of dollar benefits)
in order to facilitate comparison

<http://drugtopics.modernmedicine.com/drug-topics/content/how-set-hypertension-screening-program?page=full>

<http://over39.com/news/middle-aged-get-their-flu-shots>

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Cost-benefit analysis

CBA requires translating effects such as disability days avoided and life-years gained into their dollar benefit

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Cost-benefit analysis

To sum up,

Cost benefit analysis can be used in the following cases:

- Effects, though common to both alternatives, are multiple
- The effect(s) are not common to the alternatives
- The results of the analysis might be stated:
 - As a ratio of dollar costs to dollar benefits
 - Sum representing the net benefit (loss) of one programme over another

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Cost-benefit analysis

The do nothing alternative

- (In theory) CBA provides information on the absolute benefit of programmes in addition to info on their relative performance
- That is, there is an implicit assumption that the alternatives are compared to a do-nothing alternative which has no costs and no benefits
- In cost-effectiveness, however, the implicit assumption is that such an alternative does not exist
- This may lead to choosing a program which does not pay for itself. We assume that the output, in terms of health effects, is worth having and the only issue is choosing the most cost-effective one

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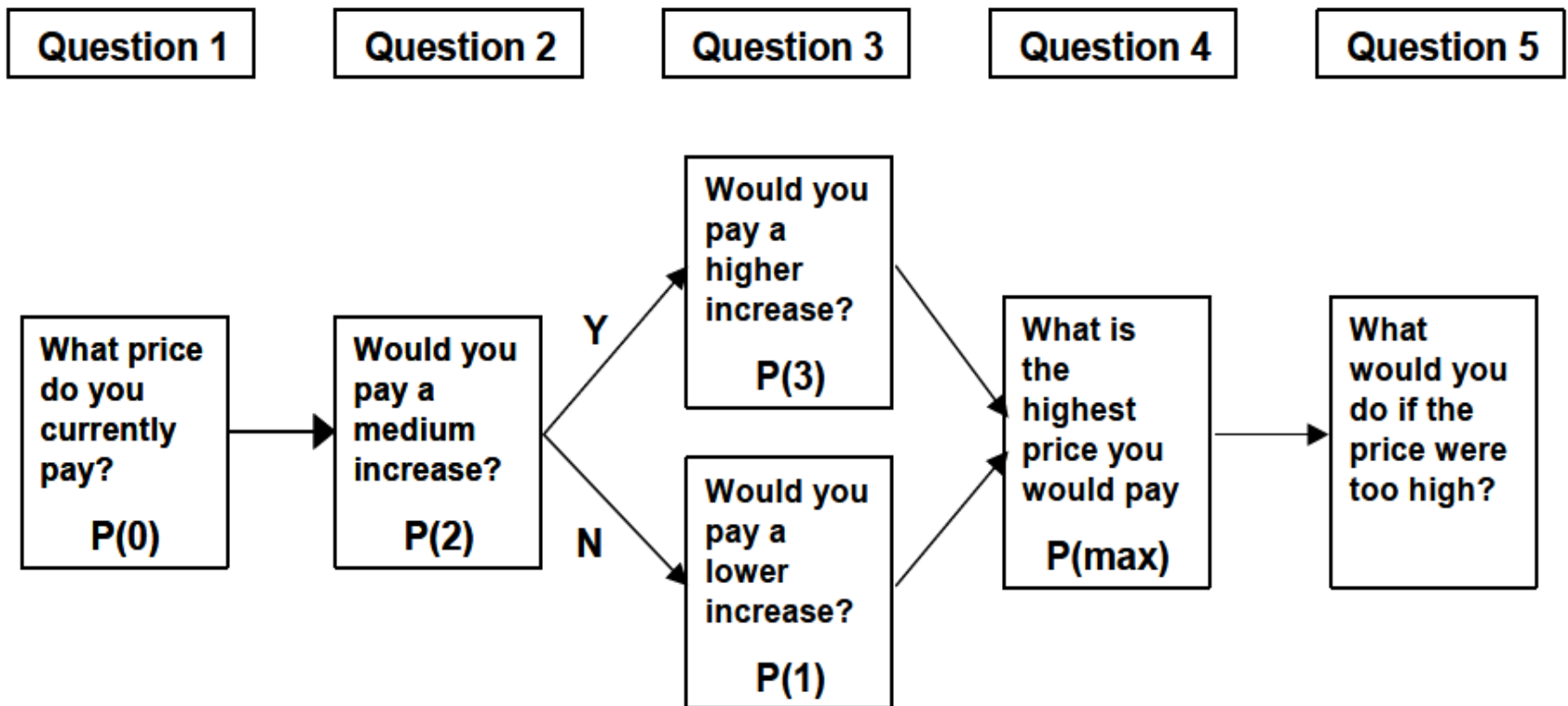
Cost-benefit analysis

- CBA requires translating effects such as disability days avoided and life-years gained into their dollar benefit
- Better to use **willingness-to-pay (WTP)** figures for health benefits if they exist
- Asking individuals directly in a hypothetical survey
 - the maximum amount they are WTP to have the commodity in question, or
 - the minimum amount they would be willing-to-accept (WTA) in compensation to be deprived of it.
- Note that if cost-benefit analysis is restricted to only those items which can be measured easily, then the resulting analysis would be narrower than cost-utility analysis

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Cost-benefit analysis

Sequence of Willingness to Pay Questions



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Cost-Utility analysis

- Valuing benefits in dollar terms is not always preferred
- An alternative measure of value is *utility*, analyses that use **utility** as a measure of the value of programme effects are called cost-utility analyses

Utility refers to: the preferences individuals or society may have for any particular set of health outcomes

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Cost-Utility analysis

Utility of an outcome, effect or level of health status differs from the outcome, effect or level of health status itself.

Example: When asked to rank a health status on a scale of 0 to 1 (0:death 1:perfect health) different people may provide different rankings

The rank of “having a broken leg” would differ between a footballer and a writer due to occupation.

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Cost-Utility analysis

Cost-utility analysis is a very useful technique because:

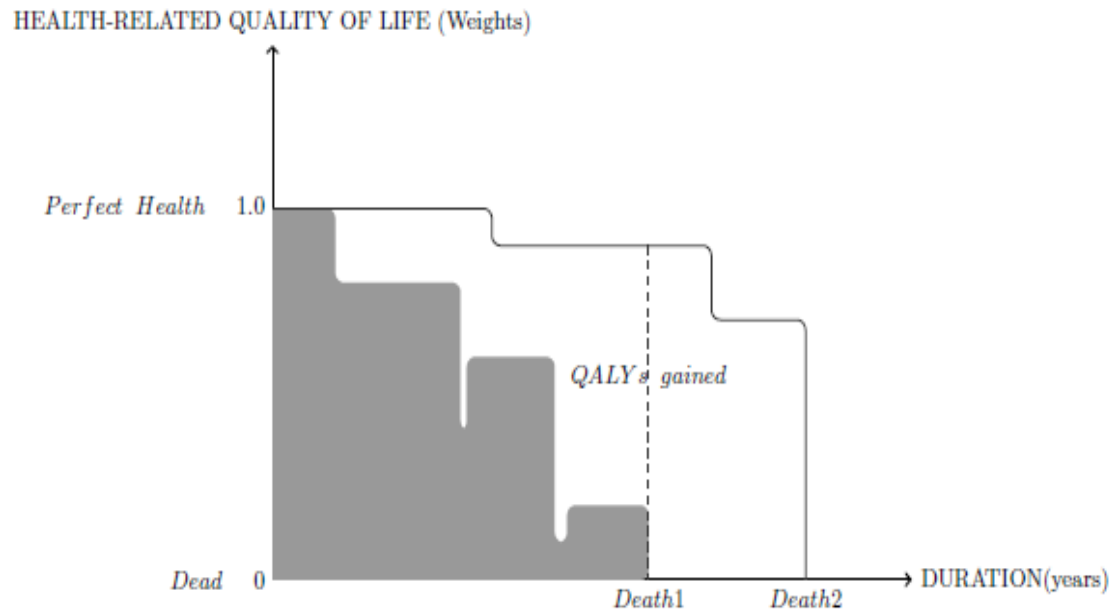
- It allows for **quality of life adjustments** to a given set of treatment outcomes
- It provides a **generic outcome measure** for comparison of different programmes
- The generic outcome is usually expressed as *Quality-Adjusted-Life-Years* (QALYs) (a very important concept for this course!!)

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Cost-Utility analysis

QALY is calculated by adjusting the *length of time affected* (through the health outcome) by the *utility value* of the resulting level of health status

(We will discuss it in detail later.)



An introduction to the basic methods

Cost-Utility analysis

The results of the cost-utility analysis are typically expressed in terms of

- Cost per healthy year

- Cost per quality-adjusted life-year

gained by undertaking one programme instead of another

Note that some authors prefer not to make a distinction between CEA and CUA

The different approaches are sometimes used together since each explores a different dimension of value

Relevant Costs and Consequences In the Economic Evaluation of Health Care Programmes

Suppose we would like to make an economic evaluation of a healthcare programme

What type of data do we need?

Table 3.—Cost Assumptions for Screening, Routine Treatment, and Complications

Screening	Cost, \$*	Reference No.
Screening		
Fasting plasma glucose test	28	13
Hemoglobin test	38	13
Oral glucose tolerance test	106	13
Routine treatment		
Drugs		
Insulin and oral agents	714/y	21, 44
Insulin	513/y	21, 44
Oral agents†	402/y	44
Self-testing		
Insulin users	222/y	16, 44
Noninsulin users	55/y	16, 44
Outpatient services		
Insulin users	618/y	13, 16
Noninsulin users	533/y	13, 16
Case management	121/y	13
Combined average costs of routine care‡	1007/y-1277/y	13, 16, 44
Complications		
Blindness (direct medical cost)	1997/y	13
Photocoagulation treatment	2682 (lifetime)	23
Eye examination	84	23
Neurologic examination	130	13
Renal examination	1129	13
End-stage renal disease	68 131/y	30
Lower-extremity amputation		
Toe (39%)	31 246	29, 45
Transmetatarsal (12%)	31 625	29, 45
Below knee (47%)	32 252	29, 45
Cardiovascular disease	2757/y	46

The cost-effectiveness of screening for type 2 diabetes
 CDC Diabetes cost-effectiveness study group JAMA,
 November 25 1998 Volume 280 No 20

Relevant costs and consequences

The appropriate form of analysis to be used depends on

- The problem at hand
- The institutional framework
- The practical measurement challenges
- Perspective the analyst takes on the role of economic evaluation

The relevant costs and consequences will be determined based on this perspective!

Three perspectives on the role of economic evaluation

Analyst A (Welfarist approach)

- Ascertain the total amount that the individuals would be willing to pay for the programme (sees individuals as the best judges of their own welfare)
- Compare this amount with the costs to see whether a programme is worthwhile

Three perspectives on the role of economic evaluation

Analyst B (Health sector budget perspective)

- The purpose is to allocate the health care budget
- Compare the resources consumed with the health improvement obtained (measured in natural units, health effects or health state preference scores)
- Willingness to pay is not very useful as it may be conditioned by individuals' ability to pay and may also reflect non-health attributes to programmes (which should not be funded as part of the health care budget)

Three perspectives on the role of economic evaluation

Analyst C (Pragmatist)

- Take a broad societal perspective, but some of the costs and consequences are easier to express in monetary terms than others
- Willingness-to-pay may reflect the prevailing income distribution
- Measure and value a wide range of costs and consequences and present them to the health care DMs in a way that helps them form a better judgement

What is the appropriate perspective?

- Different perspectives can be taken.
- The perspective will determine which outcomes and resources are relevant
- A **societal** perspective considers everyone affected by the intervention regardless of who experiences the outcomes and costs (the “veil of ignorance” concept can be used to justify this view)
- However in some cases some outcomes and costs can be reasonably omitted (e.g. A CEA done for an employer)

Components of Economic evaluation

View the various costs and consequences as **building blocks**, which can be assembled in the evaluation in various ways

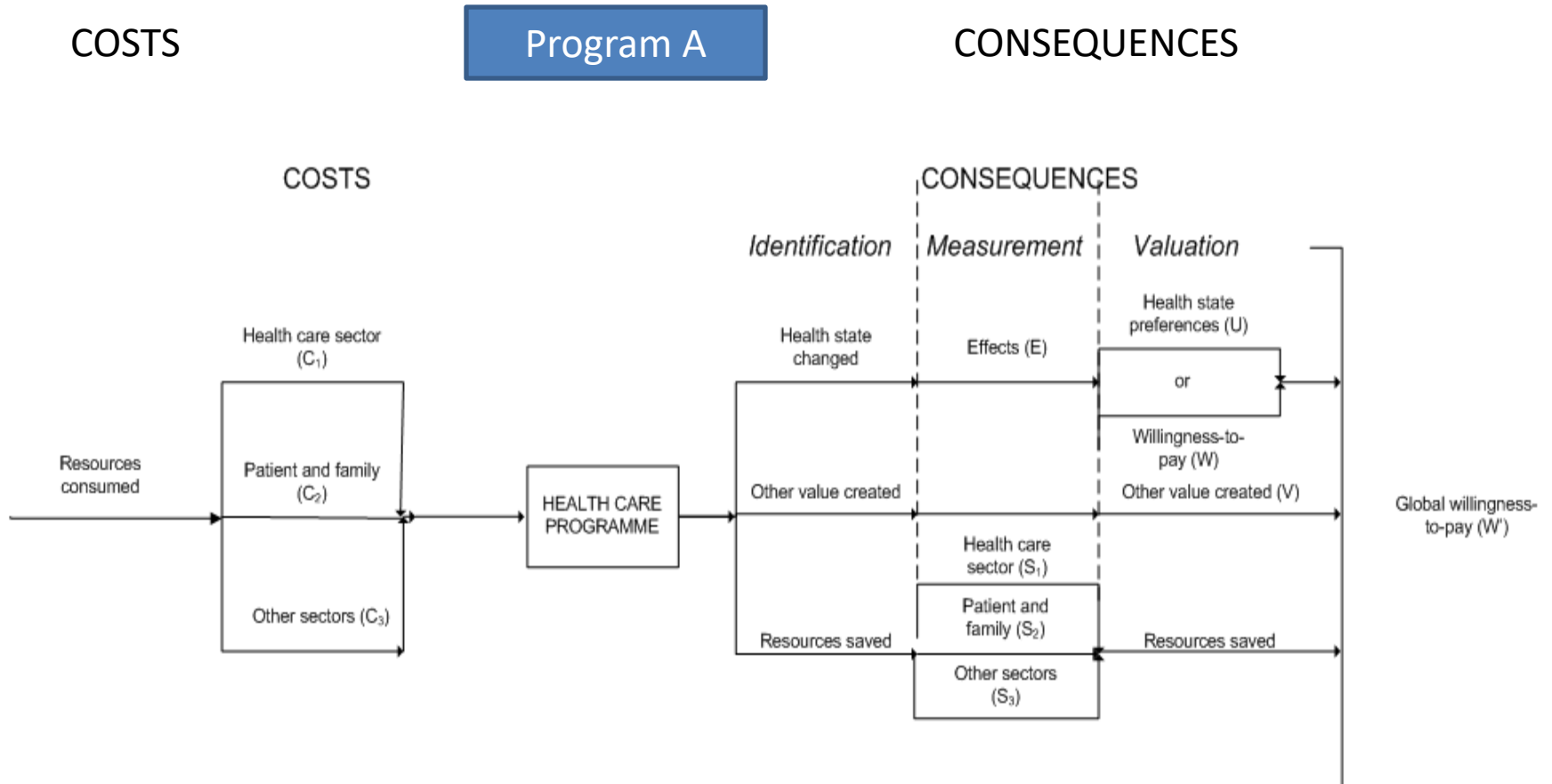
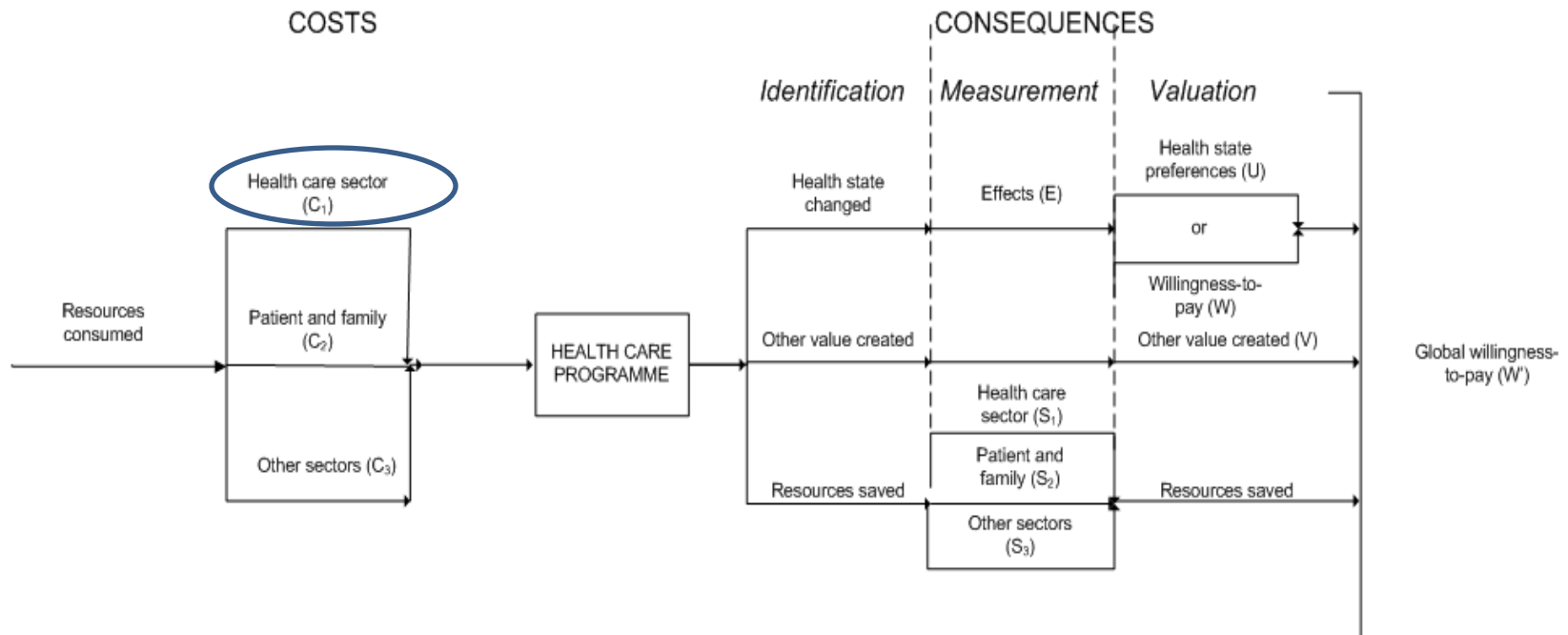


Figure 2.2. in Drummond et al. 1997

Components of Economic evaluation

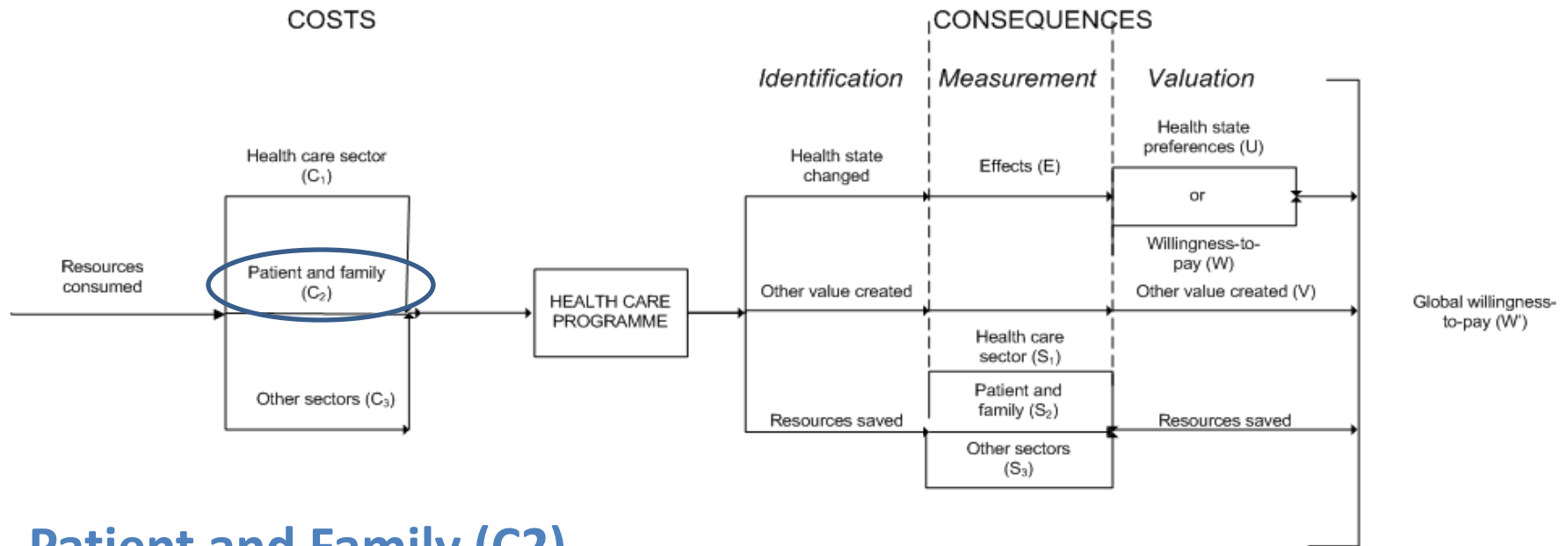


Health care sector (C_1)

Cost of drugs, equipment, hospitalization, physician visits, and so on.

In addition to the costs of providing the initial programme (e.g. kidney transplant), continuing care costs are included (e.g. Treatment of infections, Immunosuppressive drugs)

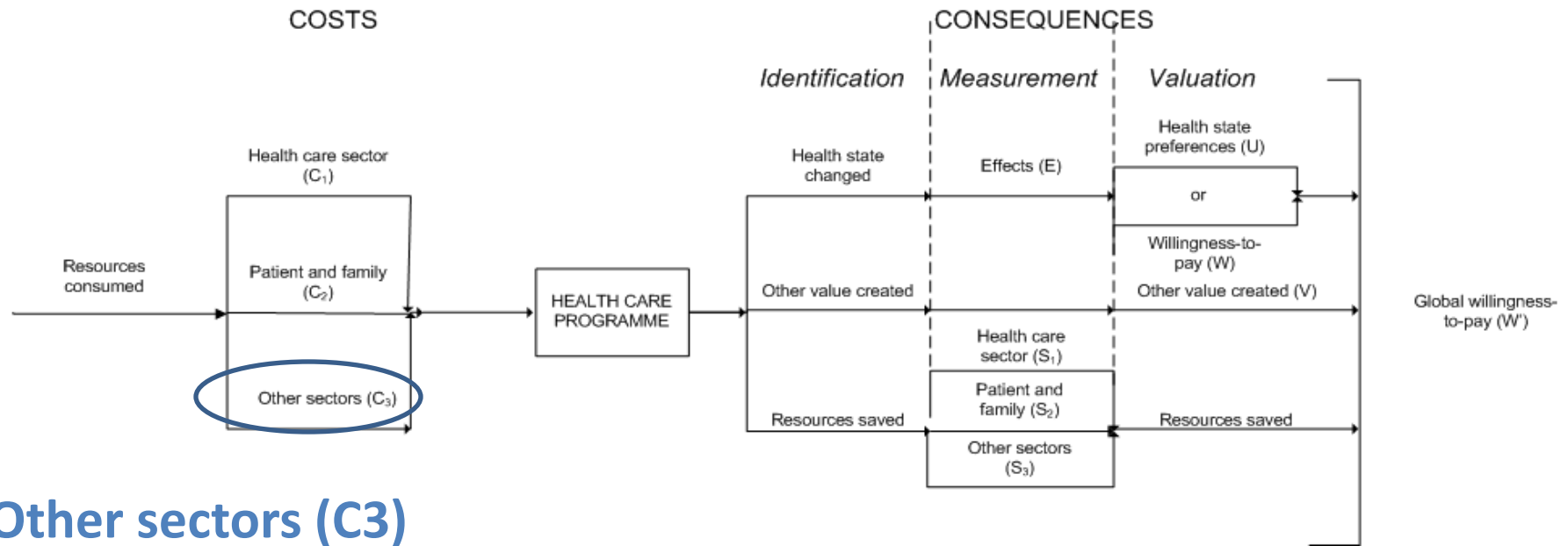
Components of Economic evaluation



Patient and Family (C_2)

- Out of pocket expenses (travelling to hospital)
- Various co-payments
- Expenditure in the home (e.g. Adopting a room to accommodate a home dialysis machine)
- Time (either from leisure activities or worktime)
 - Time of the patient in seeking and receiving care
 - Time of the family members in providing informal nursing support at home

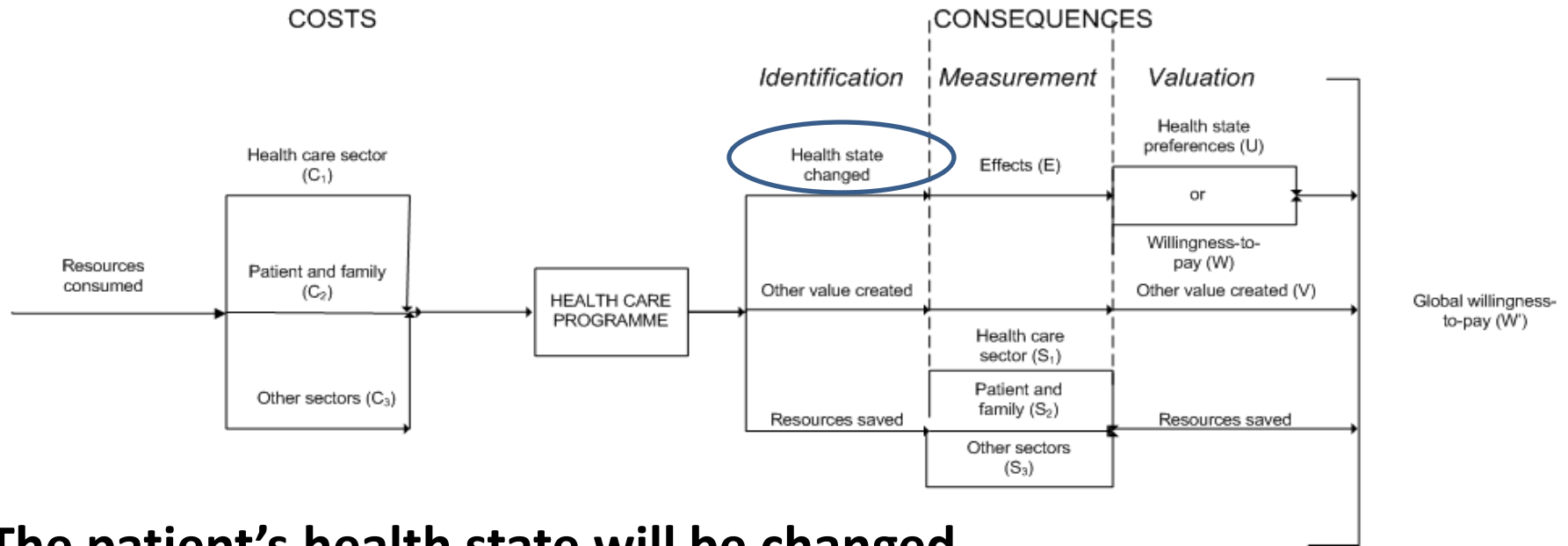
Components of Economic evaluation



Other sectors (C_3)

- Resources from other public agencies (e.g. homemaker services, nursing home care used for elderly or mentally ill)
- Resources from the voluntary sector
- A 55-mile-per-hour speed limit policy which reduces morbidity (the rate of sickness) and mortality due to accidents, but increases the price of fruit

Components of Economic evaluation

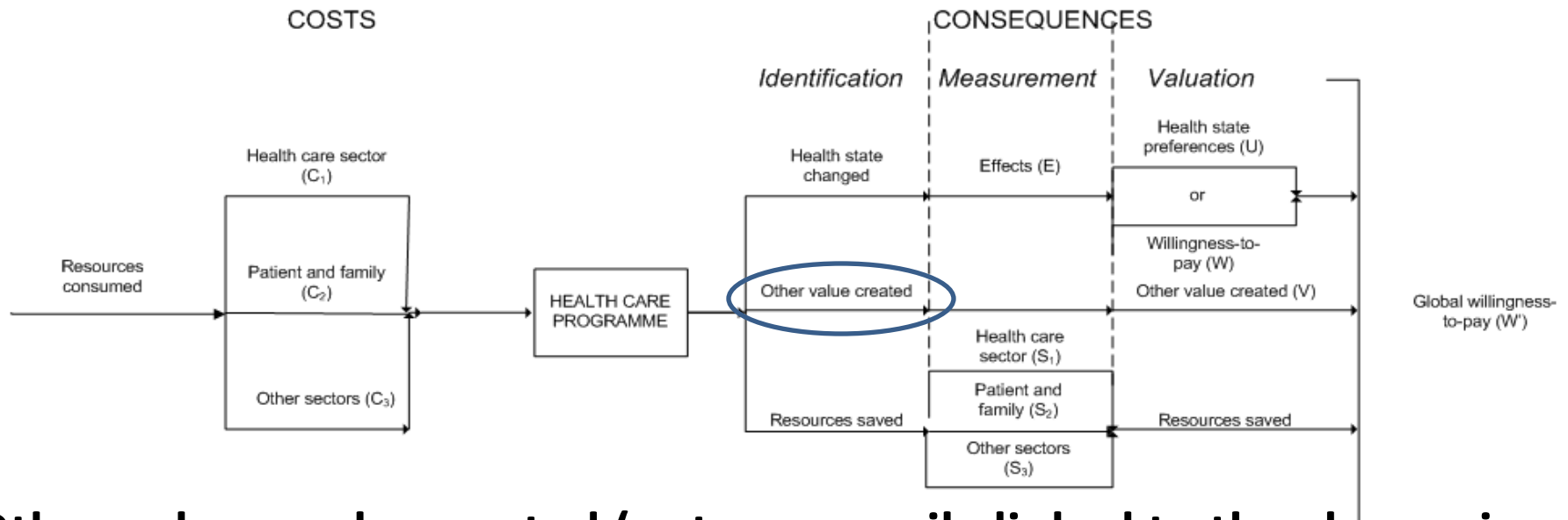


The patient's health state will be changed

Changes in the **physical, social or emotional functioning** of individuals

This change can be **measured** in terms of **effects (E)** but also **valued** either in terms of **health state preferences (U)** (in CUA) or in terms of **willingness-to-pay** (in CBA)

Components of Economic evaluation

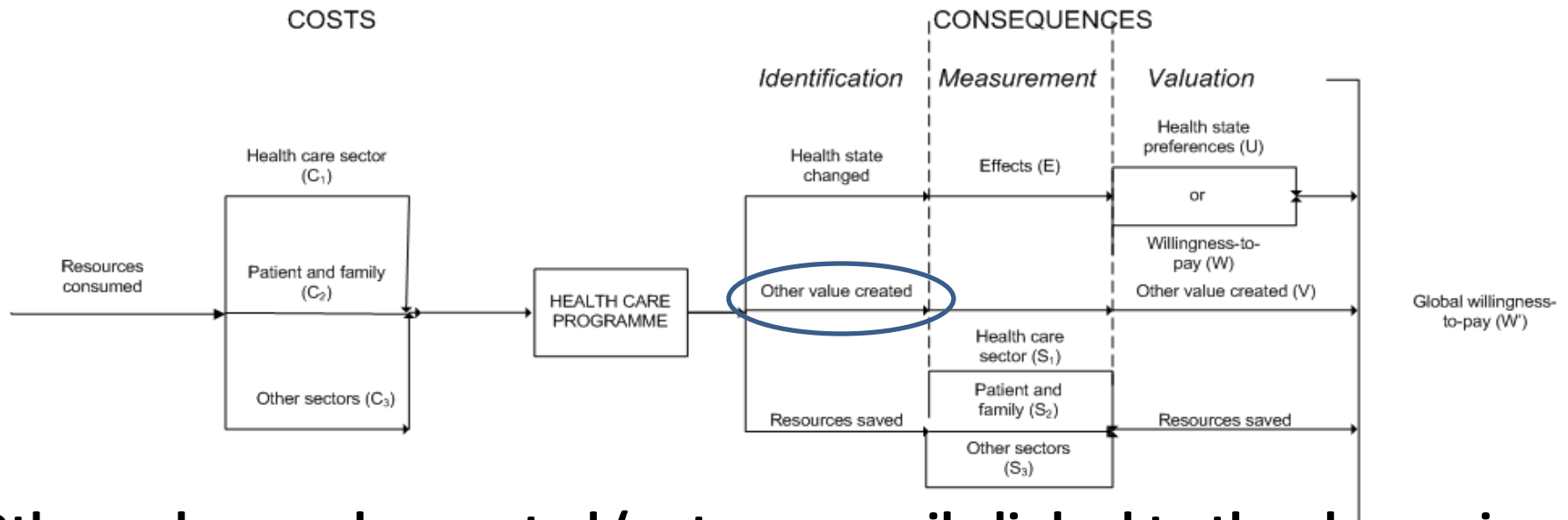


Other value can be created (not necessarily linked to the change in health state)

Value of information or reassurance about one's health

V can be separately discussed or incorporated in the measurement of U or W.

Components of Economic evaluation



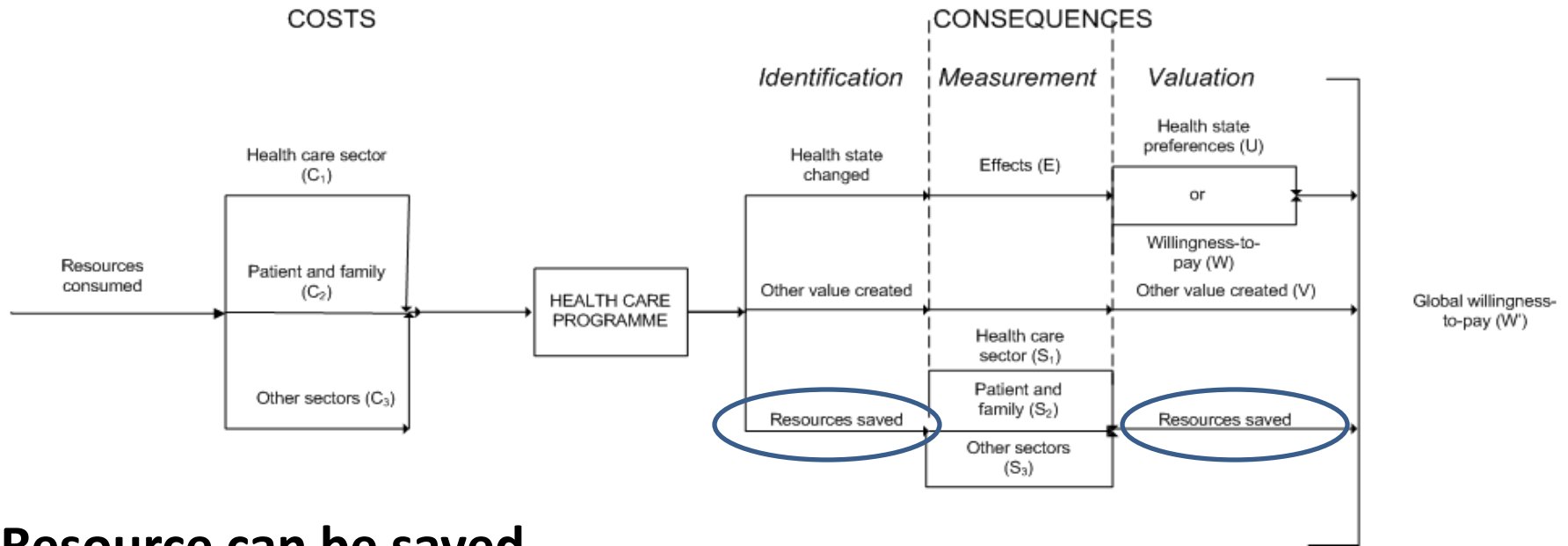
Other value can be created (not necessarily linked to the change in health state)

Examples: The value to pregnant mothers of seeing an ultrasound image of their unborn baby (Berwick and Weinstein, 1985)

Pleasure of being cared for even if one's health state was not changed

A vaccination programme may free resources if fewer individuals contract the disease and thus require treatment

Components of Economic evaluation



Resource can be saved

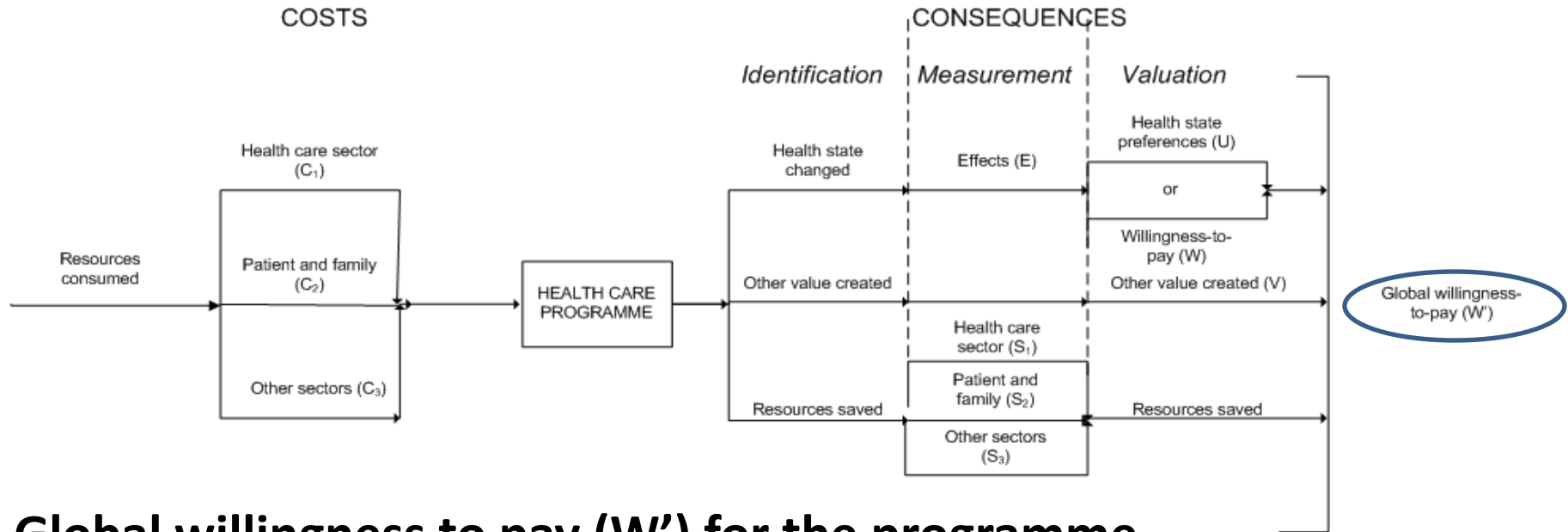
These savings (S_1 to S_3) mirror the costs (C_1 to C_3)

They are measured and valued the same way as costs

These savings (S_1 to S_3) are the costs (C_1 to C_3) **not spent on the alternative programme**

(Recall that all assessments are comparative to an alternative)

Components of Economic evaluation



Global willingness to pay (W') for the programme

This valuation could potentially include all the consequences identified in this figure

As opposed to other valuation approaches mentioned here, this approach could be applied **on the population level** (rather than on the level of an individual patient)

(One can ask a sample of the population how much extra tax they would be willing to pay for a new programme to be added to the existing ones)

Some possible formulations

Cost minimization analysis (The focus is on the costs only)

$$(C_1 - S_1)$$

only health care sector resources are considered

$$(C_1 + C_2 + C_3) - (S_1 + S_2 + S_3)$$

all sectors are considered

Cost –effectiveness analysis

$$(C_1 - S_1) / E^*$$

$$(C_1 + C_2 + C_3) - (S_1 + S_2 + S_3) / E^*$$

(*changes in effectiveness or health status compared to an alternative!)

Some possible formulations

Cost –utility analysis

$$(C_1 - S_1) / U^*$$

$$(C_1 + C_2 + C_3) - (S_1 + S_2 + S_3) / U^*$$

(*changes in effectiveness or health status compared to an alternative!)

Cost-benefit analysis

$$W' - (C_1 + C_2 + C_3)$$

$$[(W + V + S_1 + S_2 + S_3) - (C_1 + C_2 + C_3)]$$

(these results can also be expressed as ratios, but this is not best practice!)

Some issues

- Be wary of double counting!

Example: $(C_1+C_2+C_3)-(S_1+S_2+S_3) / U$

U might incorporate individuals' valuations of time savings to themselves or their family

If the above formulation is to be used the estimation of U should be made so as to exclude the value of savings in patient and family time included in S_2

- Be wary of ratios!

Ratios may not be comparable across different studies as they depend on what goes into the numerator and denominator

Example: Benefit cost ratio

$$[(W+S_1+S_2+S_3)/(C_1+C_2+C_3)]$$

Or

$$[W/ (C_1+C_2+C_3 -S_1-S_2-S_3)]$$

Some issues

- Direct, indirect and intangible costs and benefits
 - Direct costs and benefits:
 - Resources consumed (costs) or saved (benefits) by the programme (compared to an alternative).
 - May include patient's out of pocket expenses, resources from other sectors (e.g. Voluntary bodies).
 - May cause confusion as the use of the terms are not consistent across studies
 - Indirect costs and benefits
 - The time of patients (or their families) consumed or freed by the programme
 - Productivity gains or losses
 - May cause confusion as the term is used by accountants to refer to overhead costs

Some issues

- Direct, indirect and intangible costs and benefits
 - Intangible costs and benefits
 - Consequences that are difficult to measure and value (e.g. Pain or suffering associated with treatment)
 - These items are not strictly intangible as they are often measured and valued (through the utility and willingness to pay approach)

Example

COSTS	CONSEQUENCES
Health care costs \$1 000 000	Health state improvement
Patient/family resources \$5000	U(in preference scores) 10 QALYs
Costs in other sectors \$50 000	W \$2 000 000
	Health care savings \$25000
	Savings in other sectors \$20 000
	Savings in patient/ family resources \$12 000
	V (other value created) \$0

Calculate the following:

Cost-Utility Ratio (Health care resources only)

$$(C_1 - S_1) / U =$$

Cost Utility Ratio (All resource use)

Benefit-Cost Ratio (including all consequences in the numerator as benefits)

Benefit-Cost Ratio (treating resource savings as cost-offsets, deducted from the denominator)

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Calculate the following:

Cost-Utility Ratio (Health care resources only)

$$(C_1 - S_1) / U = \text{Incremental cost / Incremental Utility}$$
$$= (1\,000\,000 - 25\,000) / 10 = \$75\,000 \text{ per QALY}$$

Cost Utility Ratio (All resource use)

Benefit-Cost Ratio (including all consequences in the numerator as benefits)

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Calculate the following:

Cost-Utility Ratio (Health care resources only)

Cost Utility Ratio (All resource use)

$$\begin{aligned} & (C_1 + C_2 + C_3) - (S_1 + S_2 + S_3) / U^* = \text{Incremental Cost/Incremental Utility} \\ & = (1000\ 000 + 5000 + 50\ 000 - 25000 - 20000 - 12000) / 10 \\ & = \$77300 \text{ per QALYs} \end{aligned}$$

Benefit-Cost Ratio (including all consequences in the numerator as benefits)

Benefit-Cost Ratio (treating resource savings as cost-offsets, deducted from the denominator)

Example

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Calculate the following:

Cost-Utility Ratio (Health care resources only)

Cost Utility Ratio (All resource use)

Benefit-Cost Ratio (including all consequences in the numerator as benefits)

$$[(W+V+S_1+S_2+S_3)/ (C_1+C_2+C_3)]$$

$$=(2000\ 000+0+25000+2000+12000)/(1000\ 000+5000+50\ 000)$$

$$=2.163$$

Benefit-Cost Ratio (treating resource savings as cost-offsets, deducted from the denominator)

Example

COSTS	CONSEQUENCES
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Calculate the following:

Cost-Utility Ratio (Health care resources only)

Cost Utility Ratio (All resource use)

Benefit-Cost Ratio (including all consequences in the numerator as benefits)

Benefit-Cost Ratio (treating resource savings as cost-offsets, deducted from the denominator)

$$W / (C_1 + C_2 + C_3 - S_1 - S_2 - S_3) = 2.587$$

Limitations of economic evaluation techniques

- The techniques rely on the establishment of programme effectiveness
- They do not incorporate the importance of the ***distribution*** (*of costs and consequences*), among different patient and population groups (e.g. the elderly, the poor) into the analysis
- Equitable distribution of costs and consequences is viewed as a competing dimension upon which decisions are made, in addition to efficient deployment of resources

Limitations of economic evaluation techniques

- Different forms of analysis embody different equity criteria
 - Willingness-to-pay
 - QALY
- Assumption: The freed (or saved) resources by the preferred programs **will not be wasted** (what if they are consumed by ineffective or unevaluated programmes?)
- Is a cost benefit analysis worth the effort? It is, when:
 - Programme objectives require clarification
 - Alternatives are different in nature
 - Large resource commitments are considered

Critical assessment of economic evaluation

A checklist used in Drummond et al. 1997

Critical assessment of economic evaluation

1. A well-defined question in answerable form

- Identify alternatives to be compared
- The viewpoint of comparison
 - A specific provider
 - The patient or groups of patients
 - Third-party payer (public or private)
 - Society

*“Will a community hypertension screening programme do any good?”
(Do good to whom? Compared to what?)*

“From the viewpoint of the Ministry of Health, is a chronic home care programme preferable to the existing programme of institutionalized care in designated wards of general hospitals?”

Critical assessment of economic evaluation

2. A comprehensive description of the competing alternatives

Helps the readers in the following:

- Judge the applicability of the programmes to their own settings,
- Assess whether any costs or consequence may have been omitted,
- Replicate the programme procedures being described

In identifying the costs include the following:

- Who does what to whom
- Where
- How often

In identifying the consequences

- What are the results

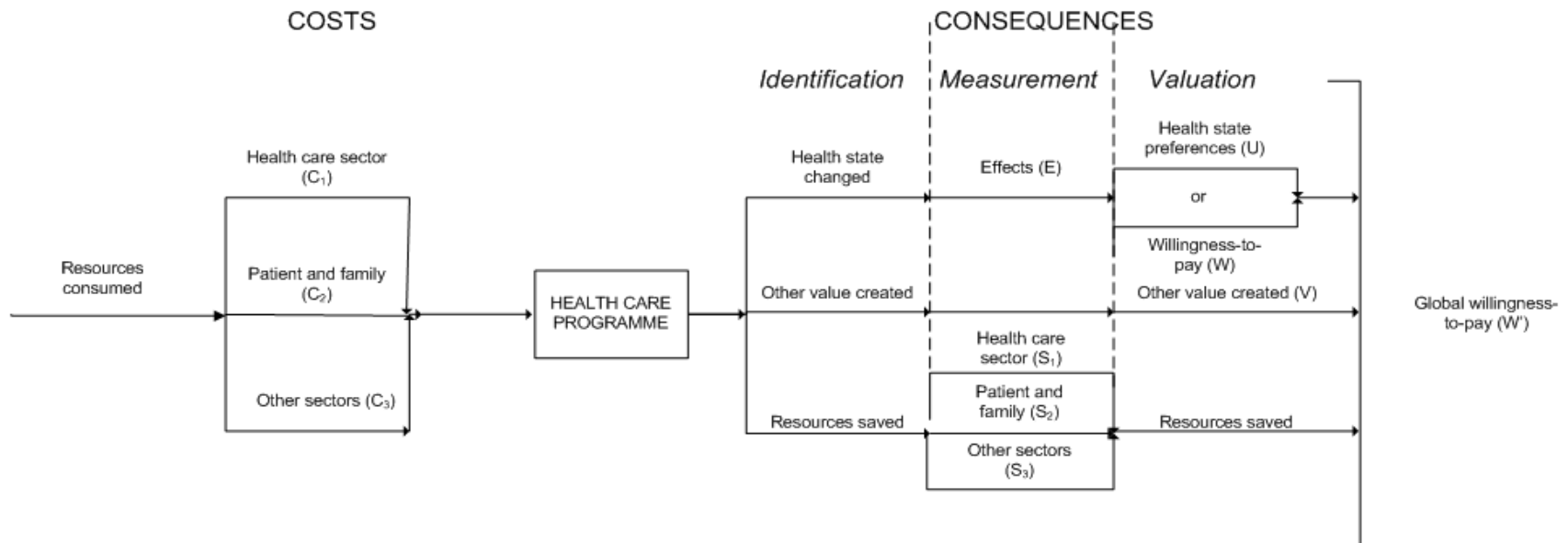
Critical assessment of economic evaluation

3. Evidence on the programmes' effectiveness

- If the economic evaluation assumes effectiveness, evidence should be provided (may be based on previous results)
- Efficiency evaluation can also be conducted simultaneously with evaluation of efficacy (the capacity for beneficial change) or effectiveness
- Efficiency evaluation by itself is incapable of establishing effectiveness!

Critical assessment of economic evaluation

- Identify all the important and relevant costs and consequences
- Provide a full identification of costs and consequences even though all of them are not necessarily measured or valued



Critical assessment of economic evaluation

The following should be apparent

- Is there a single outcome of primary interest or a set of outcomes
- Are the outcomes common to both alternatives
- To what degree each programme is successful in achieving each outcome
- Are the consequences **therapeutic effects** (CEA), or **change in quality of life of patients and their families** (CUA) or **the overall value created** (CBA)

Critical assessment of economic evaluation

5. Costs and consequences measured accurately in appropriate physical units

Use a list of ingredients

e.g. Measurement of operating costs of a particular screening program

500 physical examinations performed by physicians

10 weeks of salaried nursing time

10 weeks of a 500 square foot clinic etc.

How to handle overhead costs ?

Critical assessment of economic evaluation

5. Costs and consequences measured accurately in appropriate physical units

For consequences

Effects that relate to **mortality** can be measured in **life years gained** or **deaths averted**

Effects that relate to **morbidity** can be measured e.g. in reductions in disability days or improvements in some measure of health status or some specific measurement can be used (number of correctly identified cases in diagnosis)

Critical assessment of economic evaluation

7. Costs and consequences adjusted for differential timing

Comparison must be made at one point in time (usually the present)

Some costs and consequences do not occur entirely in the present
(e.g. some effects are immediate while some occur well into future)

Time profile of costs and consequences may differ across different programmes as well as within a single programme

Future costs and benefits are discounted

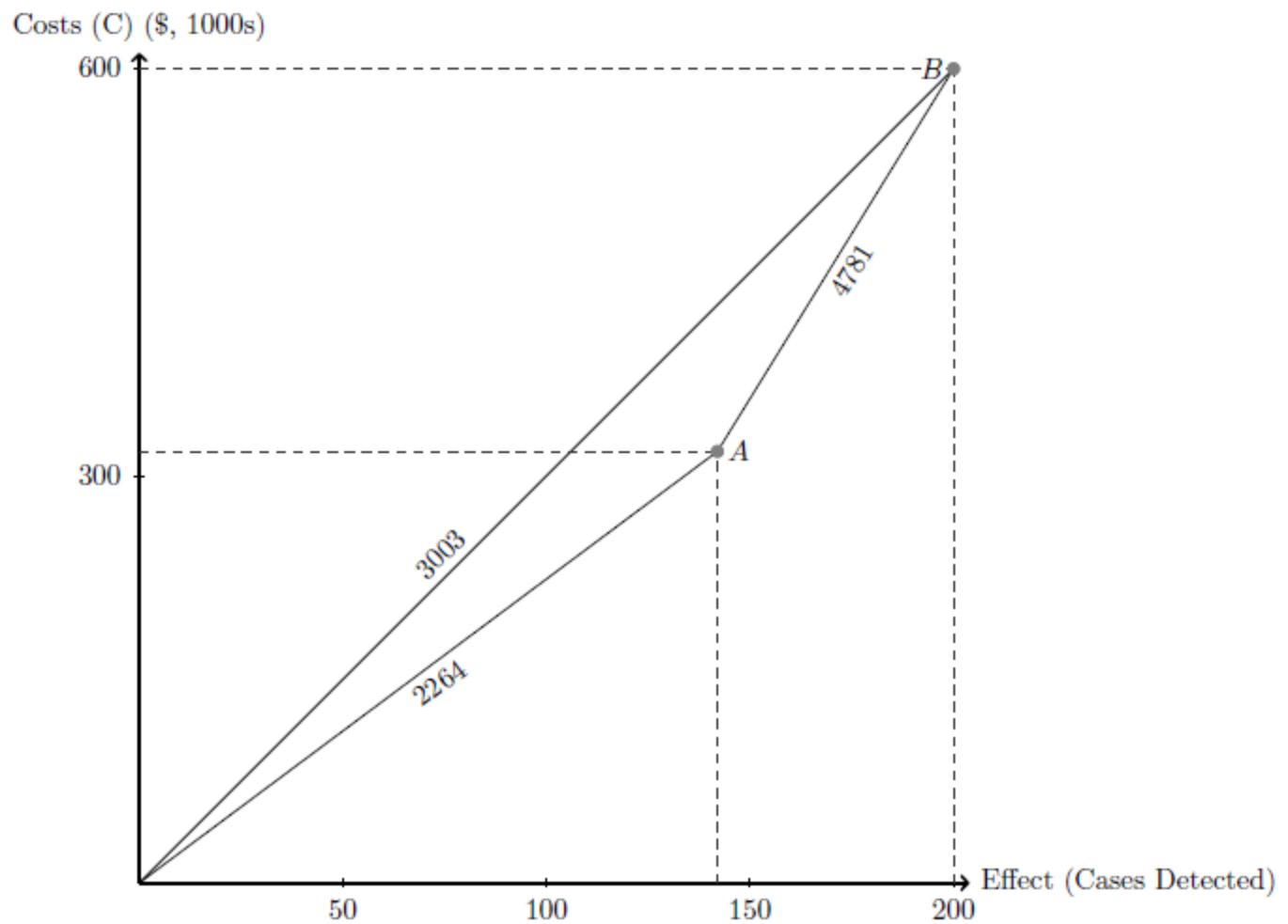
Critical assessment of economic evaluation

8. Incremental analysis of costs and consequences

Examine the **additional costs** that one programme imposes over another and, compared with the **additional effects, benefits or utilities**

How much are we paying (for each extra correct diagnosis) in adding the extra diagnostic test?

Programme	Costs (\$ US)	Outcomes	Ratio of cost to outcome
IPG (alone)	321 488	142	2264
IPG plus out-patient venography if IPG negative	603 552	201	3003
Increment (of Programme 2 over Programme 1)	282 064	59	4781



Average and incremental cost effectiveness ratios

Critical assessment of economic evaluation

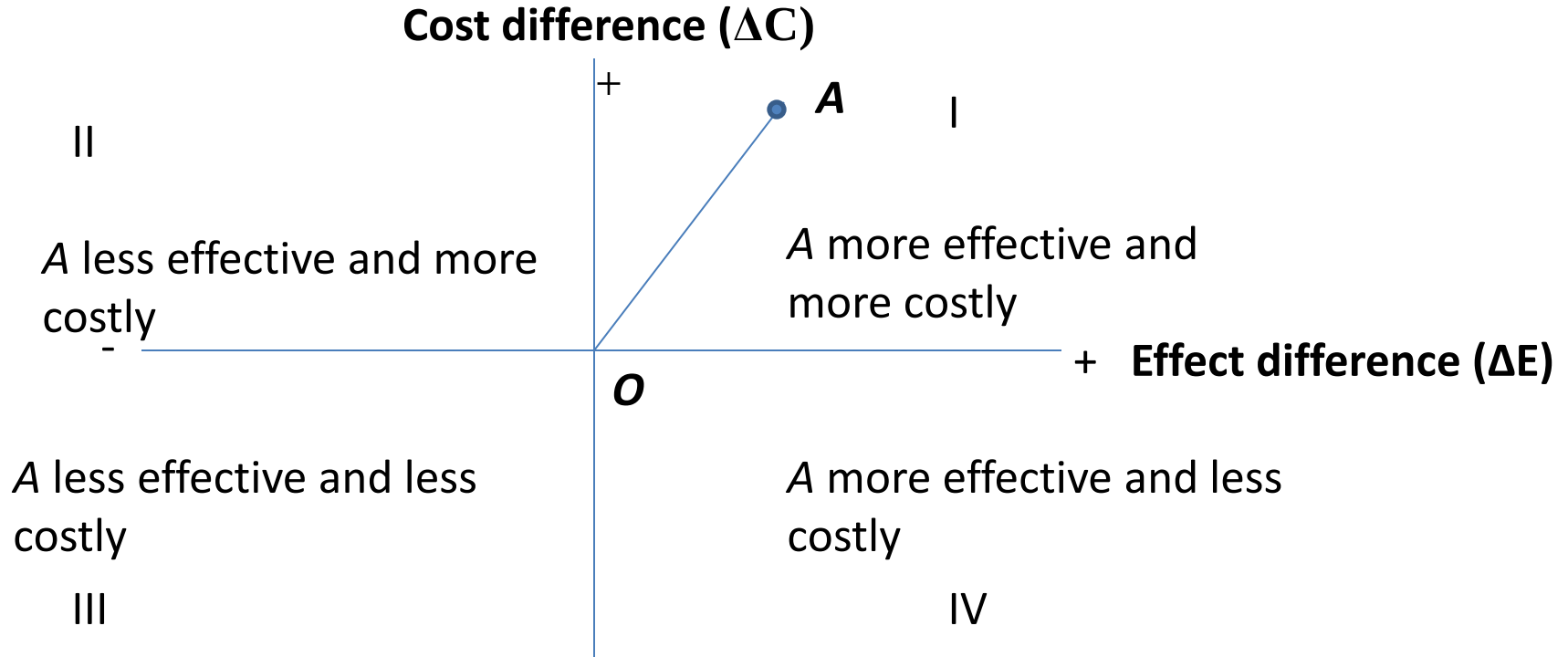
8. Incremental analysis of costs and consequences

Cost effectiveness plane for two alternatives

Intervention of interest (**A**)

Relevant alternative (**O**)

(could be the status quo or a competing program)



Critical assessment of economic evaluation

9. Allowance for uncertainty in the estimates of costs and consequences

Sensitivity analysis

Tests of statistical significance or confidence intervals around the estimates of a clinical effect

10. Presentation and discussion of results

Should include all issues of concern to users