

# Application of Pharma Economic Evaluation Tools for Analysis of Medical Conditions: A Case Study of an Educational Institution in India

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## ABSTRACT

The basic idea of a QALY is straightforward. The amount of time spent in a health state is weighted by the utility score given to that health state. It takes one year of perfect health (utility score of 1) to generate one QALY, whereas one year in a health state valued at 0.5 is regarded as being equivalent to half a QALY. Thus, an intervention that generates four additional years in a health state valued at 0.75 will generate one more QALY than an intervention that generates four additional years in a health state valued at 0.5. This paper discusses effect of self-medication on health care taking an educational institution population comprising of students, teaching and non-teaching staff in 2011.

**Keywords:** Pharma economics, QALY, measuring clinical and health excellence

## 1. INTRODUCTION

Pharmacoeconomics [Mueller et al: 1997] refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another. A pharmacoeconomic study evaluates the cost (expressed in monetary terms) and effects (expressed in terms of monetary value, efficacy or enhanced quality of life) of a pharmaceutical product.

Health care funders (governments, social security funds, insurance companies) are struggling to meet their rising costs. They make many efforts to contain drug costs, by price negotiation, patient co-payments or dedicated drug budgets. Expenditure on drug therapy is a particular target for their attention for several reasons: percentage of health care-costs in GDP, the ease of measurement of pharmaceutical costs in isolation, in contrast to most other health care costs; evidence of wasteful prescribing; and a perception that many drugs are overpriced and that the profits of the pharmaceutical industry are excessive. Pharmacoeconomic studies serve to guide optimal healthcare resource allocation, in a standardized and scientifically grounded manner.

One important consideration in a pharmacoeconomic evaluation is to decide the perspective from which the analysis should be conducted. 1- Institutional perspective that involve

direct cost and 2-Societal perspective that involves indirect cost. Generally the societal perspective is considered but the health managers facing problem of low budget concentrates on health service/institutional perspective.

Methodologies used in pharmacoeconomic evaluation are:

- Cost-minimization analysis (assumed to be equivalent in comparative groups)
- Cost-benefit analysis (expressed in terms of domestic money unit)
- Cost-effectiveness analysis (expressed in terms of natural units, for example :life years gained, mm Hg blood pressure)
- Cost-utility analysis(expressed in quality adjusted life year or other utilities)

### 1.1 Pharmacoeconomics and Drug Development

The pharmaceutical industry spends billions of dollars annually for development of new drugs. As a percentage of pharmaceutical sales, these research and development (R & D) costs are certainly higher than those found in other industries. The large number of compounds that must be evaluated to bring one drug to market contributes to the high R & D costs of drug development.

The process by which a drug is evaluated and developed for the marketplace is illustrated in figure-1

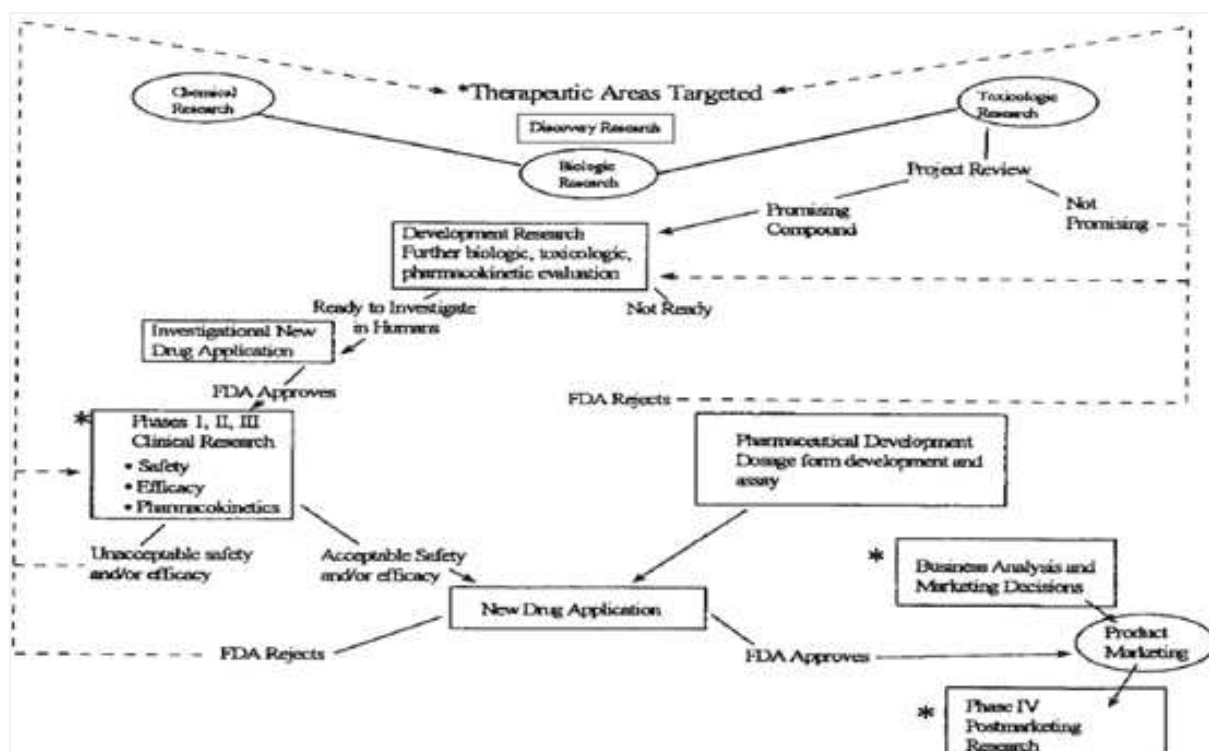


Figure-1: Source: Bootman J. L., Townsend R. J., McGhan W. F. Principles of Pharmacoeconomics. Second edition, Harvey Whitney Books Company, Cincinnati, USA, 2002, page no.11

## 2. LITERATURE REVIEW

Andrew Briggs (2010) in "Transportability of comparative effectiveness and cost effectiveness between countries" deals on the problematics faced and methods employed in transportability of data and calculating cost effectiveness of various drugs. The author identified six threats to transferability of data which deals with cost-effectiveness analysis. Various methods like fixed effect and random effect approaches, statistical modeling were discussed. In this methods, he mainly focused on pooling or splitting the data, considering separate statistical modeling of the components of cost and effect. But the threats to transferability of data and identifying methods to generalize the cost-effectiveness evaluation was not done.

SaskiaKnies, Johan L.Severens, Andre J.H.A Ament, Silvia M.A.A Evers (2010) in "The transferability of valuing lost productivity across jurisdictions. Differences between National pharmacoeconomic guidelines" examines various national pharmacoeconomic guidelines regarding the identification, measurement and valuation of lost productivity.

Considering societal perspective, valuation of health-related lost productivity has been done. The theoretical framework on how lost productivity can be identified, measured and valued is described. And then various pharmacoeconomic guidelines that suggest including costs of absenteeism from paid and unpaid in valuing lost productivity were discussed. If the data is reported transparently, it will be easier to data across jurisdiction.

Jomkwanyothasamut, SprienTantivness, YotTeerawatt - ananon (2009) in "Using economic evaluation in policy decision-making in Asian countries: Mission impossible or mission probable" aims to address the potential barriers that could prohibit the use of or diminish the usefulness of economic evaluation in Asian settings. Barriers related to production of economic information and Decision contest related barriers are discussed and potential solutions to facilitate the use of economic evaluation in decision making are provided. No case studies are given.

Amy O'Sullivan, David Thompson, Debbie Becke, Burlington. (2008) in "Country-to-Country Adaptation of Pharmacoeconomic Research: Methodologic Challenges

and Potential Solutions” focus on methodological challenges and solutions involved in adapting pharmacoeconomic research projects initiated in one country to another with different population, institutional and health care characteristics. The common approaches for pharmacoeconomic evaluation of each modeling and piggyback evaluations and issues in research adaptation are discussed. This is a relatively quicker and more efficient way of addressing information needs across country and demographic settings.

Thomas Reinhold, Bernd Bruggenjurgen, Micheal Schandler, Stephanie Rosenfeld, Franz Hessel, Stefan N.Willich (2010) in “Economic analysis based on multinational studies: methods for adapting findings to national contexts” summarizes several of the most common international methods for generating health economic analysis based on clinical studies on different settings. This paper described the possibility of transferring foreign economic study results to the country of interest by matching trial data with routine data of national databases. The role of econometric methods for cost effectiveness analysis alongside observational databases is discussed. The importance of this area of research is generalizability of randomized trials increases since it saves time and R and D costs of various countries.

Micheal Drummond, Marco Barbieri, John Cook, Henry A. Glick, Joanna Lis, Farzana Malik, Shelby D.Reed, Frans Rutten, Mark Sculpher (2009) in “Transferability of economic evaluations across jurisdictions: ISPOR good research practices task force report” focuses on what country-specific guidelines for pharmacoeconomic evaluation say about transferability, discusses which elements of data could potentially vary from place to place. They developed good researched practices for dealing with aspects of transferability by defining the decision problem, discussing steps for determining appropriate methods for adjusting cost – effectiveness information analyzing patient data from multilocation studies, study of multilevel models.

Marius A.Kemler, Jon Rapheal, Antony Bentley, Rod S.Taylor (2010) in “The cost –effectiveness of spinal cord stimulation for complex regional pain syndrome” deals with the

assessment of cost-effectiveness of the addition of spinal cord stimulation (SCS) to conventional medical management(CMM) and CMM alone in patients with complex regional pain syndrome and to determine the cost-effectiveness of non-rechargeable versus rechargeable SCS implant generators(IPG). Analysis is done through a 2 stage decision analytic model which reflected possible initial 6 months responses to SCS and a Markov model simulated costs and QALY over a 15 year time horizon. By comparing the costs of SCS and CMM over 15 year time period, SCS is found to be cost- effective. It also has been found out in this paper that when the longevity of an IPG is less than 4 years, a rechargeable IPG is the most cost-effective option.

Manueal Joore, Danielle Brunenberg, Patricia Nelemens, EmielWouters, Petra Kujipers, AdriaanHonig, Danielle Willems, Peter de Leeuw, Johan Severens, AnneliesBoonen (2009) in “The impact of differences in EQ-5D and SF-6D utility scores on the acceptability of cost-utility ratios: Results across five trial-based cost-utility studies”

This paper deals with the investigation of whether differences in utility scores based on EQ-5D and SF-6D have impact on incremental cost-utility ratios in 5 distinct patient groups. Five empirical data sets of trial based cost-utility studies that included patients with different disease condition and severity were used and compared incremental QALY's, incremental cost-utility ratio and the probability that incremental cost-utility ratio was acceptable within and across the data sets.

### 3. CALCULATION OF QALY FROM EQ-5D QUESTIONNAIRE

A QALY is the acronym for a quality-adjusted life-year is the arithmetic product of life expectancy and a measure of the quality of the remaining life-years. The National Institute for Health and Clinical Excellence (NICE) defines the QALY as a measure of a person's length of life weighted by a valuation of their health-related quality of life

The quantity of life, expressed in terms of survival or life expectancy, is a traditional measure that is widely accepted and has few problems of comparison – people are either alive or not.

Quality of life, on the other hand, embraces a whole range of different facets of people's lives, not just their health status. Even restricting the focus to a person's health-related quality of life will result in a number of dimensions relating to both physical and mental capacity.

A number of approaches have been used to generate these quality of life valuations, referred to as health utilities; for example, standard gamble<sup>[2]</sup>, time trade-off<sup>[3]</sup> and the use of rating scales. The utilities that are produced represent the valuations attached to each health state on a continuum between 0 and 1, where 0 is equivalent to being dead and 1 represents the best possible health state. Although some health states are regarded as being worse than death and have negative magnitudes there are several instruments which measure health related quality of life. They are: EQ-5D, SF-36, SF-12, SF-6D. EQ-5D and SF-6D are used for economic evaluation i.e. QALY measurement.

Each of the 5 dimensions comprising the EQ-5D descriptive system is divided into 3 levels of perceived problems:

Level 1: indicating no problem

Level 2: indicating some problems

Level 3: indicating extreme problems

A unique health state is defined by combining 1 level from each of the 5 dimensions. The 5 dimensions are:

1. Mobility
2. Self-care
3. Usual activities
4. Pain/discomfort
5. Anxiety/Depression

A total of 243 possible health states is defined in this way. Each state is referred to in terms of a 5 digit code. For example, state 11111 indicates no problems on any of the 5 dimensions, while state 11223 indicates no problems with mobility and self-care, some problems with performing usual activities, moderate pain or discomfort and extreme anxiety or depression. Two more states are included, i.e. unconscious state and death.

#### 4. A CASE STUDY

**CONVERTING EQ-5D STATES TO A SINGLE SUMMARY INDEX AND SURVEY IN BITS Educational campus, Goa, India:**

EQ-5D health states, defined by the EQ-5D descriptive system, may be converted into a single summary index by applying a formula that essentially attaches values (also called weights) to each of the levels in each dimension. The index is calculated by deducting the appropriate weights from 1, the value for full health (i.e. state 11111). Information in this format is useful, for example, in cost utility analysis.

Value sets have been derived for EQ-5D in several countries using the EQ-5D visual analogue scale (EQ-5D VAS) valuation technique or the time trade-off (TTO) valuation technique. The list of currently available value sets with the number of respondents and valuation technique applied is presented in table 1. Most of the EQ-5D value sets have been obtained using a representative sample of the general population.

#### 4.1 Survey Results and Calculation of QALY

Survey is conducted among BITS-Pilani, K.K.Birla Goa campus Students. Sample population is N=95. Valuation is based on UK TTO based value sets and is calculated using EQ-5D index calculator. By grouping the data from the survey, the following table was generated:

EQ-5D DIMENSIONS	LEVEL	% OF PEOPLE
MOBILITY	Level 1	95.7
	Level 2	4.21
	Level 3	0
SELF-CARE	Level 1	90.53
	Level 2	9.47
	Level 3	0
USUAL ACTIVITIES	Level 1	89.47
	Level 2	10.53
	Level 3	0
PAIN/DISCOMFORT	Level 1	84.21
	Level 2	13.68
	Level 3	2.1
ANXIETY/DEPRESSION	Level 1	62.1
	Level 2	31.58
	Level 3	6.31

Table-1: Grouping the survey results: EQ-5D

DIMENSIONS

Sr. No.	Mobility	Self-care	Usual Activities	Pain/Discomfort	Anxiety/Depression	Health State	Valuation
1.	Level 1	Level 1	Level 1	Level 1	Level 2	11112	0.848
2.	Level 1	Level 2	Level 2	Level 1	Level 1	12211	0.779
3.	Level 1	Level 2	Level 1	Level 1	Level 3	12113	0.31
4.	Level 1	Level 2	Level 2	Level 2	Level 2	12222	0.485
5.	Level 1	Level 1	Level 1	Level 1	Level 3	11113	0.414

Table2- Individual Results

The basic idea of a QALY is straightforward. The amount of time spent in a health state is weighted by the utility score given to that health state. It takes one year of perfect health (utility score of 1) to generate one QALY, whereas one year in a health state valued at 0.5 is regarded as being equivalent to half a QALY. Thus, an intervention that generates four additional years in a health state valued at 0.75 will generate one more QALY than an intervention that generates four additional years in a health state valued at 0.5.

#### 4.2 Effect of Self-Medication on QALY

Self-medication is a term used to describe the usage of drugs including alcohol or other self-soothing forms of behavior to treat untreated and often undiagnosed mental dullness, stress and anxiety including mental illness and/or psychological trauma

Divide self-medication into two parts for the convenience of study.

1. Drugs used for illness either physical or mental illness i.e. health care
2. Drugs used for pleasure and alcohol

Here only the economic aspects of drugs used for health are discussed.

QALY can be used for studying the economic aspects of drugs. QALY is used in assessing the value for money of a medical intervention.

1-Increase in QALY 2-Decrease in QALY

1. Increase in QALY:

QALY can be increased in case of self-medication if the drugs react to the illness positively and there is no requirement of further medical intervention

2. Decrease in QALY:

Decrease in QALY in self-medication can be divided into two parts for the convenience of our study. 1-Neutral 2-Negative

i. Neutral: even after self-medication the illness is not cured then the patient has to go for medical intervention which increases the overall cost of the treatment.

ii. Negative: sometimes self-medication leads to side effects due to lack of knowledge about dosage etc. This increases the cost of medical intervention due to side effects

The cost utility of the self-medication over the medical intervention is discussed. By calculating the additional QALY obtained by self-medication cost utility results are generated.

Cost utility ratio=

$$\frac{\text{cost of self medication} - \text{cost of medical intervention}}{\text{No. of QALYs produced by self medication} - \text{No. of QALYs produced by medical intervention}}$$

## 5. CONCLUSION

While QALYs provide an indication of the benefits gained from a variety of medical procedures, in terms of quality of life and survival for patients, they are far from perfect as a measure of outcome. For example, the use of QALYs as a single outcome measure for economic evaluation means that important health consequences are excluded. QALYs also suffer from a lack of sensitivity when comparing the efficacy of two competing but similar drugs and in the treatment of less severe health problems. Chronic diseases, where quality of life

is a major issue and survival less of an issue, are difficult to accommodate in the QALY context, and there is a tendency to resort to the use of disease-specific measures of quality of life. QALYs and cost-utility analysis provide additional information for decision-makers as they grapple with addressing the healthcare dilemma of where to allocate resources to generate the maximum health benefits for their communities and society as a whole

**6. ANNEXURE-I**

**SF-36v2 Health Survey Scoring Demonstration**

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Compared to one year ago, how would you rate your health in general now?

Much now year ago	than	better now year ago	Somewhat than	better now year ago	About as	the now year ago	Somewhat than	worse now year ago	Much than	worse one
<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all	
a	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c	Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d	Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e	Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f	Bending, kneeling, or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g	Walking more than a mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h	Walking several hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i	Walking one hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j	Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All	Most	Some	A little	None
	of the time of the time of the time of the time of the time				
a	Cut down on the amount of time you spent on work or other activities				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b	Accomplished less than you would like				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c	Were limited in the kind of work or other activities				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d	Had difficulty performing the work or other activities (for example, it took extra effort)				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All	Most	Some	A little	None
	of the time of the time of the time of the time of the time				
a	Cut down on the amount of time you spent on work or other activities				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b	Accomplished less than you would like				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c	Did work or activities less carefully than usual				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little	None of the time
a Did you feel full of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b Have you been very nervous?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c Have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d Have you felt calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f Have you felt downhearted and depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g Did you feel worn out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h Have you been happy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i Did you feel tired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
A I seem to get sick a little easier than other people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B I am as healthy as anybody I know	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C I expect my health to get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D My health is excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**EQ-5D Questionnaire (UK English version)**

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

**Mobility**

- 1.I have no problems in walking about
- 2.I have some problems in walking about
- 3.I am confined to bed

**Self-Care**



- 1.I have no problems with self-care
- 2.I have some problems washing or dressing myself
- 3.I am unable to wash or dress myself

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

- 1.I have no problems with performing my usual activities
- 2.I have some problems with performing my usual activities
- 3.I am unable to perform my usual activities

**Pain/Discomfort**

- 1.I have no pain or discomfort
- 2.I have moderate pain or discomfort
- 3.I have extreme pain or discomfort

**Anxiety/Depression**

- 1.I am not anxious or depressed
- 2.I am moderately anxious or depressed
- 3.I am extremely anxious or depressed

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