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SUMMARY REPORT

Working Group on Policy-making in Health Care - Changing Goals and New Tools

Maastricht, Netherlands
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TARGET 27

Rational and preferential distribution of resources according to need

By 1990, in all Member States, the infrastructures of the delivery systems should be organized so that resources are distributed according to need, and so that services ensure physical and economic accessibility and cultural acceptability to the population.

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Introduction

The introduction and use of new medical technology in health care represents a difficult and challenging problem for health policy-makers. Better tools are needed for the decision-making process itself and more knowledge about the effects of steering mechanisms.

Twenty-two senior health professionals and managers involved in policy-making in the health service sector in six countries joined a working group meeting to analyse and discuss the determining factors in policy development and the mechanisms for making policy decisions.

The meeting, arranged jointly by the WHO Regional Office for Europe and the Universities of Linköping (Sweden) and Limburg (Netherlands), was concerned with health service policy development. It focused not only on the role of medical technology assessment but also on the models and tools necessary for making proper assessments. Are there enough data to permit comprehensive assessment? Do we have good methodological standards? Are the results presented in a way that makes them useful for policy-makers?

How do we transform the results of technology assessments into health policies? Are comprehensive assessments made in important policy areas? Is the timing of the assessments coordinated with the policy-making process? What kinds of steering mechanism are used - legal and regulatory control, economic and prestige incentives, or education?

Discussion

The meeting, lasting one and a half days, was divided into two parts. Part One set the scene, with four lectures on central issues:

- health policy development: governing factors and actors;
- the role of medical disease models in policy decisions;
- economic evaluation of health care technology; and
- cost-effective use of medical technology: regulatory instruments and economic incentives.

There was also a presentation on the WHO programme for quality assurance and medical technology assessment.

Speakers laid particular emphasis on the pace of technological development and diffusion. In general, existing planning procedures are too slow to be useful in policy-making. Given the accelerating rate of biomedical innovation and this slow planning process, a way of solving the problem may be to use a formal scenario technique to simulate the future.

One explanation for the dissonance between the innovation/diffusion process and the planning/policy process is the communication gap between physicians on the one hand and administrators and policy-makers on the other. This gap is due to their different frameworks for thinking about, for example, illness or disease as opposed to health, the evaluation of effectiveness and quality in clinical work, and ethical issues. These disparities demand a more formal methodology for assessing health care which combines both the clinical and social perspectives.

Economic evaluation is an important feature of a comprehensive approach to technology assessment. It helps reveal the costs and benefits of different uses of technology, thereby increasing the efficiency of the resources spent to improve and protect the health of the population. Economic evaluation is a complement to medical evaluation, making use of the same data from clinical trials and epidemiological studies. It focuses on the costs and benefits of the different alternatives.

The perspective of the economic evaluation is that of society as a whole. Its relevance to policy increases, however, when costs and benefits are looked at from different angles. Only if proper incentives for cost-effective decision-making at different levels of the health care system are introduced can the full potential of economic evaluation in health policy-making be achieved.

Technology assessments are time-consuming and costly. This is why it is important for not only governments but also health care providers, health care institutions and industry to grasp that they have a responsibility for collecting information for new forms of technology to be assessed. This not only helps the government to take regulatory action but also improves the performance of the other parties in terms of efficiency.

Finally, it is difficult to interpret assessment results. Research study designs remain inconsistent, and information on the cost-effectiveness of medical procedures is still rather scanty.

Part Two of the meeting, the workshop, consisted of group discussions on four policy issues chosen as examples of preventive, diagnostic and treatment technology. They were:

- prevention of coronary heart disease by lipid reduction;
- screening for breast and cervical cancer;
- the use of gastroscopy in ulcer treatment; and
- extracorporeal shockwave lithotripsy in renal and biliary stone management.

A brief introduction on each of the four was followed by a group discussion on the central policy issues, and the meeting ended with a general discussion.

Prevention of coronary heart disease by lipid reduction

The first workshop session was on secondary prevention of coronary heart disease by pharmaceutical treatment of hypercholesterolaemia. Multivariate logistic regressions from the Framingham Study and epidemiological data from several Netherlands studies were used to develop a model of the incidence of coronary heart disease in the Netherlands. The incorporation of data on prognosis, treatment and treatment costs provided a model of life expectancy and future coronary heart disease treatment costs as a function of sex, age, serum cholesterol, blood pressure, smoking behaviour, left ventricular hypertrophy and glucose intolerance. The model makes it possible to simulate interventions and calculate their cost-effectiveness ratio, i.e. the net medical care cost per year of life saved. The example presented was a comparison of two cholesterol-lowering agents used in the Netherlands.

Modelling technique in the analysis of data was held to be a valuable weapon in the technology assessment arsenal. However, it involves a risk, because data are often poor or lacking. There are also risks in transposing epidemiological and effectiveness data from one country to another. Furthermore, it may be difficult for policy-makers to expose a complex analysis based on poor data. Generally speaking, it is important to maintain a critical attitude to data before incorporating them into models. In good research the key assumptions are explicitly laid out. If the clinical data are not broadly accepted there will be problems in using them in economic evaluations. Independent meta-analysis might be one formal way of ensuring data quality. Another would be to publish economic evaluations in scientific journals. A central question for assessors is: do we in fact have enough data to permit a cost-effectiveness analysis that can be used for policy decisions?

Screening for breast and cervical cancer

A computer programme, MISCAN, has been used to simulate the effects of alternative mass screening policies. Several factors are relevant in predicting the effects of mass screening. Among these are prevalence, incidence and mortality from the disease; sensitivity, specificity and acceptability of the screening test; attendance at the screening programme; the natural history of the disease, the duration of the preclinical stage, and the prognosis of each stage; and the change in prognosis when the disease is treated at an early stage. To take into account all these factors and known interactions, models were developed in which the input is assumptions about all the relevant factors, and the output estimates of the yield of screening and of its effects on morbidity, mortality, life-years, medical consumption, and so on. These models are implemented in the computer programme. The approach has been tested in recent years on cervical and breast cancer. The simulation model presented is undoubtedly helpful in the policy-making process.

The control-policy issues in this case are the lack of proper data, the existence of contradictory clinical results, the shortage of radiologists, and the economic incentives in different health care systems. It would be a great advantage if an international monitoring programme could be set up to review and synthesize data from various trials. Randomized trials have obviously had an impact on policy-making in this area. The importance of using randomized designs was emphasized. The shortage of skilled radiologists calls for other solutions, such as the use of technicians trained in mammography.

The economic incentives vary from one country to another. In a fee-for-service system all kinds of screening programmes could become very costly. A reimbursement system which supports cost-effective management might guarantee the proper use of screening technology.

The use of gastroscopy in ulcer treatment

The use of gastroscopy in the management of patients with peptic ulcer disease can also be assessed by medical-decision analysis and computer modelling. A decision model for the choice between different strategies for management of patients with suspected gastro-oesophageal, gastric or duodenal ulcer was presented. There was general agreement that this type of model could eliminate the choice between different policies for diagnosis and treatment. However, a model is never better than the clinical data it is

based on, and we still lack important information about the course of the disease under different forms of management. This is particularly true of the long-term consequences. We have much better and more adequate data about acute and intermittent treatment. The flexibility of the model, which includes sensitivity and threshold analysis, can to some extent take care of the uncertainties about the probabilities of different types of outcome.

The use of gastroscopy is increasing. This is partly due to its substitution for other techniques such as X-ray, and partly to broadening indications for it. Policy on gastroscopy in different countries was reviewed. The discussion centred on the policy in Belgium, where gastroscopy is a condition for reimbursement for treatment with H_2-blockers. It was questioned whether it is ethical to use a technique of significant cost and carrying significant risks as a measure for containing health care costs. The reimbursement condition obviously influences the clinical management of patients. It was also questioned whether gastroscopy does indeed save health care resources. It is several times more costly than the treatment itself, and to this must be added the direct and indirect costs for the patient. Here an analysis examining the cost and effectiveness of different strategies for the different parties involved could be of significant value for the development of a rational policy. The discussion ended with the conclusion that it is important also to create incentives for cost-effective management of patients at the clinical level.

Extracorporeal shockwave lithotripsy in renal and biliary stone management

The first clinical disintegration of renal stone by extracorporeally generated shockwaves (ESWL) was performed early in the 1980s, and during the past five years the ESWL technique has rapidly become accepted worldwide as a standard procedure for removal of calculi from the renal tract. The ESWL technique is spectacular, and the need for lithotripsy capacity has been a central policy issue in many countries. Today the number of units is very unevenly distributed in Europe, which may reflect different policies in different countries.

The number of scientific reports and conferences on the subject is increasing, but knowledge about the total consequences of ESWL for the health services and society as a whole remains limited. No randomized clinical trial has yet been reported, and patient outcome has not been studied thoroughly enough in previous studies.

In 1986 the first series of ESWL treatments of gall-bladder stones was reported. This innovation, if it proves as effective in treating gallstones as it has in the renal tract, should give rise to a theoretically tenfold increase in the application of lithotripsy. Awareness of the need for comprehensive assessments of ESWL has grown rapidly during the last five years. Among others, the Department of Health in the United Kingdom is supporting a randomized controlled clinical trial in which lithotripsy is being compared with the conventional treatment of cholecystectomy. Patient outcome and economic effects are included in the original protocol.

Two general conclusions can be drawn from the case of lithotripsy. Firstly, bureaucratic decrees about the need for technology tend to become outdated very soon after or even before they are announced. Secondly, it is hard to compare the results in different evaluation studies because of the use

of different protocols. The problems are how to enable policy-makers to contribute to assessment, and how to create incentives so that doctors perform follow-up studies, including studies of patient outcome, and use standard protocols.

Recommendations

1. Medical technology assessment is a continuous process: its results should be available when decision-makers need them.

2. Post-marketing surveillance should include the cost-effectiveness of the technique in question.

3. Data modelling is a useful approach in technology assessment and a helpful tool for policy-makers. People engaged in data modelling should ensure the high quality of their data through meta-analysis, clarify the assumptions they use, and present their results in a way that politicians can understand.

4. If an authority wants to restrict the use of a form of medical technology in order to prevent its abuse, it should make assessments (including assessments of the economic and ethical aspects) of the effects of this restriction.

5. Health care authorities should create incentives to encourage doctors to perform follow-up studies, including studies of patient outcome, and to use standard protocols aimed at improving the comparability of results between various centres and countries.