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MEDICINES AND THE QUALITY OF LIFE

Introduction

Previous studies concerned with the benefits of modern medicines have concentrated mainly on their economic consequences (Wells NEJ 1980; Teeling-Smith G 1982). By contrast this paper discusses the more difficult problem of evaluating the contribution of medicines to the quality of life. It starts by looking at familiar British data on premature mortality and at the traditional measures of morbidity, such as numbers of days in hospitals and absence from work attributed to sickness. It puts a new interpretation on these data, in terms of bereavement and the social consequences of sickness. Next it looks at the extent of world-wide use of some medicines whose benefits derive primarily from making patients 'feel better'. It refers to the clinical evidence of the effectiveness of these medicines, and goes on to discuss the other side of the coin – the adverse effects which may be caused by medicines.

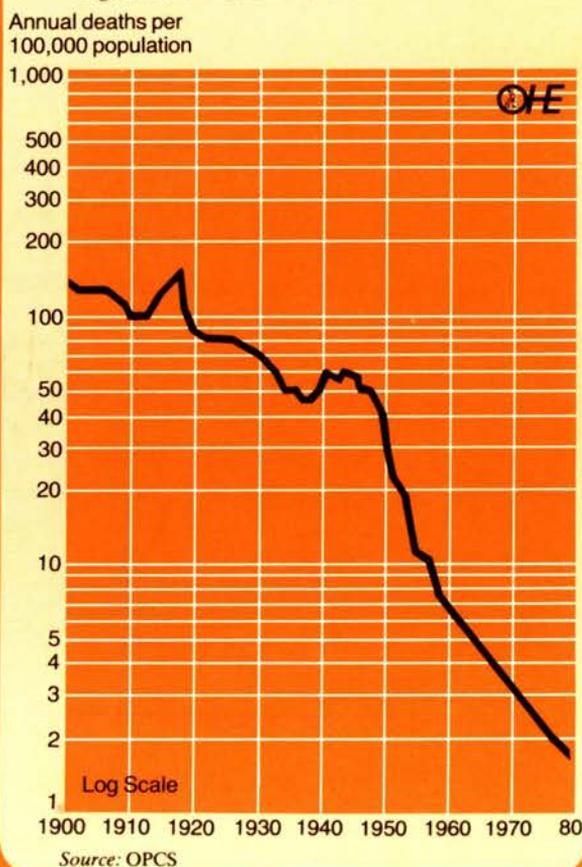
Finally, the paper turns to a new and growing area of discussion in relation to the measurement of benefits of medicines. This concerns the use of 'health indicators' or 'health indices' which attempt to measure what sociologists have called 'health status'. That is, how well people feel they are. It also discusses various 'disability ratings', which are a way of trying to measure the effects of disease and treatment on everyday performance. This discussion raises the question of whether it is possible to quantify essentially qualitative measures of wellbeing. The paper suggests that this can be done, at least for individual diseases. Furthermore, it seems probable that in the future these attempts at a formal measurement of quality of life may form a routine part of the assessment of new medicines when they are first introduced into clinical practice.

Bereavement

Bereavement which has been prevented by the development of modern medicines over the past 40 years can be categorised into three main groups. The avoidance of the premature loss of a spouse; the avoidance of the loss of a parent during childhood; and the avoidance of the death of a young child. In each case a very real tragedy is prevented. This saving in life brings emotional and social benefits which are impossible to measure.

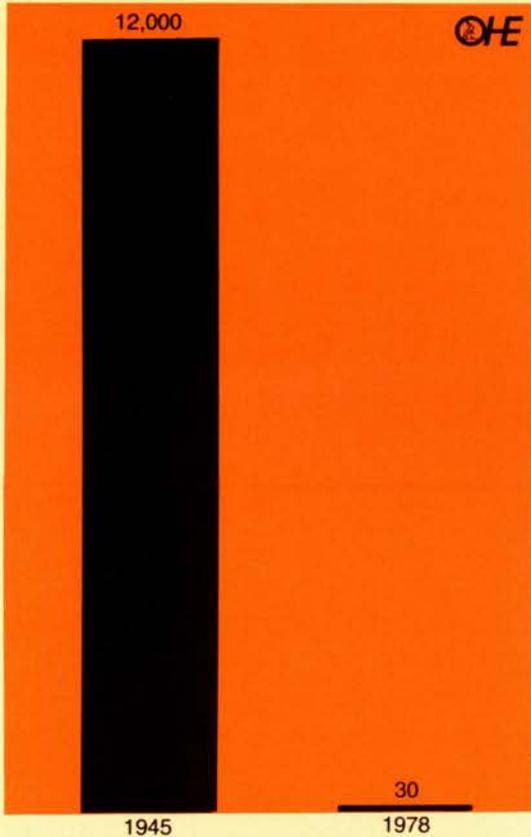
The most spectacular reduction in premature mortality due to the therapeutic revolution since the 1940s has been with tuberculosis. Figure 1 shows how the previous slow reduction in mortality was accelerated by the introduction of the antitubercular compounds in the 1940s. In 1945 about 12,000 men and women between the ages of 15 and 44 died from the disease in England and Wales. In 1978 the

Figure 1 Mortality rate from tuberculosis. England and Wales 1900-1979.



corresponding number of deaths was 30 (Figure 2). Even assuming that because of their illness fewer than normal of these young men and women would have been married and had children, it is reasonable to assume that in 1945 about 7,500 young husbands or wives would have lost a spouse and between 10,000 and 15,000 children would have lost one or other of their parents from tuberculosis. In 1978, the figure for bereaved spouses is unlikely to have exceeded 20 and the number of bereaved children is unlikely to have exceeded 50. It is perhaps hard to decide whether the loss of a mother or a father is the more disastrous to a young child. However, the fact that over 10,000 such

Figure 2 Tuberculosis deaths: ages 15-44, England and Wales.



Source: OPCS

bereavements due to tuberculosis are now avoided each year represents a very significant contribution to the wellbeing of society. Much of this reduction is due to the effectiveness of antitubercular medicines and BCG vaccination.

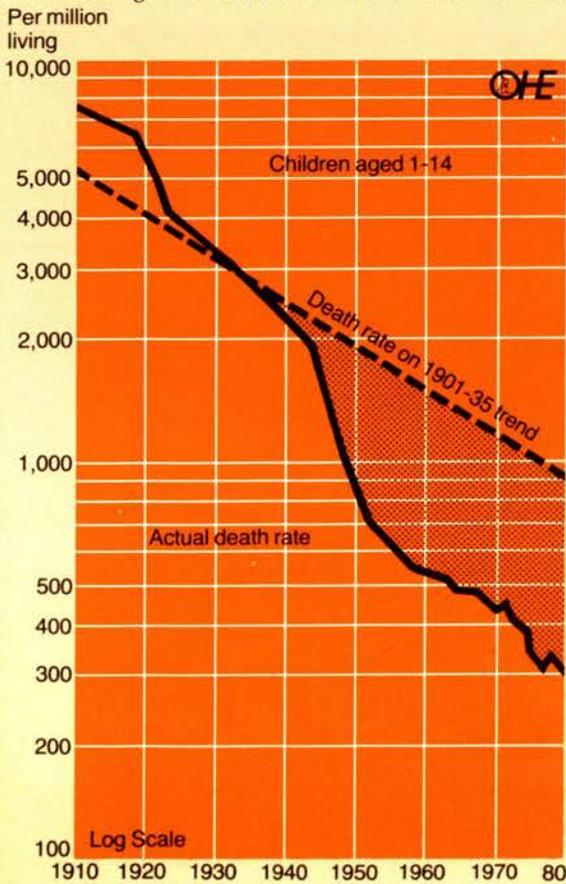
The converse tragedy is when parents experience the death of one of their young children. Here it is possible to suggest fairly convincingly the number of lives saved by the development of the vaccines, antibiotics, sulphonamides, the penicillins and the other new medicines since the 1940s. Figure 3 shows that childhood deaths in England and Wales were declining slowly up to the 1940s. At that point new therapies accelerated the decline, and the shaded area on the graph indicates the difference in number of deaths between the 1901-1935 trend, and the actual death rate since 1940 for children between the ages of one and fourteen years. It is calculated that the difference is equivalent to more than 250,000 child lives saved between 1940 and 1980. Thus modern medicines have spared half a million parents the suffering of an untimely death of one of their young children.

Finally in this section on bereavement, there is the most poignant tragedy of all: the death of a mother in childbirth. There were 647 such deaths in Britain due to childbirth fever in 1935; by 1977 the number had been reduced to two. Figure 4 shows the overall reduction in the maternal death rate per 100,000 live births between 1940 and 1977. It is hard now to realise that in the 1930s there was a greater than one in 500 chance of a mother failing to survive the delivery of her child, and hence the same risk of an infant being brought into the world motherless. With such tragic bereavements now an extreme rarity, it is difficult to recall the suffering involved for the child and its father and grandparents.

Conventional measures of morbidity

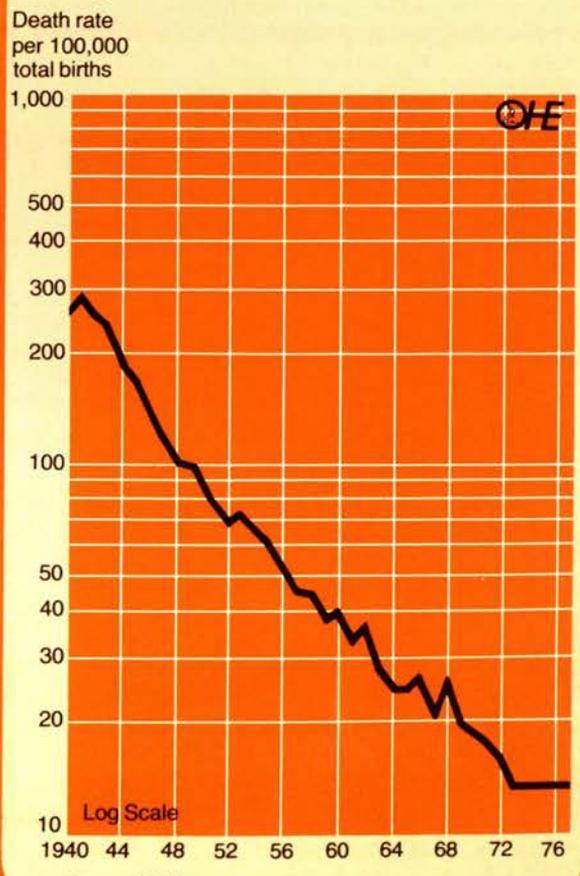
The two most obvious measures of morbidity which have been used in the past relate to hospitalisation and absence from work.

Figure 3 Child death rate per million living, England and Wales 1911/15 1980. Five yearly averages 1911/15 1961/65. Annual rates 1966/80.



Source: OPCS

Figure 4 Maternal deaths: rates per 100,000 total births, 1940-1977. England and Wales.



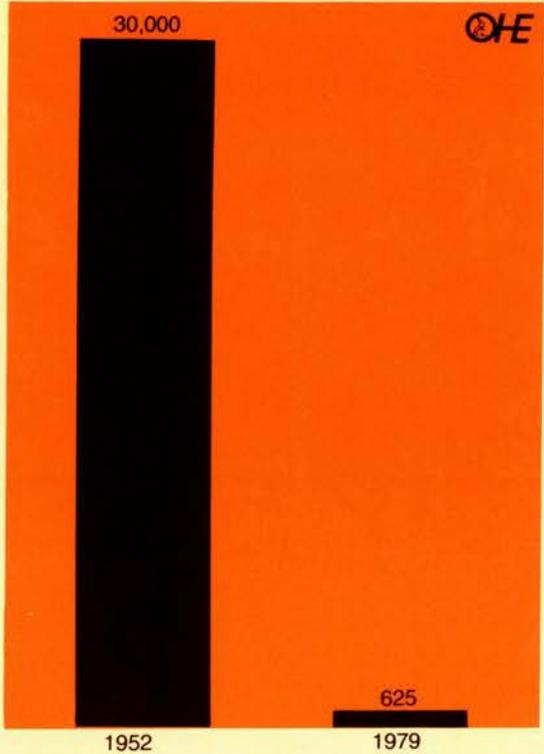
Source: OPCS

Figure 5 Total allocated NHS hospital beds: Great Britain.



Source: Annual Abstract of Statistics

Figure 6 Tuberculosis, hospital beds occupied: England and Wales.



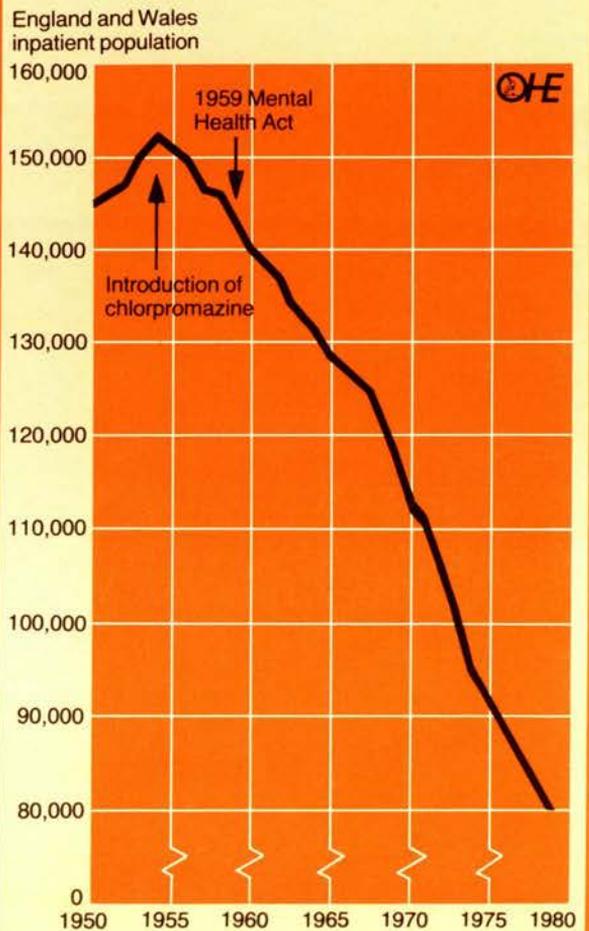
Source: DHSS

In the case of admissions to hospital and length of stay in a hospital bed, there is little doubt that these are real measures of 'reduction in quality of life'. Apart from a few eccentrics, no-one likes having to be admitted to hospital or having to stay there instead of being well at home. The only complication in this broad generalisation occurs if a sick person is genuinely more uncomfortable at home than he would be in hospital care. Generally speaking, however, a stay in hospital is unwelcome, and its avoidance or significant shortening represents an improvement in wellbeing.

Taking British statistics overall, the number of hospital beds in use has fallen from 549,000 in 1959 to 456,000 in 1979 (Figure 5). The average length of stay for all specialties fell from 30.1 days in 1965 to 20.9 days in 1977. Once again, as far as individual diseases are concerned, the greatest reduction has been in tuberculosis. The number of occupied beds in England fell from 30,000 in 1952 to 625 in 1979 (Figure 6). Another very substantial reduction has occurred with psychiatric beds. Figure 7 shows that a previously rising trend was reversed in 1954 coincident with the introduction of chlorpromazine. Figure 8 indicates that the number of occupied beds in England and Wales fell from 154,000 in 1954 to 78,000 in 1979. To give another example, Figure 9 illustrates the fact that for diseases of the chest the average length of stay fell from 41 days in 1962 to 18 days in 1979. These examples illustrate that therapeutic progress over the past 20 years has significantly reduced the need to be admitted to and to stay in hospital.

For absence from work attributed to sickness, there is a different pattern. Throughout Europe there has been an increase, especially in shorter absences, over the past 20 years. There seems, in this case, to have been a change in attitude, largely reflecting the greater economic security afforded during absence from work by the extension of sickness payment schemes. People can now afford to stay away from their job in cases where 20 years ago they could not have done so. Also, there is probably a genuinely lower threshold of acceptance of discomfort when this is caused by going to work when feeling ill. Thus for males in Britain the number of days of certified sickness absence rose from 12.2 in 1954/55 to 18.8 in 1978/79. This increase in sickness

Figure 7 Mental illness hospitals and units. England and Wales inpatient population 1950-1979.



Source: DHSS statistical reports

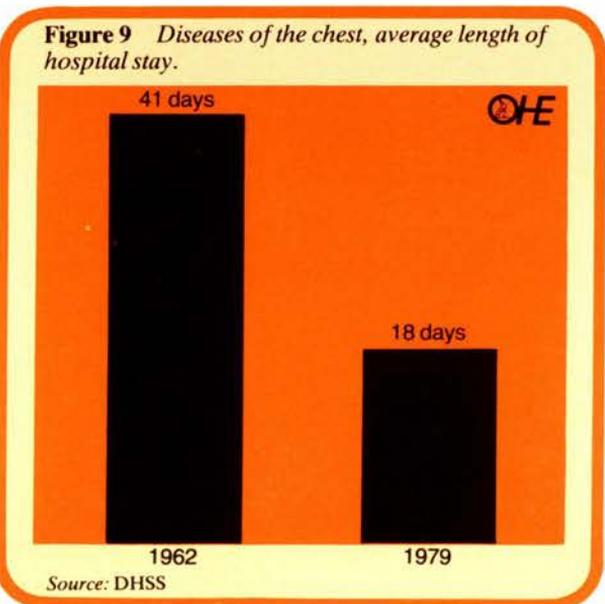
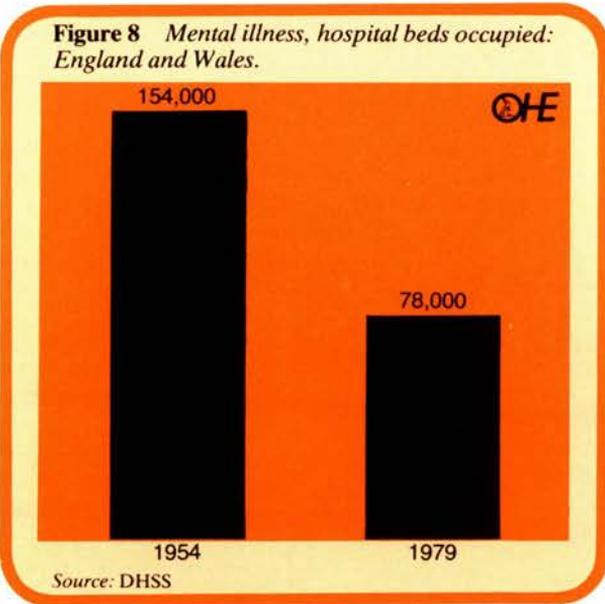
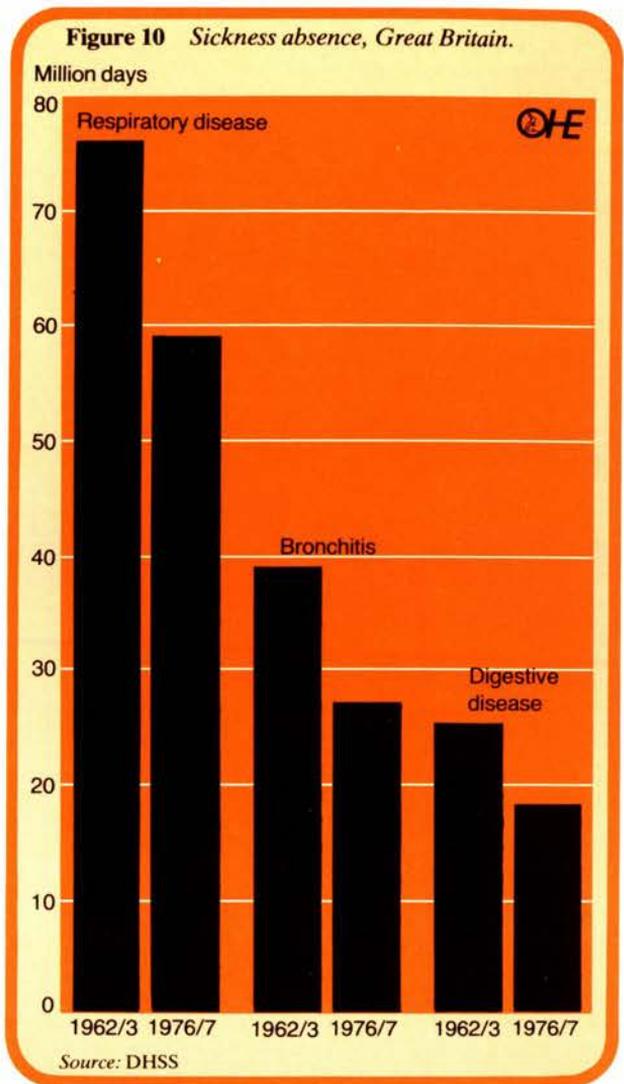
absence for predominantly trivial illness probably itself represents an improvement in the quality of life. Workers no longer have to struggle to their jobs when feeling poorly.

Nevertheless, by contrast, where there have been specific therapeutic advances for the treatment of individual classes of more serious diseases, sickness absence has been reduced. Figure 10 shows that for respiratory disease, bronchitis and digestive disease the number of days lost fell considerably between 1962/63 and 1976/77. This reduction – like the increase in absence for trivial symptoms – represents an improvement in quality of life. There has been a genuine reduction in more serious morbidity. Indeed, this conventional measure of the reduction of suffering from sickness has been much quoted in the past. However, it is clear that both hospital admissions and sickness absence need to be carefully interpreted as measures of the improvement in quality of life resulting from advances in therapeutics.

Benefits from specific medicines

It is often even more difficult to obtain hard quantitative data on benefits when one turns to examine the effect of specific medicines. However, this next section of the paper takes a small sample of medicines which have made an undoubted contribution to the quality of life, regardless of whether or not they have affected rates of admission to hospital or absence from work.

Table 1 shows the numbers of millions of patients treated with three medicines. For these three medicines alone, the



numbers treated exceed 100 million. This extent of usage itself indicates the effectiveness of these medicines; doctors do not go on prescribing preparations which they have found to be ineffective. In addition, however, there is hard clinical evidence of their efficacy. First, for Tagamet, a post-marketing surveillance study has reported that 86 per cent of patients obtained excellent or good symptomatic relief; incidentally, by contrast, only 4.4 per cent reported adverse reactions (Gifford LM et al 1980). Second, for Betnovate, a study quoted in Martindale's Extra Pharmacopoeia reported 'definite improvement' in 83 per cent out of 100 cases of pruritic dermatosis (Carter VH et al 1967). Third, for Brufen, about 70 per cent of cases respond satisfactorily when the preparation is given in adequate dosage (Goldberg AAJ et al 1971). Thus some 80 million patients have derived definite benefit from these three medicines.

Table 2 shows data presented in a slightly different form for six other medicines or groups of medicines. This gives estimates of the total number of patient-years of world-wide treatment since introduction.¹ Again, there are indications that most patients have benefitted.

¹ 'Patient-years' are calculated from the total number of doses consumed. One patient-year indicates that a single patient has been treated for one year, for example, or that twelve patients have been treated for one month each.

Table 1 Numbers of Patients Treated with Certain Medicines; Worldwide

Medicine	Indication	Patients Treated
Tagamet	Ulcers	20 million
Betnovate	Dermatoses	29 million*
Brufen	Arthritis	60 million

*Courses of treatment

Table 2 Total world usage of certain medicines; number of patient-years

Medicine	Indication	Patient-years
Intal	Asthma	3.7 million
Beta-blockers	Angina ¹	10 million
Zyloric	Gout	15 million
Indocid	Arthritis	35 million
Aldomet	Hypertension	55 million
Benzodiazepines	Anxiety	110 million ²

1 approximately three times as many scripts for hypertension.
2 usage in Germany, UK, US only; 1960-77.

Figures 11 and 12 show the improvement achieved by Intal in life-style of children in terms of their ability to walk to school and in terms of loss of sleep (Weinbren I et al 1969). In terms of lost days of schooling, in another study of 20 children this was reduced from 29 days per year to 13 days (Glass RD 1974). Intal has also been particularly helpful to sportsmen and women. Alan Pascoe, UK gold medal hurdler, has gone on record as saying that Intal was the factor which enabled him to continue training after his first asthmatic attacks threatened to end his athletic development. Paul Ringer (Welsh Rugby Player), Chris Drury (World Champion Oarsman), Ian Botham (Somerset and England All-Round Cricketer), Nicola Reid (Lacrosse Player) and Nick Gale (UK Under-21 Judo Middleweight Champion) are all individuals whose super-normal abilities have developed under the protective cover of Intal therapy.

Another important application of Intal is in occupational asthma. If skilled workers become sensitised to an agent at work and cannot or will not leave their employment then a trial with Intal may enable them to carry on working with reduced or minimal symptoms.

Next, the beta-blockers, alone or in combination with other drugs, are very effective in 70-80 per cent of patients with classic angina (Opie LM 1980). They bring important benefits by reducing the frequency and severity of attacks of angina. In addition, they allow patients to perform more exercise without experiencing anginal symptoms. This improvement in the quality of life helps patients to take a more positive and optimistic attitude to their problems (Newbould BB 1982).

For Zyloric, two quotations referring to the effectiveness of its active ingredient allopurinol indicate the extent of its benefits:

'Allopurinol was given to 24 patients with gout resistant or intolerant to uricosuric drugs. . . Response to treatment was satisfactory in all cases but one' (Bartels EC 1966) and again:

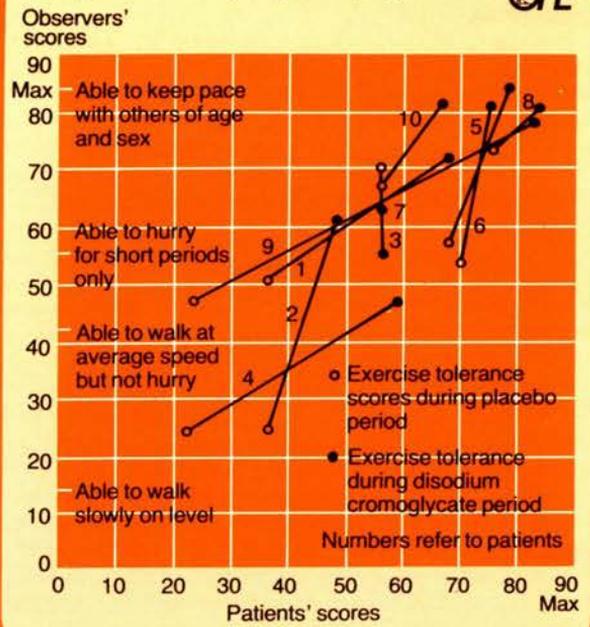
'Observations have been made on 54 cases of gout under treatment with allopurinol for from one to 5½ years. In all cases the gout was completely controlled, and two patients were able to cease treatment' (Kersley GD 1970)

With Indocid, there is only more indirect evidence of its effectiveness. This is based on a study of the extent to which patients continued with therapy after one year. Although the conclusions varied between different groups of patients, in one part of the study, 61 per cent of patients were continuing to take their Indocid tablets – and hence presumably finding them effective – after one year. By contrast, in another two groups of patients only 1 per cent and zero per cent of patients respectively were continuing to take the placebo. However, the difficulty in interpreting data on effectiveness is illustrated by the fact that in the former of these two groups only 36 per cent of patients had maintained their treatment with Indocid (Capell MA et al 1979).

For Aldomet, a typical study shows that 77 per cent of patients experienced good control of their blood pressure (Corbett AC 1972). Looking back to the days before effective treatment of blood pressure was available, in the 1950s, it must be remembered that it was a severely incapacitating disease for many people.

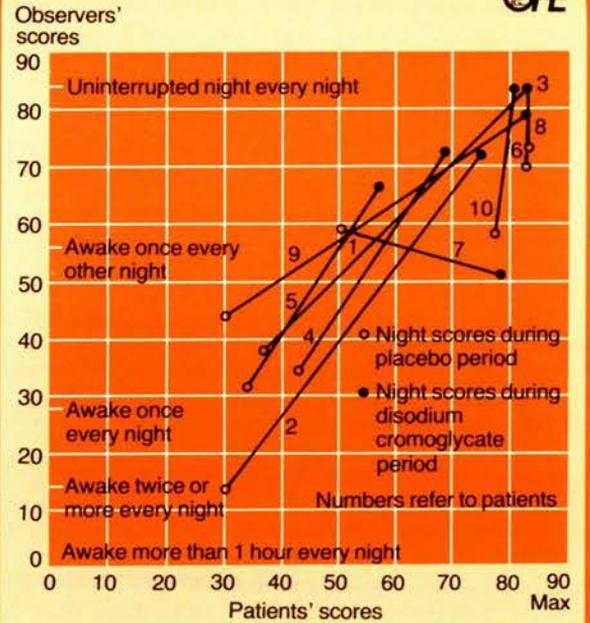
Finally, looking at the effectiveness of the benzodiazepines in anxiety, there has been probably more controversy over their use than with any other group of medicines. To some

Figure 11 Benefits of 'Intal', day.



Source: Weinbren et al

Figure 12 Benefits of 'Intal', night.



Source: Weinbren et al

extent, of course, this is because of their enormous volume of prescription, which is underlined by the incomplete, and hence understated number of patient-years of treatment quoted in Table 2.

To understand the therapeutic importance of the benzodiazepines it is first necessary to appreciate the extent of clinical anxiety in society. It has been estimated, for example, that 30 per cent of all patients consulting their doctor exhibit symptoms of anxiety (Lader M 1980). Another study estimates that 25 per cent of all sickness absence from work is attributable to anxiety (Newton J 1980). Against this background it appears that 70 per cent of such patients improve when taking Valium, the most widely prescribed benzodiazepine (Tessler R et al 1978). Furthermore, 80 per cent of cases relapse and anxiety recurs without further treatment; this recurrence is frequent in 30 per cent of cases (Rickels K 1978; Ayd F 1981). This explains the need for long-term or repeated therapy, and the benefits obtainable from it.

Against the benefits from the benzodiazepines, there has been enormous publicity given to their potential risks and disadvantages. In an extensive study of the much vaunted risk of dependence, Marks has concluded, however, that the risk of dependence on the benzodiazepines is much less than is often suggested. He estimates the number of published cases of dependence to be equivalent to one case per 5-10 million patient-months on the medicines. Excluding the effects of deliberate abuse of the benzodiazepines, he concludes that published reports of dependence due to therapeutic use alone represent no more than one case per 50 million patient-months (Marks J 1980).

Thus from this rather piecemeal discussion of the use and of the benefits of certain medicines, a clear picture of improved wellbeing emerges, amounting to some two hundred million patient-years.

Adverse reactions

In any discussion of the benefits of medicines it is important also to recognise the other side of the coin: the potential which medicines have to do harm as well as good. This is part of a much more general social phenomenon. Few innovations are totally free of risk or of adverse effects. All progress is a matter of balance between the benefits and the social and economic costs. However, at least with medicines, there is a growing understanding of the problem, and measures have been and are being taken to minimise the risks of adverse effects from therapeutic progress.

Over the past 40 years, the most disastrous example of damage done by a medicine has been with thalidomide. This tragedy led to the introduction of much stricter measures for the testing of all new medicines in order to improve their safety and hence the ghastly price paid by the thalidomide victims was not altogether in vain. Furthermore, the thalidomide disaster must also be seen in perspective. It has already been pointed out that in Britain over 250,000 childhood deaths were avoided by the medical developments between the 1940s and the 1970s. By contrast, the number of British children tragically damaged by thalidomide was fewer than 500. That is over 500 lives saved for each damaged child. No-one would argue that such a ratio makes the thalidomide disaster 'acceptable' in any sense. But it does indicate that benefits and risks from medicines must be seen as a question of balance. Clearly it would have been unacceptable to have foregone all pharmaceutical innovation in the 20th century even to have avoided the price paid by the thalidomide victims.

Apart from the example of thalidomide – which stands out as a unique disaster – there have been many other cases where medicines have done less catastrophic or less widespread harm. There are, however, two points which are relevant. First, each case of harm being done needs to be judged against the offsetting benefits. The most obvious example in this context is with whooping cough vaccination. Here the disease was virtually eliminated when vaccination was first introduced; but it returned as a significant source of mortality and morbidity when fears of brain damage from vaccination scared parents away from having their children vaccinated. In assessing the balance of risks in this case, the British Government Report on the subject concluded decisively in 1977 that the risk of the disease itself was worse for society than the risk of immunisation (DHSS 1977). Yet it is only in the 1980s that some public perspective is being restored, and the immunisation programme is once again becoming acceptable.

More generally, the risk of a medicine must be seen not only against the extent of its benefit but also in the light of the seriousness of the condition it is treating. If a medicine can be life-saving for an otherwise inevitably fatal condition, very severe adverse effects may be acceptable. On the other hand, for a more or less trivial medication, for example to relieve a headache or a sore throat, the risk of adverse effects must so far as possible be avoided altogether.

Second, there are very real prospects that the harm done by medicines can be reduced by scientific advances and by improved epidemiology in the 1980s. The potential scientific advances can be illustrated by the example of the

prospect of being able to eliminate the occurrence of symptoms similar to systemic lupus erythematosus (SLE) as an adverse reaction to the anti-hypertensive agent, hydralazine. It has recently been shown that this risk of developing SLE is associated with a particular type of antigen. It is possible to screen patients for the presence of this antigen. In consequence the development of this particular drug-induced adverse reaction could be largely prevented if those with the vulnerable genotype were excluded from treatment with it. It seems probable that many other adverse reactions will also be found to be associated with specific antigens, and hence other screening programmes would be able to prevent other adverse reactions. More generally, a better understanding and application of pharmacogenetics should help to predict and hence to reduce adverse reactions. For example, poor acetylators of medicinal compounds can be identified, and dosage reduced accordingly if detoxification of the medicine depends on acetylation.

On the epidemiological side, there have already been important advances in 'post-marketing surveillance' to give early warning of adverse reactions. More recently, this concept has been widened under the description of 'Prescription Event Monitoring'. In Britain, doctors who have prescribed two particular new medicines have been identified from National Health Service prescriptions, and have been asked to report any significant event which occurred in patients for whom these medicines were prescribed. In these preliminary studies it is reported that the expected adverse reactions stood out clearly from the 'noise' of the many insignificant events which were also recorded. On this basis, it is anticipated that an *unexpected* significant adverse reaction would also be easily identifiable, and that early identification would substantially reduce the risk of harm being done to patients (Inman WHW 1982).

Thus the adverse effects of medicines need to be seen in perspective against the very great benefits achieved. They are also, however, likely to be reduced substantially in the future by scientific and epidemiological progress.

A more quantitative approach in the future

Much of the discussion of social benefits of medicines has so far been based on the extent of usage and on a clinical assessment of improvement in health. There has been no more than a general reference to the overwhelming balance of the good as opposed to the harm done by medicines, and no attempt has been made to quantify the equation. Furthermore, there has been no discussion of the economic cost of the medicines themselves, which clearly has to be taken into account in evaluating the benefits which they bring. In this final section of the paper, it is, therefore, argued that in the future a more specific approach is likely to be developed, in which the improvements in the quality of life achieved by medicines will be measured on more quantitative scales. These more precisely quantified benefits can then be judged against equally precisely quantified risks and against the cost of the medicine. This sort of economic approach to the assessment of the benefit of medicines will probably become increasingly important because more emphasis is likely to be put on specific measurements of the social and economic outcome of all forms of therapy in the future.

Many recent economic studies (eg Reekie WD 1977; Reekie WD 1981; Reekie WD and Weber MH 1979; Teeling-Smith G 1975) have indicated that there is price competition in the pharmaceutical market. However so far this competition has operated in the absence of systematic economic evaluation of the benefits of the competing medicines or of alternative therapies. This situation is unlikely to continue. It is possible that in the future the various national Social Security Schemes and Health Services concerned with reimbursement of the cost of medicines will start to look for more economic evidence of their value.

More positively, pharmaceutical manufacturers themselves may increasingly want to demonstrate the cost-benefit ratios from their products in relation to the economic 'costs' of

alternative therapies – or indeed no therapy at all. These benefits will not always be in financial terms. However, they can still be quantified even in the absence of monetary measures. This final section of the paper discusses ways in which economists have already developed analytical tools which could start to be used more systematically in the evaluation of the benefits of medicines.

Recapitulating at this stage, the social and economic benefits of medicines can arise in a variety of ways. They can reduce premature mortality. This can bring economic benefits which can be calculated by a number of methods and which include a reduction in suffering due to bereavement. Medicines can reduce health service costs, by avoiding the necessity of hospital treatment or surgery. They can avoid the economic loss due to sickness absence. Finally, most relevant to this paper, they can reduce disability and discomfort. There may be direct financial savings involved, for example if previously immobile patients can start to look after themselves without help. More often, however, the reduction of disability and discomfort must be measured in social terms; that is, in terms of the quality of life or wellbeing of the patient.

Many economists and clinicians have started to be concerned with these questions of the measurement of the quality of life. As a result, the concepts of 'health indices' as measures of 'health status' have been introduced into economics and medicine to aid the process. One of the most comprehensive pieces of work in this connection has been undertaken by Rosser and Watts (1974) in Britain. They used a 'matrix' of health status, of the sort shown in Figure 13, based on eight categories of disability along one axis and four categories of distress down the other. This gave a total of 32 possible classes of 'health status' into which individuals could be placed. Based on this matrix, they then allocated each patient in St Olave's Hospital in South London into one of the 32 boxes, depending on their individual degree of disability and distress.

In order to produce a relative value for each box they repeated the process, allocating cases of injury and industrial disease from the legal textbook, Kemp and Kemp, into corresponding boxes. Kemp and Kemp gave, for each case, an amount of a court award for monetary compensation for the injury. This allowed Rosser and Watts to calculate a scale of cash values for each box depending on the average court award attributable to each. From this, turning the cash values into ratios, they produced what they called a 'Sanitive Index' for the hospital.

A month later, they reassessed the same patients on the same basis, and hence could calculate a reduction in the index as a result of therapeutic interventions during the month. It is in fact doubtful whether such a comprehensive and theoretical exercise served much purpose. However, the principle of evaluation of 'health status' is important in economic terms.

More recently in Britain, the Department of Community Medicine, Nottingham has developed 'The Nottingham Health Profile'. This is described as 'a standard and valid measure of perceived health' (Hunt SM et al 1982). The profile is in two parts: part 1 contains 38 statements pertaining to problems in six areas – pain, energy, physical mobility, sleep, social isolation and emotional reactions. Part 2 contains

Table 3 Nottingham Health Profile: patients with peripheral vascular disease

Percentage of respondents answering affirmatively on statements in part 1 of the profile (n=93)	
Statement	Percentage of respondents
Physical mobility	
I find it hard to reach for things	22.6
I find it hard to bend	19.3
I have trouble getting up and down stairs or steps	45.1
I find it hard to stand for long (eg at the kitchen sink, waiting for a bus)	49.5
I can only walk about indoors	15.0
I find it hard to dress myself	8.6
I need help to walk about outside (eg a walking aid or someone to support me)	34.4
I am unable to walk at all	2.1

seven statements referring to the effects of health on occupation, ability to perform tasks around the home, personal relationships, sex life, social life, hobbies and holidays.

The respondent simply indicates 'yes' or 'no' according to whether the statement applies to him or her 'in general'. The statements in part 1 concern problems which vary in severity and, therefore, have been weighted empirically to reflect this fact. The maximum score on any section is 100; thus the attainment of such a score would indicate that the patient had every problem listed in that section. Statements in part 2 are scored one for an affirmative response and zero for a negative one.

Although the profile is intended as a tool for the survey of health problems in a population, it is also useful as a means of evaluating the outcomes and as an adjunct to the clinical interview. It has been found to relate well to other indicators of health such as the presence of chronic illness and the frequency of medical consultations and it is sensitive to changes over time. It thus provides a valid and reliable means of measuring the patients' assessment of their health.

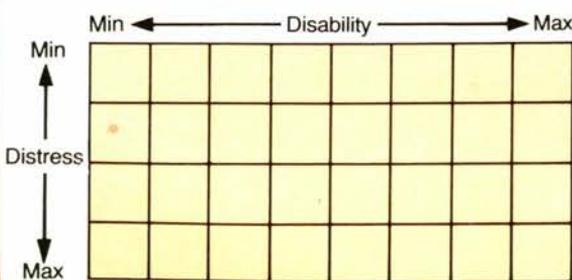
Table 3 shows the percentage of positive responses for the question from part 1 of the profile relating to physical mobility for 93 patients suffering from peripheral vascular disease. Clearly scales of this sort can be used to measure the subjective improvement which patients experience as a result of taking a specific medication. More generally, for chronic disease, they can measure the way in which therapy affects the progress of the disease over time.

Apart from the general measurements of health status based on studies such as these, there have also been more specific attempts to measure disability or incapacity on quantitative scales. Some of these are 'all-purpose' measurements intended to cover a wide spectrum of disease. Others relate to a single disease. For example, a meeting in Stockholm in August 1980 spent two days discussing various ways of assessing the degrees of disability caused by Multiple Sclerosis. Figure 14 shows one of the many incapacity scales discussed at the meeting (Kurtzke JF 1980).

The development of both health indices and scales of disability in relation to pharmaceutical therapy is in an embryonic state, but significantly it has already started. One example was reported in Arthritis and Rheumatism at the beginning of 1980 (Fries JF et al). This paper presented a paradigm of outcome based on five separate dimensions: death, discomfort, disability, drug toxicity and dollar cost. Each dimension, in the US context, represented an outcome directly related to patient welfare. The measurements were quantified by interview or patient questionnaire and the authors concluded that 'the techniques appear extremely useful for evaluation of long-term outcome of patients with rheumatic diseases'.

More recently, and more directly relevant to the pharmaceutical industry, the clinical trials now being undertaken by Smith Kline and French on their new gold preparation for rheumatoid arthritis, include specific measurements on its effects on the quality of life. These are

Figure 13 Matrix providing a 'sanitive index'.



Source: Rosser and Watts

Figure 14 Incapacity Scale.



Function	Performance				
	normal	Impaired but able to do:			
		with-out aid	with mech-anical aid	with human aid	not at all
score	0	1	2	3	4
1 Stair climbing					
2 Ambulation					
3 Chair/bed transfer					
4 Bowel function					
5 Bladder function					
6 Bathing					
7 Dressing					
8 Grooming					
9 Feeding					
10 Communication					
11 Physical problems (tentative)					
12 Societal dependence					
Total					sum

Source: Kurtzke

based on interviews conducted by non-medical interviewers, using a standard questionnaire (Paterson ML 1982). It seems likely that a similar approach will be developed for other pharmaceutical innovations in the future. No one protocol or method of measurement will be appropriate for all new medicines; but it seems likely that the general principle will become established in the future, to demonstrate more clearly the positive benefits of medicines on the quality of life. Indeed the Office of Health Economics is organising a Summer School at Brunel University in 1983 in order to discuss and develop these ideas more fully. Already the principle has the support of the more forward looking clinical pharmacologists and economists in Britain.

Conclusions

With an already ageing population, emerging largely as a result of the control of the main causes of premature mortality, medicine should be increasingly concerned to improve the quality of life rather than merely further to extend its length. So far, there have been few systematic attempts to measure the benefits of therapy in this respect. This paper has suggested that the modern medicines developed over the past 30 years have made a significant impact in improving wellbeing in subjective terms. In terms of mere numbers, for example, it is hard to grasp the extent of the benefits world-wide.

Nevertheless, the need to develop either measures of incapacity or 'health indicators' as measurements of 'health status' before and after treatment is likely to increase in the future. There is a growing concern about the cost of medical care, and one way to justify the rising expenditure is to demonstrate more clearly the benefits. It is probable that once appropriate methods of measurement have been developed, the benefits of modern medicines will become even more obvious than they are from the crude discussion contained in this paper.

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