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A QUALITY OF LIFE TOOL KIT IN CHRONIC VEINOUS DISORDERS

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The quality for whom?

2

Who should decide what is qualitatively acceptable: the physician, or the informed citizen

- For the physician, all value judgments must be excluded within a rigorous scientific approach.
 - The items are equally weighted.
 - No global score is calculated;→The synthesis and interpretation of the data are left to clinical judgment
- The society need allocative rules to make choices when the resources are scarce . The relative desirability of health statutses, is determined by informed citizens considered to be representative of the general interest
- The choice of an instrument supposes a preliminary definition of the user's needs: *search of a disagregated definition of the patient unmeet needs , or product an overall morbidity index through whitch the effect of the actions influencing heath could be judged*



THE PSYCHOMETRIC APPROACH

Why should we measure the perception of patients

4

- In the privacy of his office, the physician does not need a questionnaire to assess the quality of life of his patient,
- The situation is different when evaluating a treatment. Selection of the best protocols depends on the use of reproducible measuring instruments in different patient groups..
- According to psychometricians, the discipline of measurement and numbers has to be imposed to the realm of the mind. Only the use of numbers allows uncertain data derived from observation to be converted into solid and reliable information

The quality of what?

5

- The first step of any quality of life study is to define the perimeter of the universe to be analysed.
- Once defined, the universe must be disaggregated into its various dimensions,
- Exploration of those dimensions requires the definition of criteria or indicators
- and the definition of adequate calibration rules

Definition of the universe to be studied

- Quality of life : broad concept, includes all aspects of life: family circumstances; finances; housing and job satisfaction.
- Health related quality of life (HRQL) : narrower concept, that only includes aspects of life dominated or significantly influenced by mental or physical well-being;

Quality of life domains

7

- Batteries of health status indicators ; survey of patient perspectives about their own function, well-being and other important health outcomes
- Profiles of standardized quality life scales summaries the health state of an individual, for a specific period, or at a particular time, along various attributes of health.
 - Disease specific scales: created to be sensitive to changes in symptoms or functional impairment due to a particular disease process, score by addition;
 - Generic health status profile: multiple scales to cover broad scope of health, not tied to one disease or organ system, score by addition;

Choice of the indicators

8

| | Questionnaires | | | | | |
|---|--------------------|--|---------------------|--|------------------|------------------|
| | SF-36 ² | | HUI ^{3, 4} | | NHP ⁵ | SIP ⁶ |
| | 36 | | 31 | | 38 | 136 |
| Dimensions | | | | | | |
| Positive health variables | 19% | | 3% | | 0 | 0 |
| Physical variables | 31% | | 90% | | 55% | 44% |
| Psychological variables | 14% | | 7% | | 32% | 21% |
| Social variables | 25% | | 0 | | 13% | 35% |
| Overall perception of the health state | 11% | | 0 | | 0 | 0 |

Positive health variables: movements, dexterity, sleep, pain; Psychological variables: Mood changes, fatigue, anxiety Feeling of good health, vitality/energy, physical strength, mental stability ; Physical variables: Vision, hearing, speech, mobility, arm /distress, intellectual efficiency

Scaling procedures

9

Calibration, i.e., all the rules governing attribution of numbers to the various positions of the indicator

- **The number can be used exclusively for identification** for example, 1 = female, 2 = male, or vice versa. No mathematical operations can be performed with these numbers;
- **The number can also be used as a ranking instrument** example: you suffer, 1 = very little, 2 = slightly, 3 = moderately, 4 = severely. Any series of numbers which preserve the order relation is just as acceptable as the series of numbers initially established.
- **The distance between two levels of the scale is standardized by the use of a common unit** over its entire range, then differences between points on the scale make sense but the absolute value of one level of the graduation can never be a multiple of another one.
- When it is possible to **define a zero value and a common unit** of measurement, then a state of health can be said twice more severe than another

Les Deux Composants du SF-36

10

PHYSICAL COMPONENT

- 4 Dimensions, 22 Questions
 - ⇒ Distributed between the items 1, 2, 3, 4, 7, 8, 11
 - Physical functioning (PF)
 - Role-Physical functioning (RP)
 - Bodily pain (BP)
 - General health (GH)

MENTAL COMPONENT

- 4 Dimensions, 14 Questions
 - => Distributed between the items 5, 6, 9, 10
 - Vitality (VT)
 - Social functioning (SF)
 - Role-Emotional functioning (RE)
 - Mental health (MH)

SF-36 Item Recoding

11

Physical functioning



- (3a) **Vigorous activities**, such as running
- (3b) **Moderate activities**, such as moving a table
- (3c) Lifting or carrying groceries
- (3d) Climbing **several** flights of stairs
- (3e) Climbing **one** flight of stairs
- (3f) Bending, kneeling, or stooping
- (3g) Walking **more than a mile**
- (3h) Walking **several blocks**
- (3i) Walking **one block**
- (3k) Bathing or dressing yourself

Role-Physical functioning



- (4a) Cut down the **amount of time** you spent on work or other activities
- (4b) **Accomplished less** than you would like
- (4c) Were limited in the **kind** of work or other activities
- (4d) Had **difficulty** performing the work or other activities

Bodily pain



- (7) How much **bodily** pain have you had during the **past 4 weeks**?
- (8) During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

General health



- (1). Etat général de santé
- (11a).Tombe malade plus facilement que les autres
- (11b).Se porter aussi bien que n'importe qui
- (11c). S'attendre à une dégradation ;
- (11d). Excellente santé

SF-36 Item Recoding

12

Vitality



- (9a) Did you feel full of pep?
- (9e) Did you have a lot of energy?
- (9g) Did you feel worn out?
- (9i) Did you feel tired?

Social functioning



- (6) During the **past 4 weeks**, to what extent has your **physical health or emotional problems** interfered with your normal social activities with family, friends, neighbors?
- (10) During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends)?

Role-Emotional



- (5a) Cut down the **amount of time** you spent on work or other activities
- (5b) **Accomplished less** than you would like
- (5c) Didn't do work or other activities as **carefully** as usual

Mental health



- (9b) Have you been a very nervous person?
- (9c) Have you felt so down in the dumps that nothing could cheer you up?
- (9d) Have you felt calm and peaceful?
- (9f) Have you felt downhearted and blue?
- (9h) Have you been a happy person?

Computing the Score SF-36

| | | Dimension | Questions | # Modality | Min score | Max score | Expanse |
|--------------------|-----------|----------------------|-----------|------------------------|-----------|-----------|---------|
| Physical component | PF | Physical functioning | 10 | 3 | 10 | 30 | 20 |
| | RP | Role-Physical | 3 | 2 | 3 | 6 | 3 |
| | BP | Bodily pain | 2 | 4 (Q. 21) 5 (Q. 22) | 2 | 9 | 7 |
| | GH | General health | 5 | 5 | 5 | 25 | 20 |
| Mental Component | VT | Vitality | 4 | 5 | 4 | 20 | 16 |
| | SF | Social functioning | 5 | 5 | 5 | 25 | 20 |
| | RE | Role-Emotional | 4 | 2 | 4 | 8 | 4 |
| | MH | Mental health | 2 | 4 (Q. 20) 5 (Q. 32) | 2 | 9 | 7 |



THE UTILITY PREFERENCE APPROACH

Definition of the universe to be studied

15

- Health Related Quality of life index preference: weighted aggregate scores summarizing overall health; econometric methods are used to elicit utility weights (preferences) for health states;
- Quality adjusted life years (QALY's): combines quality of life index and mortality into a single number.

EQ-5D : Profile, Score, Index

16

EQ-5D provide three principal approaches to analysis:

- **the EQ-5D profile:** the patients' self reported health on the dimensions/levels of the descriptive system.
- **the EQ-VAS:** the patients' own global rating of their overall health, on a scale from 0 (worst possible health) to 100 (best possible health)
- **the EQ-5D Index :** Profiles are summarised using 'value sets' () which reflect the preferences of the general public

EQ-5D-3L Profile

17

Mobility

I have no problems in walking about

☐

I have some problems in walking about

☐

I am confined to bed

☐

Self-Care

I have no problems with self-care

☐

I have some problems washing or dressing myself

☐

I am unable to wash or dress myself

☐

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities

☐

I have some problems with performing my usual activities

☐

I am unable to perform my usual activities

☐

Pain/Discomfort

I have no pain or discomfort

☐

I have moderate pain or discomfort

☐

I have extreme pain or discomfort

☐

Anxiety/Depression

I am not anxious or depressed

☐

I am moderately anxious or depressed

☐

I am extremely anxious or depressed

☐

EQ-5D-3L VAS

18

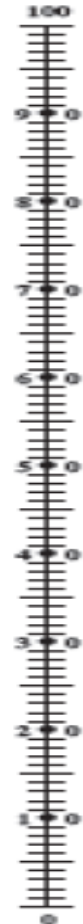
Q24. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Sample

Your own
health state
today

Best
imaginable
health state



Worst
imaginable
health state

Index weighting of the EQ-5D profile

19

This weight depends on:

- who is asked
- which stated preference method is used
- how the preference data are modeled

By placing a tick in one box in each group, please indicate which statement best describes your health today.

Mobility
I have no problems in walking about ☒
I have some problems in walking about ☐
I am confined to bed ☐

Self-Care
I have no problems with self-care ☒
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

Usual Activities
I have no problems with performing my usual activities ☒
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

Pain/Discomfort
I have no pain or discomfort ☐
I have moderate pain or discomfort ☒
I have extreme pain or discomfort ☐

Anxiety/Depression
I am not anxious or depressed ☒
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

Levels of a perceived problem are coded as follows:

- ☒ Level 1 is coded as a "1"
- ☒ Level 2 is coded as a "2"
- ☒ Level 3 is coded as a "3"
- ☒ Level 3 is coded as a "3"
- ☒ Level 1 is coded as a "1"
- ☒ Ambiguous response is coded as an "8"
- ☐ Missing response is coded as a "9"

The health state is derived from the descriptive system.

| | | | | | |
|--------------|---|---|---|---|---|
| health state | 1 | 2 | 3 | 3 | 1 |
|--------------|---|---|---|---|---|

To score a health state you simply read off the corresponding value from a value set.

| | |
|-------|------|
| score | 0.07 |
|-------|------|

A value set:

| | | | | | |
|---|---|---|---|---|------|
| 1 | 2 | 3 | 3 | 3 | 0.09 |
| 1 | 2 | 3 | 3 | 1 | 0.07 |
| 1 | 2 | 3 | 3 | 2 | 0.00 |

Quality of Life Coefficients

20

| Etat de santé | Score | Etat de santé | Score | Etat de santé | Score | Etat de santé | Score | Etat de santé | Score |
|---------------|-------|---------------|-------|---------------|-------|---------------|--------|---------------|--------|
| 11111 | 1 | 13121 | 0.388 | 13321 | 0.200 | 31313 | 0.062 | 32132 | -0.113 |
| 11112 | 0.910 | 22212 | 0.387 | 21223 | 0.199 | 32311 | 0.053 | 32222 | -0.116 |
| 11121 | 0.888 | 11331 | 0.372 | 22131 | 0.193 | 13331 | 0.047 | 33212 | -0.117 |
| 21111 | 0.845 | 21321 | 0.371 | 12231 | 0.192 | 21233 | 0.046 | 32213 | -0.118 |
| 11211 | 0.844 | 22221 | 0.365 | 23211 | 0.190 | 23321 | 0.045 | 23133 | -0.124 |
| 11122 | 0.798 | 31112 | 0.364 | 31131 | 0.189 | 32122 | 0.040 | 13233 | -0.125 |
| 12111 | 0.788 | 11133 | 0.357 | 31221 | 0.186 | 33112 | 0.039 | 23223 | -0.127 |
| 21112 | 0.755 | 21123 | 0.355 | 13123 | 0.184 | 22231 | 0.038 | 33131 | -0.137 |
| 11212 | 0.755 | 11223 | 0.354 | 22312 | 0.181 | 32113 | 0.038 | 33221 | -0.140 |
| 21121 | 0.733 | 12131 | 0.348 | 31312 | 0.176 | 31231 | 0.033 | 32322 | -0.149 |
| 11221 | 0.732 | 23111 | 0.345 | 11333 | 0.168 | 13133 | 0.031 | 33312 | -0.150 |
| 12112 | 0.698 | 13211 | 0.345 | 21323 | 0.167 | 23123 | 0.029 | 32313 | -0.151 |
| 21211 | 0.689 | 31121 | 0.342 | 21232 | 0.160 | 13223 | 0.028 | 13333 | -0.158 |
| 12121 | 0.675 | 12312 | 0.335 | 12331 | 0.160 | 33121 | 0.016 | 23323 | -0.159 |
| 21122 | 0.643 | 11323 | 0.321 | 22321 | 0.158 | 21333 | 0.013 | 23232 | -0.165 |
| 11222 | 0.642 | 21132 | 0.316 | 23311 | 0.157 | 22331 | 0.005 | 22233 | -0.167 |
| 11311 | 0.638 | 11232 | 0.315 | 31321 | 0.154 | 31331 | 0.000 | 31233 | -0.171 |
| 22111 | 0.633 | 12321 | 0.313 | 32112 | 0.152 | 32212 | -0.004 | 33321 | -0.172 |
| 12211 | 0.632 | 13311 | 0.312 | 13132 | 0.145 | 13323 | -0.004 | 32231 | -0.180 |
| 11113 | 0.622 | 21213 | 0.311 | 12133 | 0.144 | 23132 | -0.010 | 33123 | -0.188 |
| 21212 | 0.600 | 13122 | 0.299 | 23122 | 0.144 | 13232 | -0.011 | 23332 | -0.198 |
| 12122 | 0.586 | 31211 | 0.298 | 13222 | 0.143 | 22133 | -0.011 | 22333 | -0.199 |
| 21221 | 0.577 | 12123 | 0.297 | 22123 | 0.142 | 12233 | -0.012 | 31333 | -0.204 |
| 11131 | 0.561 | 13113 | 0.296 | 12223 | 0.142 | 23222 | -0.012 | 32331 | -0.212 |
| 11312 | 0.548 | 11332 | 0.283 | 23113 | 0.141 | 22223 | -0.013 | 33132 | -0.227 |
| 22112 | 0.543 | 21322 | 0.281 | 13213 | 0.140 | 23213 | -0.015 | 32133 | -0.228 |
| 12212 | 0.542 | 21313 | 0.279 | 31123 | 0.138 | 31133 | -0.015 | 33222 | -0.229 |
| 11321 | 0.526 | 22222 | 0.275 | 32121 | 0.130 | 31223 | -0.018 | 32223 | -0.230 |
| 22121 | 0.521 | 22311 | 0.270 | 33111 | 0.128 | 32131 | -0.024 | 33213 | -0.232 |
| 12221 | 0.520 | 31311 | 0.266 | 21332 | 0.128 | 32221 | -0.026 | 33322 | -0.262 |
| 11123 | 0.510 | 12132 | 0.259 | 13322 | 0.110 | 33211 | -0.027 | 32323 | -0.263 |
| 13111 | 0.500 | 23112 | 0.256 | 12323 | 0.109 | 32312 | -0.037 | 33313 | -0.264 |
| 21222 | 0.488 | 13212 | 0.255 | 13313 | 0.108 | 13332 | -0.043 | 32232 | -0.269 |
| 21311 | 0.483 | 22113 | 0.255 | 22132 | 0.104 | 12333 | -0.044 | 23233 | -0.280 |
| 22211 | 0.477 | 12213 | 0.254 | 12232 | 0.103 | 23322 | -0.045 | 33231 | -0.293 |
| 11132 | 0.471 | 31122 | 0.252 | 23212 | 0.100 | 22323 | -0.046 | 32332 | -0.302 |
| 21113 | 0.467 | 21231 | 0.250 | 31132 | 0.099 | 23313 | -0.047 | 23333 | -0.312 |
| 11213 | 0.466 | 31113 | 0.250 | 22213 | 0.099 | 31323 | -0.051 | 33331 | -0.325 |
| 31111 | 0.454 | 32111 | 0.242 | 31222 | 0.097 | 22232 | -0.052 | 33133 | -0.341 |
| 11322 | 0.436 | 13131 | 0.235 | 31213 | 0.094 | 31232 | -0.057 | 33223 | -0.344 |
| 11313 | 0.434 | 23121 | 0.233 | 32211 | 0.086 | 32321 | -0.059 | 33323 | -0.376 |
| 22122 | 0.431 | 13221 | 0.232 | 23131 | 0.080 | 33311 | -0.060 | 33232 | -0.382 |
| 12222 | 0.430 | 12322 | 0.223 | 13231 | 0.079 | 33122 | -0.073 | 32233 | -0.384 |
| 12311 | 0.425 | 13312 | 0.222 | 23221 | 0.078 | 32123 | -0.075 | 33332 | -0.415 |
| 13112 | 0.411 | 12313 | 0.221 | 12332 | 0.070 | 23231 | -0.076 | 32333 | -0.416 |
| 12113 | 0.409 | 21331 | 0.217 | 22322 | 0.068 | 33113 | -0.076 | 33233 | -0.497 |
| 21131 | 0.406 | 31212 | 0.209 | 23312 | 0.067 | 22332 | -0.085 | 33333 | -0.529 |
| 11231 | 0.405 | 21133 | 0.202 | 22313 | 0.066 | 31332 | -0.089 | | |
| 21312 | 0.393 | 11233 | 0.201 | 31322 | 0.064 | 23331 | -0.108 | | |

Quality Adjusted Life Years

21

- A health-status index is essentially a weighting scheme: Each definable health status, ranging from death to ... full health, ... is assigned a weight zero to one, and then number of years spent at a given health status Y_s is multiplied by the corresponding weight, λ_s to yield a number $\lambda_s Y_s$ that might be thought of as an equivalent number of years with full health -a number of quality -adjusted life years (QALYs). **The source of these weights is ultimately subjective...**

Weinstein & Stason, 1977

Increasing Number of Validated Questionnaires

22

| QUESTIONNAIRE | NUMBER OF STATES |
|-----------------------------------|------------------|
| Rosser & Kind Matrix | 30 |
| EQ-5D 3L | 243 |
| Quality of Well Being Scale (QWB) | 2,200 |
| EQ-5D 5L | 3,125 |
| SF-6D (SF-36) | 18,000 |
| HUI Mark 2 | 24,000 |
| HUI Mark 3 | 972,000 |
| 15 D | 3,052,000,000 |

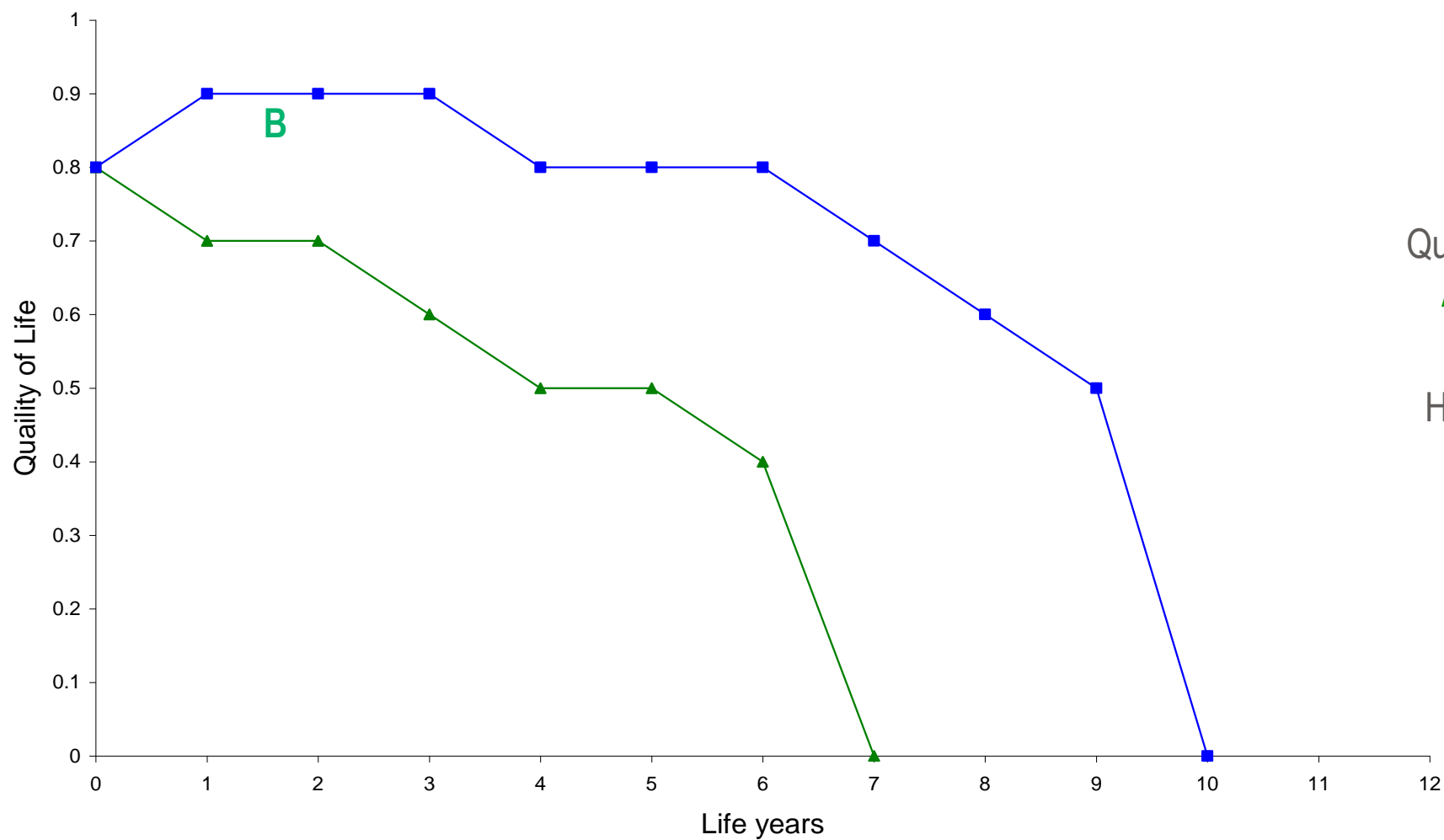
What decisions should be made?

23

- Should a technology be adopted given existing information?
 - Which clinical strategies are worthwhile?
 - For which patient groups?
- Is current evidence sufficient to support use in NHS?
 - Do we need more evidence?
 - What type of evidence is required?
 - What additional research should be conducted to provide this evidence?

IS it worthwhile?

24



Quality adjusted life years (QALYs)

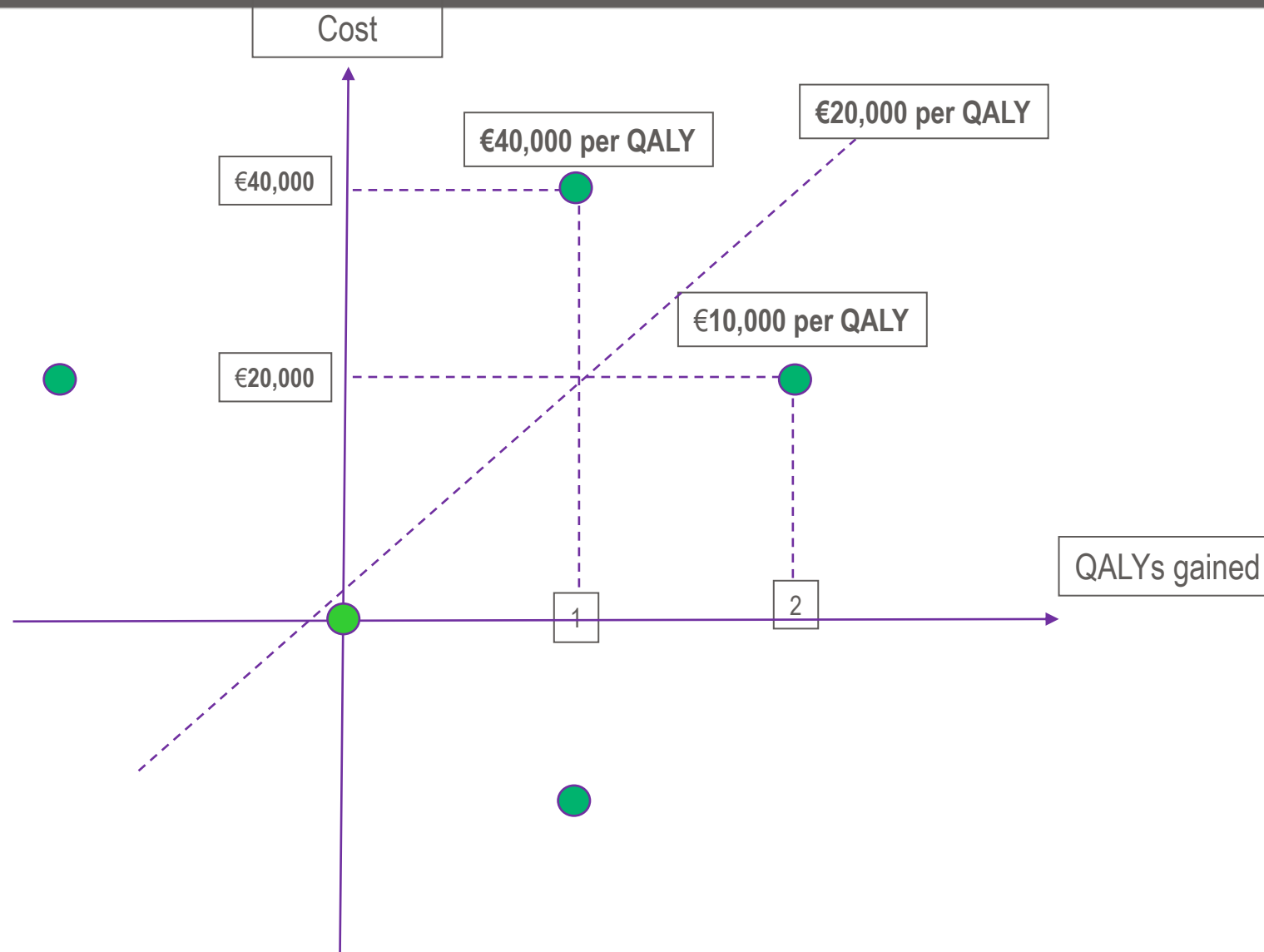
A = 4.2 QALYs

B = 7.7 QALYs

Health Gain = 3.5 QALYs

But what about costs?

25



Is it cost-effective?

26

Is the ICER less than the cost-effectiveness threshold?

$$\text{ICER} = \frac{\text{Additional cost}}{\text{QALYs gained}} = \frac{\text{€20,000}}{2 \text{ QALYs}} = \text{€10,000 per QALY}$$

If the cost-effectiveness threshold is €20,000 per QALY, B is cost-effective

Is net benefit positive?

$$\begin{aligned} \text{Net health benefit} &= \text{QALYs gained} - \text{QALYs lost} \\ &= 2 - \frac{\text{€20,000}}{\text{€20,000}} = 2 - 1 = 1 \text{ QALY} \end{aligned}$$

$$\begin{aligned} \text{Net money benefit} &= \text{€ value of QALYs gained} - \text{additional costs} \\ &= 2 \times \text{€20,000} - \text{€20,000} = \text{€20,000} = 1 \text{ QALY} \end{aligned}$$

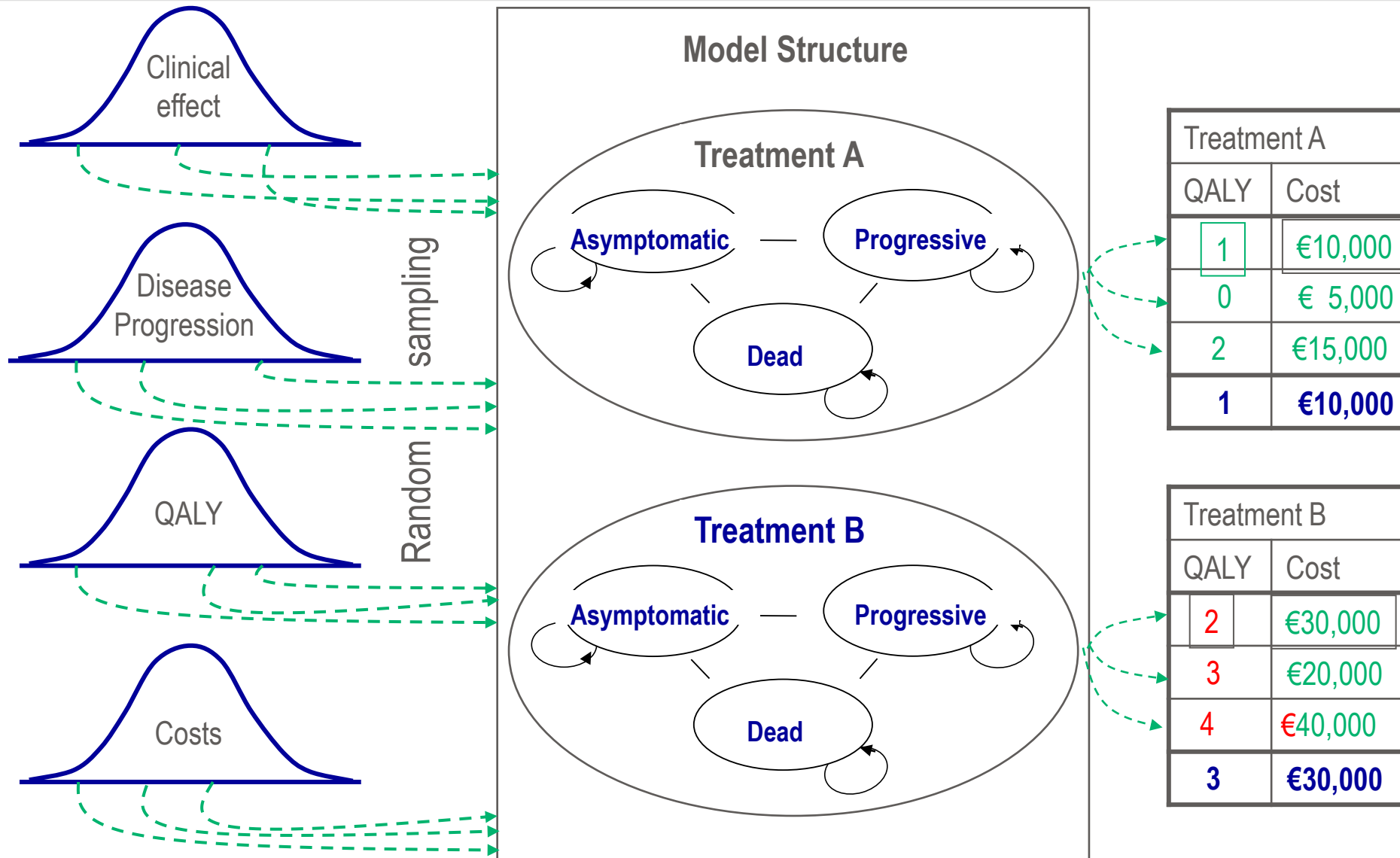
What do we need?

27

- Estimate QALYs gained and costs
 - Over time (often patient's life time)
 - For each alternative
 - For each patient group
- Relevant evidence?
 - Clinical evidence of effect
 - Progression of disease and events
 - Quality of life
 - Resource use and costs

Need to Combine evidence

28



Should a technology be adopted?

29

| Treatment A | |
|-------------|---------|
| QALY | Cost |
| 1 | €10,000 |
| 0 | € 5,000 |
| 2 | €15,000 |
| 1 | €10,000 |

| Treatment B | |
|-------------|---------|
| QALY | Cost |
| 2 | €30,000 |
| 3 | €20,000 |
| 4 | €40,000 |
| 3 | €30,000 |

$$\text{ICER} = \frac{\text{Additional cost}}{\text{QALYs gained}} = \frac{€20,000}{2 \text{ QALYs}} = €10,000 \text{ per QALY}$$

Is the ICER less than the cost-effectiveness threshold?

€10,000 per QALY < €20,000 per QALY, B is cost-effective

Is net benefit positive?

Net health benefit = QALYs gained – QALYs lost

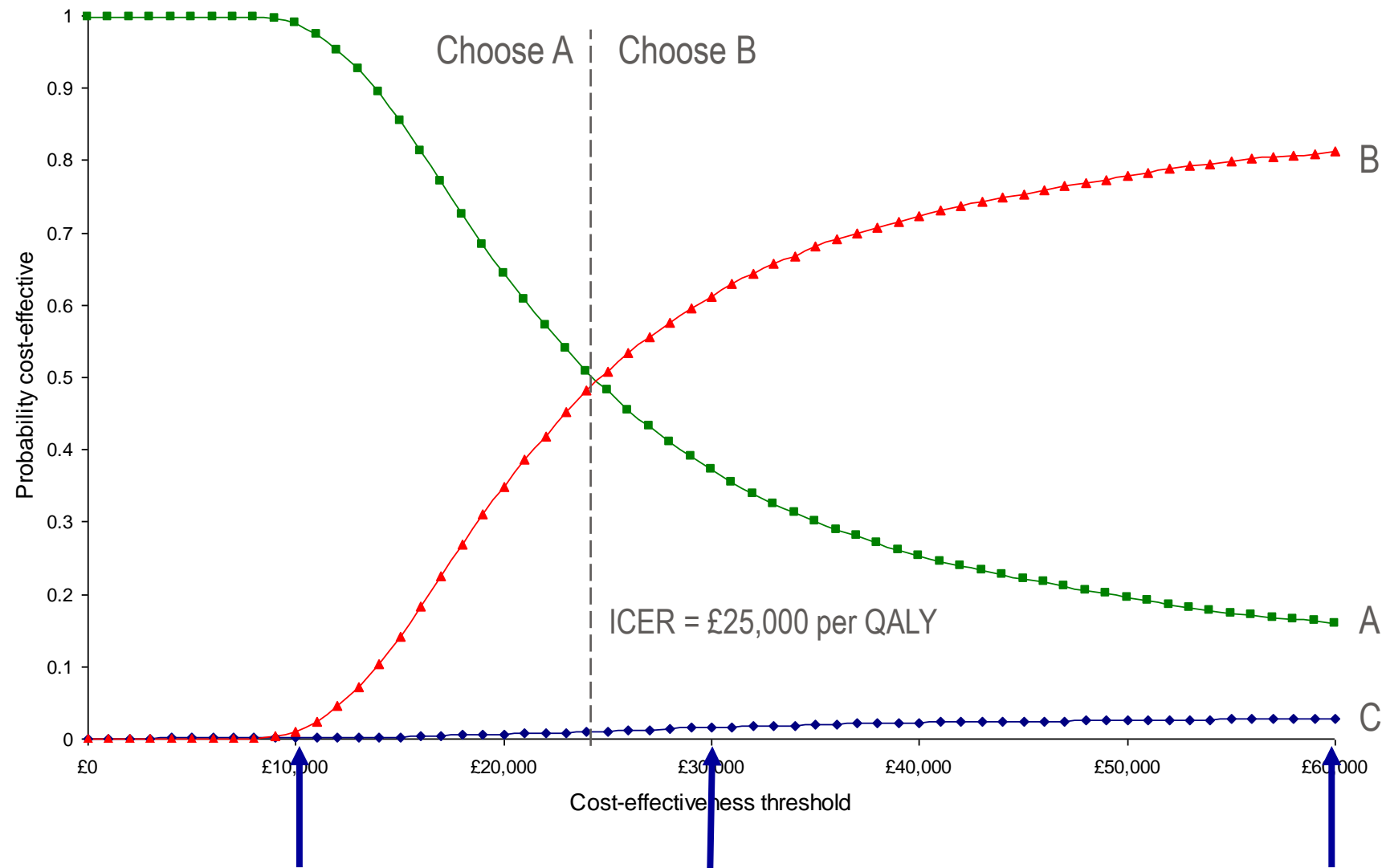
$$= 2 - \frac{€20,000}{€20,000} = 2 - 1 = 1 \text{ QALY}$$

Net money benefit = £ value of QALYs gained – additional costs

$$= 2 \times €20,000 - €20,000 = €20,000 = 1 \text{ QALY}$$

How uncertain is the decision?

30



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