

Economic evaluation and appropriate care in Sweden

Economic evaluation has developed into a major new health policy instrument in Sweden over the last thirty years. This has been possible through the building of competence and capacity for performing and assessing such studies in academia, government, the health care system and industry. Significant advancements are also seen in the creation of new data sources, for example registries, necessary and relevant for economic evaluation. The major challenge today is in the implementation of decisions about reimbursement and treatment guidelines to secure the goals for appropriate care.

in the papers of the term 'appropriate care', both papers are highly relevant in relation to that topic. For all health economists of this generation, the above observations for many countries were a great 'call to the arms', giving rise to the development of health economic evaluations as a tool for changing resource allocation within the healthcare system. It was obvious that neither the continuous increase in healthcare costs, nor the cost-containment policies aimed at controlling the price and volume of input proved to be sustainable solutions. This contributed to the realisation that decisions regarding appropriate care will have to be based on considerations of both the costs and the outcomes of relevant alternative health care interventions. A subsequent question obviously is to what extent economic evaluation has managed to change the situation for the better. The establishing of the Institute of Health Policy & Management (iBMG) in 1982 and the Centre for Health-Technology Assessment (CMT) at Linköping University Sweden in 1985 responded to the demand for studies on the effectiveness and cost-effectiveness of both new and old health technologies. Thus, this seems a good opportunity to reflect upon the developments over the last three decades in Sweden, and to attempt to answer the following big question in doing so: *Has the publication of a growing number of economic evaluations contributed towards a more appropriate – i.e. more efficient and equitable – healthcare in Sweden?* Since we cannot ob-

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In their first paper, published in 1975, Van der Gaag *et al.* (1975) make the observation that the frequency and length of hospitalizations in the Netherlands is mainly determined by the availability of hospital beds. In a second paper (Rutten and Van der Gaag, 1977), the authors conclude that the payment system for specialists, capitation or fee for service, determines the patterns of their practices. Though there is no explicit mention

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serve the counterfactual, a Sweden without economic evaluation, I will try to arrive at an answer based upon observations of the development of methodology and economic evaluation data, as well as on the implementation of the results of such studies within clinical and administrative decision-making in Sweden.

METHODOLOGY

For economic evaluation to be useful, one needs a sound methodology. There is nothing more practical than a good theory and method. To outside observers it may look as if health economists cannot agree upon a common methodology for economic evaluation, but this is not true. The scientific discussion focuses on controversial issues, so that it is easy to overlook the fact that there is agreement on fundamental principles.

One fundamental principle is that any appropriateness of care cannot be judged from the cost side alone. There is a need to consider outcomes as well, and one of the major shifts in health policy since the early 1980s has been the change in focus from resource input to outcome. There is a debate as to what outcome measurements ought to be used for a specific study, but defining the appropriate outcome measure is an important part of an economic evaluation (Johannesson *et al.*, 1996).

One of the major areas of health improvement during the last decades is seen in the prevention and treatment of heart disease, which has reduced mortality by more than fifty per cent. This significant progress did not come from a single drug or procedure. There are and have been a huge number of potentially beneficial interventions, and patients with heart disease also differ in terms of their risk factors for different events and their capacity to benefit from treatment. Another major contribution that economic evaluation has made to the definition of appropriate care is to always ask the question: what is the alternative?

As there are several alternative interventions and many manifestations of heart disease, there is a need for an outcome measure that will make it possible to compare between treatments and patients (table 1). Since mortality has been the major unmet medical need, it was natural to use the number of life years gained as the primary outcome measure in economic evaluations regarding cardiology. But when needed, for example in studies of coronary by-pass operations, the measure of quality-adjusted life years (QALYs) was used as an outcome measure. Quality adjustment has

two effects: the first is to adjust for the fact that survival may be increased but with a reduced quality of life, and the second is to include the quality-of-life benefit due to a reduction in symptoms or non-fatal events. The two effects point in different directions.

In an early study, Martens *et al.* (1989) showed the cost-effectiveness of simvastatin for treatment of hypercholesteremia. This study was based on data from clinical trials as to the reduction of lipid levels. In a later study, Swedish researchers based their estimates of cost-effectiveness on event reduction, including overall mortality (Johannesson *et al.*, 1997). Since we now have data over a longer period of time, I will use these studies as one example of the contribution of economic evaluation towards appropriate care regarding the prevention and treatment of heart disease.

As is seen from Swedish data, the use of simvastatin has increased very slowly, and it was not until new survival data in 1995 and a later price reduction after patent expiration that its use was shown to be widespread (figure 1). Economic evaluations have been important in establishing its appropriate use for different risk groups, taking both the costs and outcomes into account. The early studies based on risk-factor reduction predicted the cost-effectiveness correctly, but uncertainties surrounding clinical effectiveness and safety weighed heavily upon the uptake. When this

Benefit assessment in economic evaluation – heart disease as an example TABLE 1

Outcome	Measurement	Valuation
Number of deaths avoided	Number	Value of life
Number of cardiovascular events avoided	Number of MI Number of strokes	No valuation; comparisons of same events only
Number of life years saved	Estimation of survival analysis	Value of a life year gained
Number of quality-adjusted life years gained	Estimation survival weighed by quality of life	Value of a QALY gained

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was at least partly resolved by the 4S study, the focus shifted towards cost-effectiveness within the different risk groups (Jönsson, 2001).

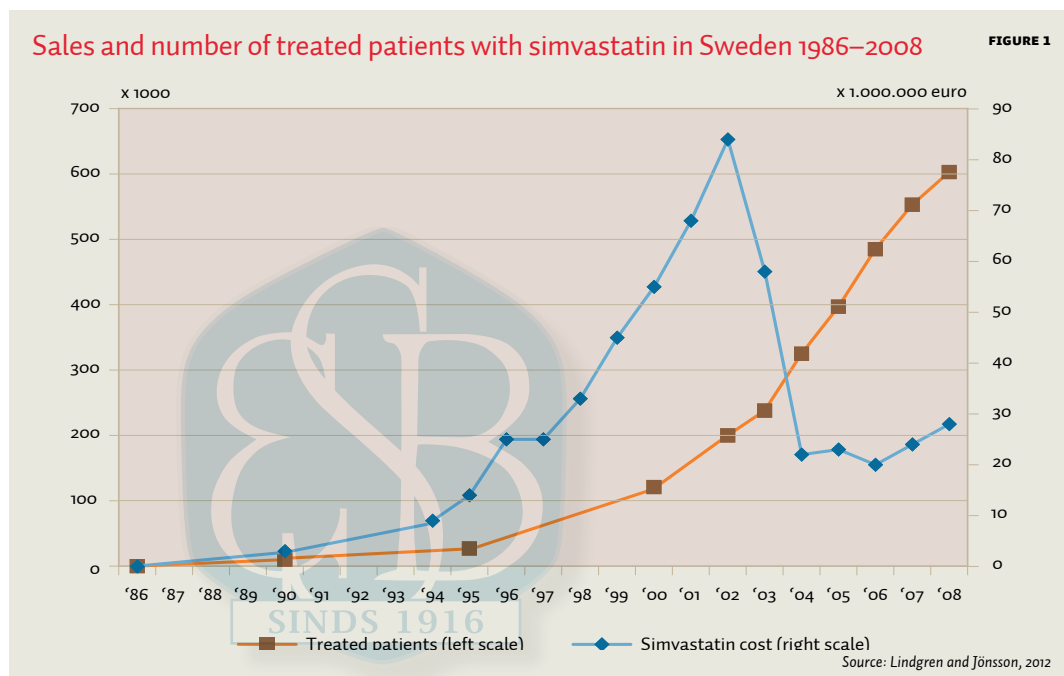
The life years gained served well as an outcome measure for cost-effectiveness studies in preventive and interventional cardiology. When relevant, this was later complemented by estimates of the quality-adjusted life years (QALY) gained. The QALY has been established as a useful and acceptable outcome measure for economic evaluations in Sweden. One example of this is the role economic evaluation has played in reimbursement decisions as to new treatments for rheumatoid arthritis (RA) and multiple sclerosis (MS) (table 2).

Economic evaluation has played a part in the positive decision to reimburse biological drugs for RA that are without doubt of great value to many patients. But the data from the patient register, which was set up to follow and evaluate their use may give rise to some concern. First, the very fast expansions into new indications have not been properly studied, and the great variations in use between different county councils indicate that there is no general definition of what constitutes appropriate care (figure 2).

Costing in economic evaluation

While it is accepted that outcome is a relevant concept in deciding on resource allocation and the assessment of medical technologies, the explicit consideration of costs in relation to outcomes (cost-effectiveness) is still controversial in many countries – most notably in the United States, but also in Germany and France. However, in Sweden as well as the Netherlands this is not the case: costs can and must be included in making decisions about what is appropriate care. The Swedish healthcare law states the principle of cost-effectiveness as one of the key ethical principles for resource allocation in healthcare, together with the principle of human dignity (equal access to care) and the principles of need and solidarity (those in greatest need should be given priority). Not considering costs is unethical, since it may lead to a lower or more unequal distribution of health among the population.

In principle, cost-effectiveness is supported by legislation, but the law does not state how it should be implemented. It is up to the public authorities responsible for making the decisions to determine what is appropriate care. The basic principle as to costing in



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Sweden is that all costs should be included, but only once, what is called a social perspective. There are two main explanations for the Swedish position on costing in economic evaluations. The first is the tradition of using cost-benefit analysis to inform political decisions in many different areas of public policy. The second is the methodological principles supported by leading Swedish health economists. Behind both explanations lies the conviction that omission of relevant costs and double counting may lead to conclusions and decisions that are not appropriate.

There are two aspects on costing that may be commented on. The first is the importance of indirect costs in terms of lost production and income. Compensation for sickness and early retirement has been generous in Sweden. In a high-tax society, loss of income also means loss of taxes. Inability to work has thus a double negative effect for society, in addition to the loss for the individual. What is more, Sweden has had a shortage of skilled labour for decades. The potential benefits from improved health in terms of a greater ability to work are thus a factor that receives much attention.

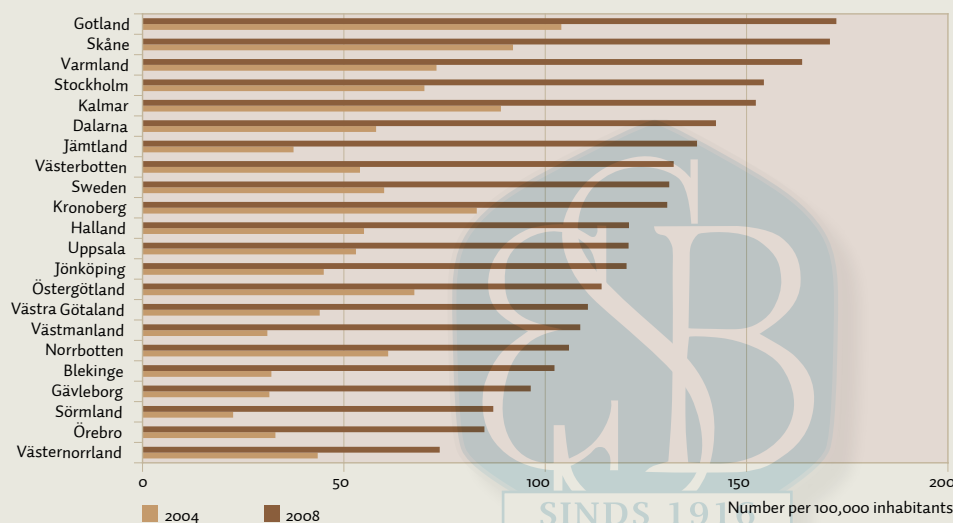
It is my impression that Swedish and Dutch

health economists share the view that considering indirect costs is important. One significant difference is in the calculation of indirect costs, where the principle and practice in Sweden is to calculate opportunity costs based on the assumption that these are reflected in the wages. The Dutch principle, the 'friction method', is based on the assumption that the economy can adapt to a reduced labour supply over time, which reduces the loss. As can be seen from Swedish comments on the friction method, any discussion on methodology includes arguments about internal as well as external validity (Johannesson and Karlsson, 1997; Liljas, 1998).

Another important methodological issue in costing is including costs during the added years of life when an intervention increases life expectancy. The Swedish perspective has been to include all costs in the added years of life. This is also the methodological recommendation in the guidelines for the economic evaluation of new drugs in Sweden (General Guidelines, 2003). There seems to be a common Dutch and Swedish stand about the importance of including them, but a difference as to whether only healthcare costs should be included or

Number of patients treated with biological drugs for rheumatic arthritis, in Sweden and the Swedish counties

FIGURE 2



Source: Svenska Reumatologiska kvalitetsregistret

other costs as well (Tan *et al.*, 2012). But man does not live by healthcare alone, and it can be somewhat arbitrary whether a specific cost is defined as healthcare or not, for example: whether a person is taken care of at home or in a hospital or nursing home. But we agree that it is important to publish these costs separately, so that their impact can be taken into account during the decision-making process. All costs are not equal, but all should be included, and differentiating the perspective as to who pays for the various costs is an important part of an economic evaluation.

But the greatest improvement, at least from Swedish perspective, has been in developing registries where one can study resource use and outcome over time in large populations

DATA

For economic evaluations to be useful in informing decisions about appropriate care, they must be based on a consistent and relevant methodology. Over the last three decades we have seen the development of an international standard with some national variations, which are well understood and a source of further discussion and development. But access to data is equally important for its practical application to and impact upon resource allocation in healthcare. Health economists once started by analysing the available data on hospitalisations, physician visits and other service variables at the time. Data on outcome were scarce, and if available, for example in statistics on mortality and morbidity, it was not possible to link them to outcomes. The first step was to link costs to diseases in what is called ‘cost-of-illness studies’. Cost-of-illness studies have been an important and often overlooked step in order to link resource use to specific diseases, and not only to administrative units. But cost-of-illness studies do not address the issue of cost-effectiveness, where you need data linking costs to outcomes for different treatment options.

Most early cost-effectiveness studies were thus based on models, which used data from different sources. In heart disease for example, it was common to use data from clinical trials, combined with epidemiological data such as the Framingham study, while data on costs were taken from accounting statistics in the healthcare sector. Over time there has been a dramatic improvement in the availability of data for economic evaluation, which have made them much more relevant and useful for decisions about appropriate care. Clinical trial data have been supplemented with economic and quality-of-life variables, and the design of studies is more and more decided upon with the aim of making a study useful as input for an economic evaluation.

But the greatest improvement, at least from the Swedish perspective, has been in developing registries where one can study resource use and outcome over time in large populations. The assessment of the external validity of data from international clinical trials in heart disease was made possible when patients with the same characteristics could be selected from population-based registries, so that treatment patterns and outcomes could be compared.

We can thus observe that economic evaluations in Sweden for chronic diseases – such as heart disease, RA, MS and osteoporosis – are to a large extent based on registry data. Increasingly, registries also include the necessary data for undertaking economic evaluations (Jönsson *et al.*, 2011).

But at the same time that data access improved, the demands on economic evaluation started to increase. Economic evaluations are today the main policy instrument for making decisions about new and often very expensive technologies, for example new cancer drugs and orphan drugs. The problem is that a decision has to be made before there are any data on their use in Sweden. We thus once again have to revert to ‘modelling’ as a tool for understanding the potential impact on Swedish healthcare. International collaboration on data collection is one way to get a faster access to the relevant data for analysis and decision-making.

As a response to the uncertainty surrounding the estimates of the impact upon clinical practice early in the use of new technologies, there are initiatives for the systematic follow-up after introduction, and for reassessment of for example the reimbursement decision once those data are available. Predictions from models will thus be followed up on behalf of confirmation in a more systematic way than has been the case previously.

IMPLEMENTATION

A Swedish cardiologist has remarked that “health economics is as relevant to healthcare as ornithology is to birds”. I would agree that this is true for some research in health economics, and that it is also true for some research in cardiology. And it may moreover also serve as a perfect introduction to a few final thoughts about the influence of economic evaluation upon the development of appropriate care in Sweden. Because carrying out economic evaluations to inform important policy questions, with a relevant methodology and appropriate data, is of course necessary, but it is not sufficient to actually change healthcare in practice.

Until the late 1980s, the influence on patterns of clinical practice had been mainly indirect. Economic evaluation was used informally for decisions on the pricing and reimbursement of new drugs. A review of the link between pricing and therapeutic value indicates that the decisions have been appropriate in the sense that more valuable drugs have received higher prices (Ekelund and Persson, 2003). We do not know exactly to what extent economic evaluation has contributed to this. Economic evaluation has also been used to inform *ad hoc* decisions on vaccination and screening programmes, besides diagnostic technologies such as CT and shock-wave lithotripsy, a treatment for kidney stones.

It was with the establishment in 1987 of SBU, the Swedish HTA agency, that economic evaluation acquired a position where it could make recommendations as to appropriate care. The head of SBU was a health economist, although supervised by a cardiologist who was the chairman of the board. I was the only health economist on the scientific advisory board, and must admit that initially my influence was marginal. Over time the influence of evidence on cost-effectiveness has increased, simultaneously with the overall impact of HTA reports.

A milestone in the impact of economic evaluation was the establishment of LFN (Pharmaceutical Benefits Board), later called TLV (Dental and Pharmaceutical Benefits Agency), in order to make reimbursement decisions on prescription pharmaceuticals. Cost-effectiveness is often the most important criterion, and while the criterion of cost per QALY in Sweden is used ‘softer’ than in England, the role of both economic evaluation and health economists has been a decisive one. The experience has been so successful that there are plans to extend the system to include all

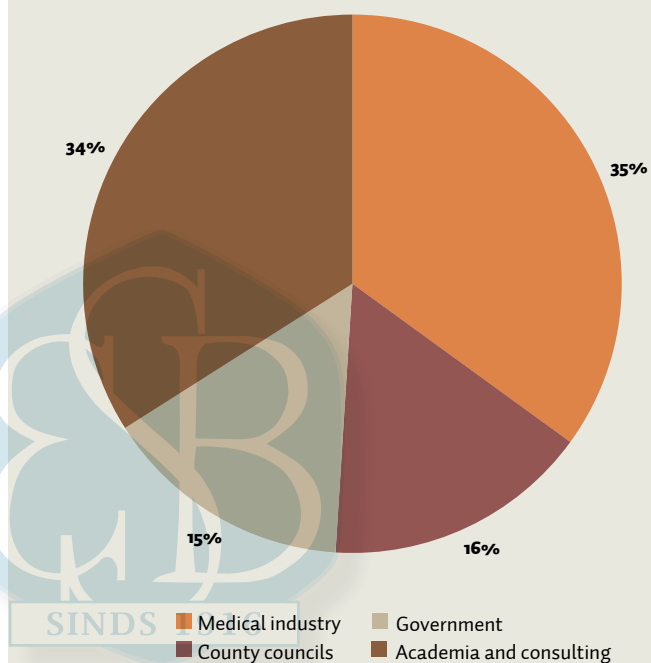
new health technologies, and not only drugs.

Economic evaluation also plays an important part in the national guidelines for treatment of different diseases, which are developed by the National Board of Health and Welfare. Figure 3 shows the distribution of health economists on the mailing list for SHEA (Swedish Health Economics Association). The largest number of health economists is to be found in industry and academia/consulting, but there are now also many health economists on county councils and in government.

Over fifty health economists work for the different government bodies dealing with healthcare. Both the large number of health economists at TLV and the large number of them employed by the pharmaceutical industry show that economic evaluation has a particularly strong position within decisions on new pharmaceutical treatments.

Distribution as to employers of 339 health economists in Sweden

FIGURE 3



SUMMARY AND CONCLUSIONS

Economic evaluation has gained a lot of influence on decisions about appropriate care in Sweden. This influence is particularly felt regarding decisions on the use of drugs. This is a consequence of the LFN/TLV's establishment in 2002. The positive experience of a formal process in order to assess prescription drugs for reimbursement has created an interest in extending this process to all technologies. However, as yet no decisions have been taken in this direction. The establishment of SBU, the Swedish HTA agency, has also given economic evaluation a position as a part of the HTA studies. The role of the economic aspects of HTA seems to have increased over time. At the national Board of Health and Welfare, economic evaluations play an important part in the development of national guidelines for the treatment of different diseases.

Economic evaluation has been accepted as an important tool in health policy with a view to evidence-based and appropriate care. The trend is that this will continue, mainly because there is no alternative policy instrument on the horizon. Nonetheless, there are certainly some challenges. The rapid introduction of new treatments for cancer and rare diseases at very high costs gives rise to questions about the applicability of economic evaluation. There may be reasons to create new processes for decision-making and data collection, and to develop decision criteria in order to take all relevant aspects into account. But the basic principle that new treatments should be evaluated in relation to alternatives, in terms of costs and outcomes, still seems valid. It may be tempting to create specific regulatory and budgetary solutions for new innovations as regards particular diseases or patient groups, but such short-term solutions may lead to sub-optimization in the longer run.



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