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QALYS
and their use by the Health Service

by

CLAIRE GUDEX

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The Author

Claire Gudex is a Research Fellow in the Centrè for Health Economics, University of York.

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Summary

Despite considerable progress and achievements in health care over the last century, we still cannot give every ill person as full a treatment as possible. With limited resources, decisions have to be made to determine priorities in the health care system. These decisions should be based on both costs of resource inputs and on the health outcome for the patients involved. However, there is little emphasis on outcome data in present decisions and its importance and usefulness needs to be highlighted. In a joint project between the University of York and the North Western Regional Health Authority (NWRHA), one measure of health outcome, the quality-adjusted-life-year (QALY) was combined with cost data to provide a new criterion for use in determining resource allocation.

The NWRHA found this cost/QALY data to be a useful adjunct to their decision-making and they will require details of both resource inputs and of health outcome to be given in subsequent bids. It is hoped that with the further development of a QALY-type measurement, it will be easier to include such information in the decision-making process and those concerned will be reminded that quality of life is a factor that should not be ignored.

In this paper the background to the project and the methods used are described. This is followed by a discussion of the QALY results in terms of their usefulness to a health authority, and in the context of some shortcomings that have yet to be resolved.

1. Background

Each year, the NWRHA receives a sum of money to allocate according to its own allocation guidelines. One of the principal funds is that

provided for 'Regional Specialty Developments'. These are primarily life-saving proposals or those designated 'national priorities'. Competing for resource allocation within the Regional Specialty Development Fund are bids for activities such as renal dialysis and kidney transplantation, open heart surgery, cancer treatment, neonatal intensive care, orthodontics, and the development of pathology and cytogenetic laboratories. With such a range of medical procedures, affecting patients of quite different ages in many cases, and affecting people's lives in very dissimilar ways, it is extremely difficult to compare the merits of each proposal in a systematic way. Any such comparison has two components. Firstly, the resources required to develop or expand it, and secondly, the effects of its development or expansion on the health of the patients at whom it is aimed.

At present there is a considerable emphasis on assessing the input of resources required for a procedure. This is usually presented in terms of costs, covering increased expenditure for medical and administrative staff, medical supplies or surgical equipment, and expansion and maintenance of wards, theatres, and laboratories. The costing exercise is often incomplete, omitting costs to social security, to the Family Practitioner Committee and to households.

Information on outcome is even less detailed. It is common practice to specify the increased workload, by way of stating the number of additional patients seen or beds occupied, but there is rarely any consideration of outcome in terms of the benefit to patients' health. There is rarely any mention of the improved quality of life or survival (additional life years) of the patients for whom the extra funding is provided. Surely this type of feedback is necessary to evaluate the health

system which, after all, has as its principal function, the maintenance of the health of the general population.

Although the concept of 'quality of life' is difficult to define and to quantify, there are already clinical scales in common use which attempt to do this, at least in part e.g. the Karnofsky Index (Hutchinson 1979), the Nottingham Health Profile (McEwen 1980), the Canadian Heart Association Classification of Angina (Campeau 1976). If a method could be developed to allow measurement of the diverse components of quality of life, it would be possible to envisage the routine application of a systematic measure of outcome.

Combining this measure of health outcome with the resource inputs, one would obtain a basic unit by which a range of health care procedures could be compared. This is exactly how the unit of cost/QALY could be used. It combines the cost of resources required for a procedure, with the outcome for the patients in terms of both their quality of life and their survival.

2. Project Details

2.1 Proposals studied

Four areas of medical care were chosen for which QALYs were calculated. These were areas in which it was likely that information on quality of life and survival would be relatively easily available from previously published data, and they all had a strong patient orientation. They covered a range of procedures, both medical and surgical, and a range of patient age groups and characteristics.

The four topics were:

1. Treatment in end-stage renal failure, both renal transplant and dialysis, including home maintenance haemodialysis, and continuous ambulatory peritoneal dialysis (CAPD).
2. Upper limb joint replacement.
3. The use of a new drug, ceftazidime, in the treatment of cystic fibrosis.
4. Surgical treatment of scoliosis.

The information required for the QALY calculation was gathered under two headings. These were data on quality of life, and data on survival, for patients undergoing each of the procedures.

2.2 Assessment of quality of life

The scale used to estimate quality of life was the Classification of Illness States developed by Rosser and Kind (1978) (Williams 1985). See Figures 1 and 2. For each of the topics chosen, it was necessary to find information on patient outcomes that would be comparable with the illness state descriptions in that classification. Six weeks were spent searching through medical and paramedical journals for any studies which included assessment of quality of life for the patient, before and after the procedure. Two measures of quality of life were required, one of social and physical disability (e.g. mobility, interference with employment, housework), and one of distress (e.g. pain, emotional status, satisfaction with life).

For scoliosis surgery and treatment in renal failure, few data on quality of life for British patients were available, although overseas studies were found. Many articles on cystic fibrosis patients presented only anecdotal information which proved difficult to translate into the

FIGURE 1. ROSSER'S CLASSIFICATION OF ILLNESS STATES

DISABILITY		DISTRESS	
I	NO DISABILITY	A.	NO DISTRESS
II	SLIGHT SOCIAL DISABILITY	B.	MILD
III	SEVERE SOCIAL DISABILITY AND/OR SLIGHT IMPAIRMENT OF PERFORMANCE AT WORK ABLE TO DO ALL HOUSEWORK EXCEPT VERY HEAVY TASKS	C.	MODERATE
		D.	SEVERE
IV	CHOICE OF WORK OR PERFORMANCE AT WORK VERY SEVERELY LIMITED HOUSEWIVES AND OLD PEOPLE ABLE TO DO LIGHT HOUSEWORK ONLY BUT ABLE TO GO OUT SHOPPING		
V	UNABLE TO UNDERTAKE ANY PAID EMPLOYMENT UNABLE TO CONTINUE ANY EDUCATION OLD PEOPLE CONFINED TO HOME EXCEPT FOR ESCORTED OUTINGS AND SHORT WALKS AND UNABLE TO DO SHOPPING HOUSEWIVES ABLE ONLY TO PERFORM A FEW SIMPLE TASKS		
VI	CONFINED TO CHAIR OR TO WHEELCHAIR OR ABLE TO MOVE AROUND IN THE HOUSE ONLY WITH SUPPORT FROM AN ASSISTANT		
VII	CONFINED TO BED		
VIII	UNCONSCIOUS		

See: Kind, Rosser and Williams: 'Valuation of Quality of Life: Some Psychometric Evidence' in Jones-Lee, M.W. (editor) The Value of Life and Safety, North Holland, 1982.

FIGURE 2. ROSSER'S VALUATION MATRIX : ALL 70 RESPONDENTS

DISABILITY RATING	DISTRESS RATING			
	A	B	C	D
I	1.000	0.995	0.990	0.967
II	0.990	0.986	0.973	0.932
III	0.980	0.972	0.956	0.912
IV	0.964	0.956	0.942	0.870
V	0.946	0.935	0.900	0.700
VI	0.875	0.845	0.680	0.000
VII	0.677	0.564	0.000	-1.486
VIII	-1.028	NOT APPLICABLE		

Fixed points: Healthy = 1 Dead = 0

See: Kind, Rosser & Williams: 'Valuation of Quality of Life: Some Psychometric Evidence' in Jones-Lee, M.W. (editor) The Value of Life and Safety, North Holland, 1982.

illness states. Follow-up surveys for upper limb joint replacements were extremely useful, as the parameters used for pre- and post-operative assessment were generally pain, ability to carry out activities of daily living, and employment status.

2.3 Survival

Survival data were also difficult to ascertain, as it was more relevant to have recent British data which related directly to the type of patient undergoing the procedures in question. It was clear that survival estimates would change with the characteristics of the patients, particularly their age, severity of illness, presence of other medical conditions, and the pathology involved.

2.4 Discounting

Discounting was used in calculating future benefits. This was done to reflect the phenomenon that individuals would rate future benefits as being worth less than immediate benefits. The rate of discount used here was 5% per annum (Drummond 1980).

3. QALYs As A Measure of Health Outcome

The detailed calculations of individual QALYs are given in Appendices 1 to 5. Presented here are summary tables for each area studied.

3.1 QALYs for treatment of end-stage renal failure

No British study with applicable data was found during the literature search, and the studies used were all based on the results from American patients. Because the follow-up periods in the studies were not sufficiently long to estimate life expectancy with treatment, a range of survival periods was used i.e. 2, 4, 6, 8 and 10 years. For marginal patients who would be accepted into a treatment programme in the event of

increased resources, survival periods would probably be at the lower end of the range.

Results are presented in the tables below, with the appropriate references.

HOME HAEMODIALYSIS : TABLE OF QALYs GAINED PER PATIENT

Survival (yrs)		2	4	6	8	10
Quality of Life	0.84[1]	1.6	3.0	4.3	5.4	6.5
	0.97[2]	1.8	3.4	4.9	6.3	7.5

HOSPITAL HAEMODIALYSIS : TABLE OF QALYs GAINED PER PATIENT

Survival (yrs)		2	4	6	8	10
Quality of Life	0.82[1]	1.5	2.9	4.2	5.3	6.3
	0.95[2]	1.8	3.4	4.8	6.1	7.3
	0.94[3]	1.8	3.3	4.8	6.1	7.3

RENAL TRANSPLANT : TABLE OF QALYs GAINED PER PATIENT

SURVIVAL (YRS)		2	4	6	8	10
Quality of Life	0.96[3]	1.8	3.4	4.9	6.2	7.4
	0.97[4]	1.8	3.4	4.9	6.3	7.5
	0.98[4*]	1.8	3.5	5.0	6.3	7.6

* Living Donor

CAPD : TABLE OF QALYs GAINED PER PATIENT

Survival (yrs)		2	4	6	8	10
Quality of Life	0.96[2]	1.8	3.4	4.9	6.2	7.4

1. Bonney et al, 1978.

2. Evans et al, 1985.

3. Procci, 1980.

4. Evans et al, 1984.

3.2 QALYs for upper limb joint replacement

A combination of British and American studies were found. There is no certainty about the duration of a joint replacement in the upper limb. Most studies have had a follow-up period of no longer than 5 or 6 years, and at that time a high incidence of loosening or Xray lucency (suggesting future loosening) has been reported.Thus for the shoulder, joint survival has been assumed to be 5, 8 or 10 years; for both elbow and wrist 5 or 8 years; and for finger replacements 8 or 10 years.

Table of QALYs Gained for Shoulder Joint Replacement

	Joint Survival	5 yrs	8 yrs	10 yrs	15 yrs	Neer Prosthesis
	Age					
RHEUMATOID	50 Yrs	0.3	0.5	0.6	0.8	Cofield
ARTHRITIS	55 Yrs	0.6	1.0	1.0	1.4	Clayton et al
	59 Yrs	0.5	0.9	1.0	1.4	Neer et al
OSTEO-	60 Yrs	0.6	1.0	1.2	1.5	Neer et al
ARTHRITIS	64 Yrs	0.4	0.7	0.9	-	Cofield
POST-TRAUMATIC	54 Yrs	0.4	0.7	0.7	1.0	Cofield
ARTHRITIS	57 Yrs	0.4	0.7	0.7	1.0	Neer et al
	57 Yrs	0.5	0.8	0.9	-	Lettin (Stanmore prosthesis)

Table of QALYs Gained for Elbow Joint Replacement

Joint Survival	5 yrs	8 yrs	
Age			
52 Yrs	0.6	1.0	Lowe et al
57 Yrs	0.5	0.9	Soni & Cavendish
55 Yrs (assumed)	0.4	0.7	Morrey et al

Table of QALYs Gained for Wrist Replacement

Joint Survival	5 yrs	8 yrs	
Age 57 Yrs	0.5	0.8	Davis et al

Table of QALYs Gained for Finger Joint Replacement

Joint Survival	8 yrs	10 yrs	
Age 63 Yrs	1.3	1.5	MCP joints (Blair et al)
62 Yrs	0.9	1.0	PIP joints (Dryer et al)

3.3 QALYs for Ceftazidime Treatment in Cystic Fibrosis

No direct data were found concerning the change in quality of life for cystic fibrosis patients treated with ceftazidime. However, the advantages of ceftazidime appear to be faster and better clinical improvement of acute respiratory infections, increased acceptance of treatment with less pain and side effects, and fewer administrations (David et al, 1983; Strandvik et al, 1983; Permin et al, 1983).

TABLE OF QALYS GAINED BY TREATING WITH CEFTAZIDIME

	Average Life Expectancy from birth			
	22 years	23 years	24 years	25 years
QALY (ceftazidime)	12.37	12.68	12.97	13.24
QALY gain over established treatment	0.4	0.7	1.0	1.3

3.4 QALYs for surgical treatment of scoliosis

No suitable data were found for a U.K. population, despite a scoliosis incidence of 2-5 per 1000 population. Because of the uncertainty of outcome without treatment, QALYs were calculated allowing for a range of life expectancies for patients not undergoing surgery. There is a suggestion that these patients face a higher than average risk of death after the age of 45 years (Nilsonne and Lundgren 1968). The life expectancies used here were 40, 50, 60 and 70 years. The most likely situation is an untreated life expectancy of between 50 and 60 years, giving QALY gains for surgical treatment of idiopathic adolescent scoliosis of between 1.2 and 2.5.

Table of QALYs gained per patient from scoliosis surgery

Adolescent Idiopathic Scoliosis				
Life expectancy of untreated patient (years)	40	50	60	70
Gain in QALYs	4.5	2.5	1.2	1.1
Scoliosis secondary to neuromuscular illness				
Life expectancy of untreated patient (years)	30			
Gain in QALYs	16.2			

4. Interpretation of QALY Data

4.1 Patient characteristics

A list can be drawn up of the procedures, in order of the gain in QALYs which they confer per patient entering treatment (see table 1).

Table 1 : List of Procedures in Order of QALYs Gained

Surgery for scoliosis in a neuromuscular patient	16.2
Renal transplant lasting 10 years	7.4
Home or hospital haemodialysis lasting 8 years	6.1
CAPD lasting 4 years	3.4
Home or hospital haemodialysis lasting 2 years	1.8
Surgery for scoliosis in a healthy adolescent	1.2
Shoulder joint replacement for rheumatoid arthritis, lasting 10 years	0.9
Elbow joint replacement lasting 5 years	0.5
Wrist replacement lasting 5 years	0.5
Treatment of cystic fibrosis with ceftazidime (compared with established treatment and assuming life expectancy of 22 years)	0.4

It is important to note that the number of QALYs gained can vary considerably depending on the characteristics of the patients undergoing the treatment.

For example, for an otherwise healthy 14-year old having an operation to correct a scoliosis, the gain in QALYs would be 1.2, if the same patient would have died at 60 years old without treatment. However, for a 14 year old with a scoliosis secondary to neuromuscular illness, the gain in QALYs would be 16.2 over no treatment.

For a 50 year old patient with renal failure, treatment by hospital haemodialysis may confer an extra 6.1 QALYs with a survival of 8 years. But is this patient had complications such as heart failure, a blocked

fistula, or recurrent infections, with a resulting survival of only 2 years, the QALYs gained may only be 1.8.

4.2 Cost/QALY Data

The above table gives an indication of the relative benefits gained from a variety of medical procedures, in terms of quality of life and survival for the patient. This alone however cannot indicate which procedures should have priority in the competition for resources. When appropriate costs are combined with the QALY data, to give values for cost/QALY gained, the list order could be quite different. These costs must be structured to the characteristics of the patients in order to make the cost/QALY figure relevant and as accurate as possible.

Table 2 presents the cost/QALY figures for the procedures discussed above. Costs cited are from the NWRHA (Gudex, Lowson and Williams 1986).

This is the table which gives an idea of the relative gains from the procedures. It is evident that different health care activities show different cost-effectiveness.

CAPD appears to be the least cost-effective procedure. The QALY gain used here, is that expected for marginal patients who would be accepted into the CAPD programme in the event of increased funding. These may be elderly patients or those with medical complications. Their poorer expectations of survival, combined with the high cost of CAPD, make the cost/QALY very high.

Haemodialysis and ceftazidime treatment in cystic fibrosis are more cost-effective, but are still expensive in terms of inputs required. These figures can be compared with the average level of GNP per head in Britain of £5000.

Table 2 : Cost/QALY Data for Each Procedure

	QALYs Gained Per Patient (discounted at 5%)	Annual Cost Per Patient	Total Cost (discounted at 5%)	Cost/ QALY
CAPD (4 years)	3.4	£12,866	£45,676	£13434**
Haemodialysis (8 years)	6.1	£8,569	£55,354	£ 9075**
Treatment of cystic fibrosiswithceftazidime (over 22 years)	0.4	£250	£3,290	£ 8225**
Kidney transplant (lasting 10 years)	7.4	£10,452	£10,452	£ 1413*
Shoulder joint replacement (lasting 10 years)	0.9	£533	£533	£ 592*
Scoliosis surgery				
- idiopathic adolescent	1.2	£3,143	£3,143	£ 2619*
- neuromuscular illness	16.2	£3,143	£3,143	£ 194*

* represents one-off costs per case, and benefits discounted over life of case

** represents recurring annual costs and annual QALYs per case

At a much reduced cost, are kidney transplantation and shoulder joint replacement. These would seem well worthwhile procedures in view of the benefits that patients perceive themselves as receiving, and the lower costs involved.

At the bottom of the list, being the most cost-effective procedure, is scoliosis surgery for neuromuscular illness. This type of surgery confers a substantial improvement in quality of life for the patients involved and is also cheap. Surgery for idiopathic adolescent scoliosis does not do so well because of the less dramatic effects on quality of life and on survival.

This sort of information would undoubtedly be of benefit to health authorities and others participating in decisions for resource allocations. Assumptions and estimates are necessary at present to fill the gaps in knowledge of benefits and costs. However the final cost/QALY figures show such variations in magnitude that even a crude calculation could give an idea of cost-effectiveness. It is suggested that such data should be used in conjunction with information presently available, to form a more reliable basis on which to make funding decisions.It is envisaged that those procedures or activities which are most cost-effective i.e. produce the most benefit for a given cost, should be developed or supplied first. Activities conferring less general benefit should be given a lower priority. This does not mean that such activities would never receive funding. In any new development of a service, and in many fields of research, initial costs can be very high, and health benefits are not always immediately obvious. These areas will continue to require funding, but it would be recommended that attention is first drawn to areas of more obvious need. Funding here would be of more immediate benefit to receivers, and also probably to the health service in the long-term. Such activities , which often involve low technology and are community or primary care orientated, tend to be easily overlooked in the current preference for cure-orientated, high technology medicine.

A method such as this for assessing bids in a more systematic way, should help the Health Service to become more efficient. Not only by placing an emphasis on activities which produce more benefit per cost, and also identifying areas of need, but also by encouraging participants to use and clarify outcome measurements. These are too visibly lacking in the present system. Outcome data would provide feedback to assess the effectiveness of the health system, and would probably increase the

participation of the general population in the health care field. This latter effect would certainly be desirable as it is this population for which the health system was established.

One would hope that such a system would also prevent the too rapid introduction of techniques and services, which are eventually found to have little or doubtful benefit, and sometimes disastrous consequences e.g. neonatal intensive care and thalidimide.

5. Discussion Points

5.1 Assessment of Quality of Life

The Classification of Illness States covers a range of factors pertinent to quality of life (QoL), but there are other important factors which are not included in the scale. There is also potential for ambiguity.

The disability scale is based on varying degrees of ability to undertake employment, and to be mobile. It is usually straightforward to identify a patient's position in the scale, but the scale can be ambiguous. For example, when a wheelchair-bound patient is able to work full-time, and feels that there is no limitation on his or her working capacity or social activities. The patient should probably be placed in the disability-distress category 1A, but that ignores the description in disability category 6, 'patient confined to chair or wheelchair'.

Although the distress component of scale is broad and can be said to cover a wide range of subjective feelings (emotional status, pain, satisfaction with life), it still does not cover some important features of QoL which are also omitted from the disability scale.

These are primarily features dealing with marriage satisfaction, sexual functioning and reproductive ability. Role fulfilment is also not considered adequately.

There is a high incidence of infertility (95%) in males with cystic fibrosis (Taussig et al, 1972), and female patients are often advised not to become pregnant because of the potential complications in pregnancy (Cohen et al, 1980). Premature delivery, and increased maternal and perinatal mortality, are thought to be related to severe pulmonary infections in the mother.

A high proportion of untreated scoliotics do not marry. In a study by Nilsonne and Lundgren (1968), 76% of female patients were unmarried (average age 62 years). Those that do marry have a higher than normal divorce rate, with fewer children per marriage and increased psychiatric consultation and suicide rates. Van Grouw et al report that 49% of their treated study population were married, with 4% divorced at an average age of 24 years.

Cochran et al record that although the birth rate for treated scoliotics compares favourably with the Swedish norm, the Caesarian Section rate was higher in the scoliotic population. When examined statistically, there was a correlation between decreasing lumbar lordosis and increasing Caesarian Section rate for the study population.

None of these factors could be included in the assessment of quality of life using this classification system.

Within the classification, there is too much emphasis placed on the ability to undertake paid employment. There are insufficient descriptions to assess the QoL for children, the mentally handicapped, and the elderly. A different emphasis, including a greater breakdown of ability to carry out activities of daily living, and mental status assessment, is required for these patient groups. Some comparisons of different health state measures have already been made (Kind 1985), but further research will be needed to elucidate those aspects which are important when measuring quality of life.

5.2 Valuation of illness states

This is probably the stage which is the most commonly criticised. The ratings used are based on the response of 70 subjects with a range of backgrounds. (Kind, Rosser and Williams, 1982) There are:

10 patients from medical wards

10 psychiatric in-patients

10 experienced state registered general nurses

10 experienced state registered psychiatric nurses

20 healthy volunteers

10 doctors each with a Membership or Fellowship of at least one Royal College

For this method of evaluation for QoL to be used as widely as it is even now, this base of 70 subjects should be much larger and wider. This is to ensure that the valuations used are not skewed by any bias within the group of subjects, and also that the evaluations are representative for the general population.

The question of who should be asked to do the valuations is open to debate. Responses from a large (500 or even 1000 subjects) sample of the

general population could be used, with the argument that the health care system is set up for the general population and therefore the latter has a right to have its own value of life represented.

Health workers could be asked because they are the ones delivering health care, and have the closest and widest contact with patients, and hence may claim to be the people best able to reflect patients' views (other than patients themselves). Or perhaps politicians and health authority officers should be asked as they are the ones charged with priority setting, resource allocation, and the planning and administration of health care. Then of course, perhaps only people already suffering from particular disabilities should be the evaluators because only they know how their QoL has been changed and to what degree. Sackett and Torrance (1978), presented results indicating differences between valuations given by healthy volunteers and by patients. The valuations of the latter were themselves dependent on the length of illness.

Further study is required in this area to determine how different subject groups value QoL.

Despite the small number of respondents, an analysis by Rosser and Kind of valuations given by various subjects, shows a surprising and encouraging consistency among respondents. It was noted however, that doctors placed more emphasis on distress, while patients felt disability to be more important.

The health state valuations used by Rosser et al were derived by the method of ratio scaling. The subjects were asked to estimate how pairs of health states compared in terms of undesirability ie. how much worse one state was compared to the other. There are other methods of deriving these

valuations. Two commonly used methods are the standard gamble and the time trade off techniques. Both of these derive the preference values implicitly, based on the subject's responses to decision situations. They do not ask the subject to be explicit about his/her values as the ratio scaling method does.

It is possible that different methods of health state valuation result in divergent values, thus causing concern over which method is the most appropriate to use. Again, little work has been done to compare results arising from alternative valuation techniques, but it is another important area where further study and analysis are required.

The basic assumption in this valuation is that the value of an individual remains the same throughout his or her life. The NHS has the basic tenet of equity, with equal distribution of and access to health for every member of the population. So it should be assumed that every individual has an equal value to society. However many people would contest this asssumption and it seems that an individual's value to society changes throughout his or her life.

The general population is often seen as a source of human capital. Patients are then assessed in terms of their actual or potential value to society with respect to income. It is thought that those patients who are likely to be useful economically to society, should receive a greater input of health benefits with a view to maximising their contribution to society. This view discriminates against several groups, in particular housewives, the elderly, and the mentally or physically handicapped. It tends not to take into account a person's past contribution to society.

On the basis of results from a recent survey (Wright, 1986), perhaps the quality of life for certain age groups should be weighted higher

relative to the quality of life for some other age groups. It appears that both males and females feel that the most important times to be in good health during their lives include early parenthood, infancy, when setting up a first home (males), at the peak of earning capacity (males), and when caring for elderly relatives (females). From these results, it could be suggested that quality of life ratings should be weighted in favour of infants and adults up to about 50 years old. This scale however would also discriminate against the elderly.

Perhaps such a weighting system should be devised to accommodate relative values for the lives of individuals. It would certainly be a controversial area, and would require a great deal of study and application to ensure its validity.

5.3 Sources of data

Information gathered on QoL can be obtained from a variety of sources. Those most commonly used are:

a) from patients themselves in the form of questionnaires

b) from the patients's relatives

c) from health care workers involved in the patient's treatment

d) from data on QoL published in the literature.

These alternatives require varying degrees of time and energy, and could produce divergent results, if indeed for example, doctors rate QoL in a different way to the patients themselves (Rosser et al 1982). Again the choice of method depends on the emphasis and aim of the study undertaken, and only further research will show whether these methods produce significant differences in their results.

In the previous section, the patient's relatives were mentioned as a possible source of QoL data. However it is not only the patient's QoL which needs to be considered, but also that of the patient's family. Few studies of QoL include an assessment of the disruption to family life through an illness and its treatment. The Rosser scale also makes no attempt to assess QoL for other family members. This aspect becomes particularly important in the case of chronically ill patients requiring long-term committed care and support. Typically a great deal of this input comes from the family. From anecdotal reports on the effects of an illness on family life, it is clear that these effects are sufficient to warrant inclusion in QoL evaluations.

It is noted in the Appendices that few British data on QoL were available for the cases under study. Clinical trials should routinely include measures of QoL before and after procedures. This would facilitate the calculation of QALYs, and would provide a much better picture of how the patient's life is affected by the procedure and in which spheres of functioning changes have occurred.

5.4 Is assessment of quality of life necessary?

It is sometimes said that assessment of QoL is not necessary. One would hope that QoL is considered implicitly in any decision made by doctors and other health care workers responsible for initiating treatment schedules. Indeed there are some areas where the near-certain prolongation of life for another 40 years would easily outweigh any deleterious effect on QoL by short-term treatment e.g. acute appendicitis, whooping cough. At the other end of the scale, there would be little doubt that an 80 year old patient in heart failure should not be at the top of a waiting list for heart surgery. However in between these extremes are illnesses and their treatments where a trade-off is necessary between QoL and survival. How

many extra months or years of life are necessary before it becomes 'worth' treating a patient for a disease with a very poor prognosis, such as oat cell lung carcinoma? Are we in fact, being kind to the patient? This is the type of illness where QoL is particularly important to assess.

5.5 Ethical concerns

When QALYs are used in resource allocation decisions, choices between patient groups competing for medical care are made explicit. There is an implication that some patients will be refused or not offered treatment for the sake of other patients. These concerns have not been traditionally part of a doctor's way of thinking. It is expected that a doctor does all that is possible for a patient to maximise his or her health. However such choices have always been made, only not formally identified. Doctors who treat private patients do so at the expense of public patients, those who work in cities do so at the expense of the rural community, those who do heart transplants do so at the expense of patients on a waiting list for pacemakers. Choices are being made all the time, and priorities are being set. The decisions are now becoming more difficult with the increasingly limited resources within the health system. But on what basis are these choices and priorities being made? And are the decisions equally fair to all patient groups? Are there any patient groups who consistently receive less or poorer health care, or who consistently suffer poorer health? As members of society, doctors have a responsibility to society as a whole and not only to individual patients, despite the fact that when faced with an ill patient it is painful to realise that treatment of this patient may be at the expense of another. We have a commitment to ensure that the choices made are the efficient and humane ones, and are not based merely on political pressure or the quest for technological advancement. With their expert knowledge of treatment and outcome, doctors have a significant role to play in this decision-making. They are

responsible for so much of the processes within the health care system, that it would be ridiculous to make decisions without their contribution. Allowing for the little expertise that a doctor usually has in the areas of management and budgeting, these decisions must be made on a cooperative basis, allowing the necessary information to be culled from several different sources. A system such as QALYs combines some of this information, and provides an aid to improve the basis for decision-making. A system which is generally agreed to be ethical and 'fair' has not yet been perfected, but with continuing research and participation by all parties involved, we can certainly come nearer this goal.

6. Conclusion

It became clear during this project that there is a considerable need for a greater emphasis on health outcomes for patients, and particularly on their quality of life, at the level of resource allocation decisions. Such methods as discussed here should be further developed to provide a framework for such information to be used, remembering that quality of life, survival, and cost must all be considered in the assessment of procedures within the health care system.

Appendix 1 : QALYs for treatment of End-Stage Renal Failure

Data from published studies were used to calculate quality of life for patients on home and maintenance haemodialysis, CAPD, and after renal transplant. Two examples of this conversion are given below in (1) and (2).

It was assumed that without treatment by dialysis or transplant, a patient with severe renal failure would have a very limited life expectancy, and thus any gain in survival due to treatment was counted as a pure gain.

The quality of life estimate for each treatment mode was then multiplied by a period of survival (discounted by 5%) to give a QALY for each mode. Since survival periods are not yet fully established, a range has been used, and therefore a range of QALYs are obtained. Full results are shown in the table in the main part of the paper.

General trends for quality of life appear as expected. Kidney transplant, with a living donor or a cadaver source, gives a higher quality of life than haemodialysis; and home and hospital haemodialysis confer very similar levels of quality of life.

Within both the home and the hospital haemodialysis estimates, there is a discrepancy between the values from data of Bonney et al (0.84 and 0.82) and of Evans et al (0.97 and 0.95).

This is partly due to the difficulty in ascribing categories from two different scales (the National Kidney Foundation Classification and the Karnofsky Index), into a third, the Rosser Classification. Although the

extent of patients' abilities are described, it is not always easy to place these into mutually exclusive Rosser grades of disability.

The main source of difference stems from the considerably smaller number of both home and hospital dialysis patients being in Rosser Disability Grades I-II, in Bonney et al's survey. There were no patients in this category from the home dialysis group, compared to 59% of Evans' group, and for hospital dialysis patients, there were 4% in categories I-II compared to 45% of Evans' group.

The mean age for each mode of dialysis was similar in both studies as was the percentage with diabetes (between 8% and 10% in all studies). The mean duration of dialysis for the patients in Evans' study was longer, and also 13% of Evans' hospital haemodialysis patients had undergone an attempted renal transplant. This may have influenced their quality of life, or perhaps reflects a healthier group of patients being studied by Evans.

(1) Quality of Life on Maintenance Haemodialysis

Procci (1980) evaluated 16 males on maintenance haemodialysis, for social disability, and included employment status in the description of patients. The average age was 37 years, and the average duration of renal failure was 41 months.

He used the Ruesch Social Disability Rating Scale (Ruesch et al 1972) which generates three subscores.

- Physical Impairment (PI)
- Behavioural Impairment (BI)
- Social Modifiers (MS)

The numerical scores for PI and BI are compared and the higher of the two is added to the MS score to yield an overall Disability Score (DS). Based on previous research, the DS scores are categorised as follows.

Disability Score		Rosser Category	No. Patients
DS < 20	No Social Disability	I	0
DS 20-49	Minor Social Disbility: can continue as usual with home or occupational activities	II	6
DS 50-79	Major Social Disability: must alter work program, if patient can work at all, rely on regular outside help	III-V	10
DS 80-109	Total Social Disability: 24 hour full care or in an institution	VI-VIII	0

The Social Modifiers score reflects the impact that physical or behavioural impairment has had upon the patient's life and takes into account the need for various forms of assistance, social interactions and also the degree to which social functioning is affected. This was felt to have the most correlation with the Rosser distress classification.

MS Score	Rosser Distress Category	No. Patients
1-5	A	0
6-19	B	11
20-39	C	3
40-55	D	2

The next step is to multiply the number of patients in each disability/distress category by the valuation for that category (see Figure 2).

6 x 0.986	= 5.92			A	B	C	D	
5 x 0.972	= 4.86		I	0	0	0	0	0
3 x 0.956	= 2.87	DS	II	0	6	0	0	6
2 x 0.7	= 1.4	(50-59)	III	0	5	3	0	8
	15.05	(60-69)	IV	0	0	0	0	0
		(70-79)	V	0	0	0	2	2
			VI	0	0	0	0	0
					11	3	2	

The total of 15.05 represents the QoL for 16 patients, thus the QoL for one patient is calculated by

15.05 / 16 = 0.94

Average quality of life = 0.94

(2) Quality of Life after Renal Transplant

Procci (1980) also evaluated 16 males who had well-functioning cadaver transplants, for social disability and employment status. The average age of the patient was 38 years, and the average duration of renal failure was 66 months.

Using the same scoring system as for the in-centre haemodialysis group, the following tables were produced.

Disability Score	Rosser Category	No. Patients
< 20	I	0
20-49	II	5
50-79	III-V	11
80-109	VI-VIII	0

Social Modifiers Score	Rosser Category	No. Patients
1-5	A	0
6-19	B	8
20-39	C	8
40-55	D	0

	A	B	C	D	
I	0	0	0	0	0
II	0	5	0	0	5
III	0	3	5	0	8
IV	0	0	2	0	2
V	0	0	1	0	1
VI	0	0	0	0	0
	0	8	8	0	

Using the same method as before, total QoL for 16 patients is 15.41, thus the average QoL for one patient is

$$15.41 / 16 = 0.96$$

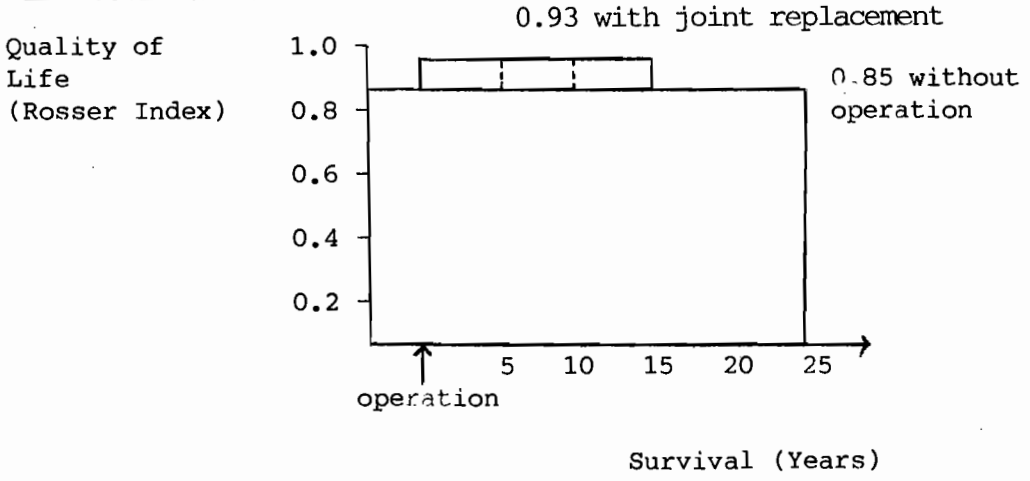
Appendix 2 : QALYs for Upper Limb Joint Replacement

Conversion of data from published studies to quality of life estimates, using the Rosser Classification, are shown in (1) and (2) below. Details of QALY calculations, with an example, are given here. Full results are shown in the main commentary.

Life expectancy has been assumed to be 74 years, between the figure given by OPCS for females (77 years) and males (71 years). After a joint has been removed, it is assumed that the patient's quality of life returns to the preoperative level.

Discounting performed at 5%.

Shoulder Joint Replacement



The QALYs have been calculated according to the age of the patients. Thus for Cofield's study, with an average age of 50 years :

Without operation	QALY	= 0.85 x 24 years discounted
		= 0.85 x 13.8
		= 11.73
With a joint lasting 5 years	QALY	= (0.93 x 5 years discounted) + (0.85 x 19 years discounted)
		= 12.07
Difference in QALYs		= 12.07 - 11.73 = 0.34

(1) Quality of life for total shoulder joint replacement

Cofield (1984) evaluated 29 shoulders in 24 patients with rheumatoid arthritis, with an average age of 50 years (range 22-72 years). Female:Male ratio was 22:7. The results were conveniently graded according to the patients' success in a post-operative exercise programme.

Most patients took part in a full rehabilitation programme, but for some patients for whom complete rehabilitation was not feasible, the aim was to achieve a lesser range of motion but to maintain stability of the shoulder joint (Limited-Goals Rehabilitation). The following classification has been made on the basis of information given by Cofield (1984) and Neer et al (1982).

Full Exercise Programme

Excellent	No or slight pain, patient satisfied. Full use of shoulder. Muscle strength near normal. Able to do usual work, and strenuous activity e.g. tennis, golf.
Satisfactory	Slight or moderate pain only with vigorous activity. Patient satisfied, good use of shoulder for full daily function, minimum of 30% normal muscle strength.
Unsatisfactory	Above criteria not met

Limited-Goals Rehabilitation

Successful	No, slight or moderate pain only with vigorous activity.
Unsuccessful	Above criteria not met

Preoperatively all patients suffered either moderate or severe pain and range of motion of the shoulder joint was significantly impaired. This was graded as a Rosser category of IV - V C/D = 0.85.

Postoperative

Full Exercise Programme	Rosser Category	No. shoulders
Excellent	1A	6
Satisfactory	II-IIIB	11
Unsatisfactory	IV-V C/D	7
Limited-Goals Rehabilitation		
Successful	IVB	3
Unsuccessful	VD	2

By the same method used earlier in Appendix 1, the QoL of 29 patients is represented by 27.0, thus the average QoL for one patient post-operatively is

$$27.0 / 29 = 0.93.$$

(2) Quality of Life for Elbow Joint Replacement

Soni and Cavendish (1984) evaluated 80 elbows in 65 patients with an average age of 57 years. Again, more of the patients had rheumatoid arthritis (85%) and the female:male ration was 36:29.

Pain Grading	Rosser category	No. elbows Preop.	Postop.
Normal	A	3	65
Slight pain	B	7	10
Moderate pain, limiting use of elbow	C	27	5
Severe, with night pain, preventing most activities	D	43	0
		80	80

Function		Rosser category	No. elbows Preop.	Postop.
Excellent	Stable, good range of movement	I - II	0	42
Good	Complications requiring revision but patient satisfied	III	0	15
Fair	Discomfort but could carry out some daily activities	IV	80	9
Poor	Poor range of motion, patient dissatisfied	V		14
				80

Using the method described in Appendix 1,

Quality of life preoperatively = 0.85
postoperatively = 0.98

Appendix 3 : QALYs for Ceftazidime in Treatment of Cystic Fibrosis

Quality of life was first calculated for patients receiving current established treatment for cystic fibrosis. An example is shown in (1) below. Assumptions were then made in order to calculate quality of life for patients receiving the new drug, ceftazidime. This is shown in (2) below.

Life-expectancy has been assumed to be 22 years for the cystic fibrosis patient on established treatment (not including ceftazidime). When the disease was first described, about 50 years ago, survival was measured in months, but now with current treatment and care survival has improved considerably. Warwick (1982) reports that not only quality of care is important, but also the presence or absence of a specialised cystic fibrosis team providing comprehensive management.

Data from specialised centres around the world show an improved prognosis e.g. 50% survival at 21 years and 22 years in the US and Canada, and 65% survival at 19 years in Australia. Using figures from Batten (1983) and Wilmott (1983), a life expectancy of 22 years was calculated for British patients - both these studies involved patients of specialised units so the figure may be too high for other patients, for whom no data was found.

Discounting at 5%, QALYs were calculated for

(a) established treatment

(b) no treatment at all

(c) treatment with ceftazidime

(a) QALY for cystic fibrosis patients regardless of age on established treatment

= 0.91 x 22 years discounted

= 0.91 x 13.2

= 11.98 per patient

(b) To establish the gain in QALYs conferred by treatment the QALYs that a patient would have with no treatment must be subtracted. For patients presenting with meconium ileus, any present improvement in life expectancy is a pure gain, as life expectancy in pre-antibiotic times (i.e. pre 1948) is assumed to be 0 effectively.

Those not presenting with meconium ileus had a better survival even before antibiotics were widely used, and from data of Mantle and Norman (1966) the life expectancy then was probably 1.5 years.

These two groups of patients have to be considered together here, as quality of life data has only been calculated for the patients as a whole. Details of these calculations are given in (1) below. As between 10-30% of patients present with meconium ileus, an arbitrary figure of 1 year was assumed for life expectancy without treatment. Using the same quality of life value as for treated patients (in the absence of one for untreated patients),

QALY = 0.91 x 1 year discounted

= 0.91 x 0.95

= 0.87

Thus the gain in QALYs with established treatment = 11.98 - 0.87

= 11.11

(c) No information was found on the effect of ceftazidime therapy on survival for cystic fibrosis patients. In the table given in the main commentary, QALYs have been calculated for a range of life expectancies,i.e. 22 - 25 years (from birth). Details of the calculations of quality of life are given in (2) below.

e.g. For an average life expectancy of 22 years

QALY (ceftazidime) = 0.94 x 22 years disc

= 0.94 x 13.16

= 12.37

Gain in QALYs over no treatment

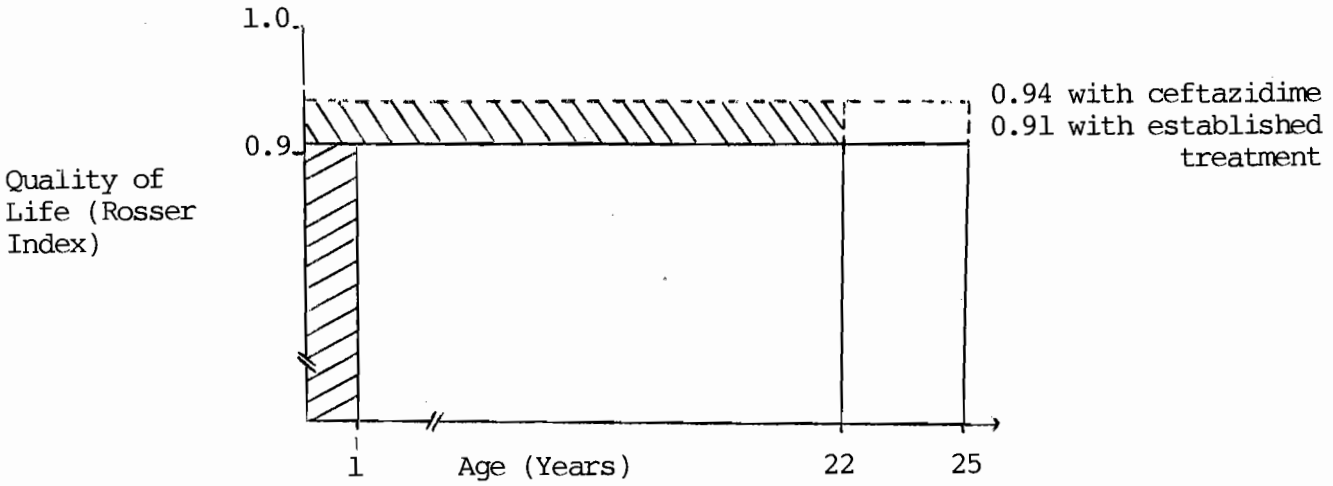
= 12.37 - 0.87

= 11.5

Gain in QALYs over established treatment

= 11.5 - 11.1

= 0.4



(1) Quality of Life with established treatment

Boyle et al (1976) provided considerable information on the psychological adjustment of 27 cystic fibrosis patients aged between 13 and 30 years (average age 20 years). Female:male ration 9:18.

All these patients had chronic pulmonary disease and had been given a rating score, according to either the National Institute of Health (NIH) Clinical Score of Taussig et al (1973), or the score developed by Shwachman and Kulczycki (1958).

These scores differ in the weighting given to their different parameters, but both include a measure of activity level of the patient. Taussig et al weighted the pulmonary component heavily, as this is recognised as being the best correlator with prognosis and the authors noted that the activity category was closely related to the pulmonary one.

Shwachman and Kulczycki's score gives equal weight to four parameters - general activity, physical examination, nutrition and X-Ray findings, each item generating a score out of 25 points. Five patients in Boyle's study had been evaluated with this score.

Although the Shwachman-Kulczycki score probably correlates less well with general activity, both scores were converted into Rosser categories as follows :

Score	Rosser Category	No. patients
> 85	I	5
71-85	II	8
56-70	III-IV	9
41-55	V-VI	4
< 40	VII	1

For the Rosser distress categories, the patients were graded on the basis of daily coping skills, which had been presented by Boyle as good, fair (functioning but performance impaired by severe anxiety) and poor.

All patients had expressed dissatisfaction with their bodies, and used clothing and hairstyles to disguise their emaciation and experienced some difficulties in dating, etc., and thus no patients were placed in category A.

Coping Skills	Rosser Category	No. Patients
Good	B	13
Fair	C	6
Poor	D	8

	A	b	C	D	
I	0	2	1	2	5
II	0	4	2	2	8
III-IV	0	4	2	3	9
V-VI	0	2	1	1	4
VII	0	1	0	0	1
VIII	0	0	0	0	0
		13	6	8	

Using the same method as in Appendix 1, the overall QoL for 27 patients is 24.57, thus the average QoL for one patient is

$$24.57 / 27 = 0.91.$$

(2) Quality of Life with Ceftazidime Treatment

The use of ceftazidime has been assumed to have no significant effect on patients' levels of disability. Nutrition and general activity may improve, but the drug will not prevent severe chest infections from recurring, and patients will still be required to undergo 3-monthly treatment regimes. The benefit therefore lies more in the levels of distress experienced.

Without knowing the ages of the patients or the severity of their illness for those treated with ceftazidime, the data from Boyle's study were used as a basis for estimating a quality of life value. It was

assumed that half the patients in each distress category moved up to the next higher category when treated with ceftazidime. Patients in category B were included in a joint A/B category.

	No. Patients		
Rosser Category of Distress	Established therapy	Ceftazidime treatment	
A	0	)	
		)	16
B	13	)	
C	6	7	
D	8	4	

The numbers in disability categories were retained.

	A-B	C	D	
I	3	2	0	5
II	4	2	2	8
III-IV	5	2	2	9
V-VI	3	1	0	4
VII	1	0	0	1
	16	7	4	

Using the same method as in Appendix 1, the overall QoL for 27 patients is 25.3, thus the average QoL for one patient is

$$25.3 / 27 = 0.94.$$

Appendix 4 : QALYs for Surgical Treatment of Idiopathic Adolescent Scoliosis

From a literature search, four previous studies were found, which included sufficient information to estimate quality of life using the Rosser classification of illness states. Two of these studies involve surveys of untreated scoliosis cases, the remaining two are follow-ups of adolescents who had undergone the Harrington rod operation. An example of each is given below in (1) and (2).

Using these 4 sets of quality of life data, QALYs were calculated by including survival figures.

Assumptions

1. It was assumed that with modern treatment, the life expectancy of a surgically treated scoliotic is equal to that of a healthy peer. The life expectancy for a U.K. female is used (77 years) (OPCS), as the majority of patients are female.

2. Operative mortality was assumed to be negligible - there are potentially severe complications from the operation (thrombosis and emboli, and paraplegia), but the patients are an otherwise healthy young population, and there is careful post-operative care.

3. The onset and treatment of symptoms is assumed to occur at age 14 years, being the average age for operation for idiopathic adolescent scoliosis.

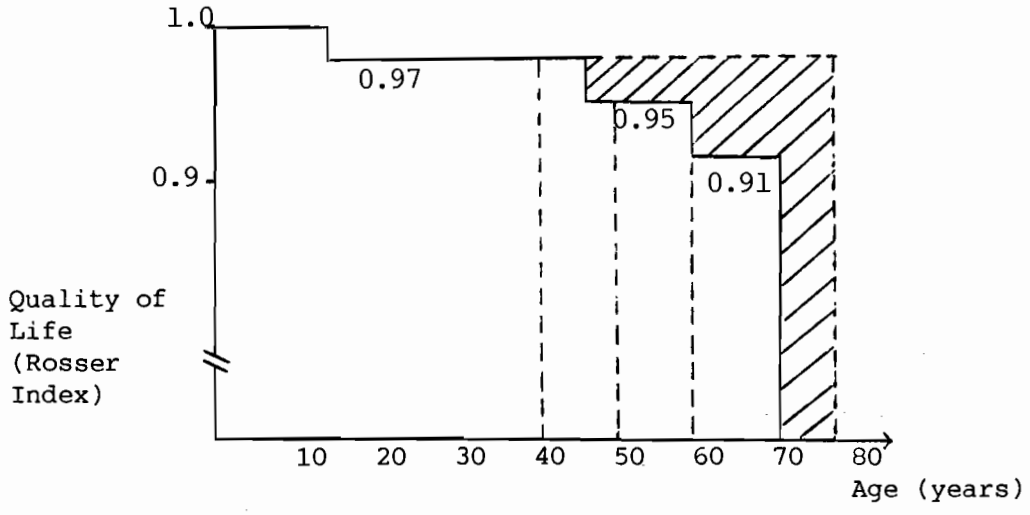
4. Collis and Ponseti showed no difference in the death rate of untreated scoliotics to that of a normal population, with an average follow-up age of 42 years. However Nilsonne and Lundgren had a longer follow-up period with a mean age of 62 years, and they noticed a significant increase in

mortality especially after 45 years of age (2.2 times the normal rate). 60% of these deaths were reported to be secondary to scoliosis, particularly cardiac failure, pulmonary tuberculosis and pneumonia. Dickson (1983) reports however, that curve magnitude was greatly in excess of that associated with adolescent-onset scoliosis and this higher mortality rate may refer to juvenile rather than adolescent idiopathic scoliosis.

Thus QALYs were calculated for untreated life expectancies of 40, 50, 60 and 70 years, the latter possibly being over-optimistic.

5. The changes in the value of quality of life were assumed to occur at ages 46 (0.97 to0.95) and age 60 (0.95 to0.91).

6. Discounting at 5%



Graph showing the expected value of extra quality-adjusted life years.

e.g. QALY with untreated life expectancy of 40 years

QALY = 0.97 x (77 - 14 years disc) - (0.97 x (40 - 14 years disc))

= (0.97 x 63 years disc) - (0.97 x 26 years disc)

= (0.97 x 19.1) - (0.97 x 14.4)

= 18.5 - 14.0

= 4.5 QALYs

Full results are shown in the table in the main commentary.

(1) Quality of life of untreated scoliotics

Collis and Ponseti (1969) surveyed 195 patients who were diagnosed as having idiopathic scoliosis between 1932 and 1948. In all the cases the deformity was said to begin after 8 years of age and so fell into the category of adolescent idiopathic scoliosis. Dickson (1983) questions the diagnosis of idiopathic adolescent scoliosis in this study and suggests that many patients, expecially those who died, had juvenile onset idiopathic scoliosis with curves of significant magnitude even before 8 years of age.

The average age at follow-up was 42 years, and the female:male ratio was 165:30. Out of an initial study population of 394, 7% of these had died by the time of follow-up but none of these were recorded as being secondary to scoliosis.

Experience of pain and employment status were recorded for the patients, and from these a table was drawn up using the Rosser categories.

Pain	Rosser grading (distress)	
Never	A	41
Rarely (1-5 times in life)	B	31
Occasionally (Few days 1-2 times per year)	C	61
Frequently (few days per month)	C	32
Daily	D	30
		195

	Employment status	Rosser grading (disability)
1	on welfare payments	V
190	employed or housewife	I-II-III
	-32 restricted activities or avoided heavy work	III
	-91 patients felt that the deformity was not noticed by others = presumably no social limitations	I
	-67 remaining	II
	190	

4 patients institutionalized with mental retardation, for whom no employment data was available, so 1 patient has been removed from each distress grading (as there was no indication of these patients' experience of pain).

	A	B	C	D	
I	19	14	44	14	91
II	14	11	32	10	67
III	7	5	15	5	32
IV	0	0	0	0	0
V	0	0	1	0	1
VI	0	0	0	0	0
VII	0	0	0	0	0
	40	30	92	29	191

Using the same method as in Appendix 1, the overall QoL for 91 patients is 186.72, thus the average QoL for one patient is

$$186.72 / 91 = 0.98.$$

(2) Quality of life for treated scoliotics

Van Grouw et al (1976) presented data for 51 patients who underwent surgery for idiopathic adolescent scoliosis between 1960-1966.

The average age at follow-up was 24 years.

The average age at surgery was 14 years.

Female:male ratio was 44:7.

Pain data were graded in the same way as that of Collis & Ponseti.

Van Grouw et al		Rosser	No. patients
Grade 1	No back symptoms	A	10 (20%)
Grade 2	Rare annoying backache	B	12 (23%)
Grade 3	Occasional annoying backache	C	15 (29%)
Grade 4	Frequent but not restrictive annoying backache	C	7 (14%)
Grade 5	Partially restrictive frequent to daily backache	D	6 (12%)
Grade 6	Incapacitating daily back pain	D	1 (2%)
			51

Activity Ratings

I = sedentary indoor activity (reading, art, sewing)

IV = most strenuous activities demanding endurance, and placing significant stresses on the back e.g. skiing, mountain climbing and all contact sports.

Van Grouw Activity Ratings	Rosser Grade (Disability)		
I	IV	6%	(3)
II	IV	16%	(8)
III	III	55%	(28)
IV	I-II	23%	(12)
			(51)

	A	B	C	D	
I&II	2	3	5	2	12
III	6	6	12	4	28
IV	2	3	5	1	11
	10	12	22	7	

Using the same method as in Appendix 1, the overall QoL for 51 patients is 48.98, thus the average QoL for one patient is

$$48.98 / 51 = 0.96.$$

Appendix 5 : QALYs for scoliosis secondary to neuromuscular illness

It was assumed that patients were operated on at 14 years of age. The operation is to prevent patients (who are already chairbound) from becoming bedridden.

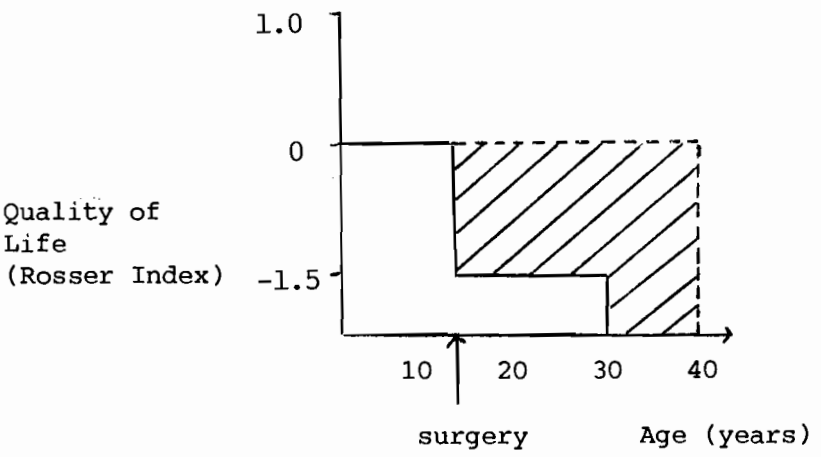
	Rosser Category
i.e. Without operation	VII D
With operation	VI D
Pre-operation	VI D

Life expectancy assumed to be 40 years with operation

30 years without operation

QALY = (0 x 26 years) - (-1.49 x 16 years disc)

= +16.2



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