Priority-setting criteria in the Norwegian health services

PERSPECTIVES

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The severity of illness, the efficacy of interventions and their cost-effectiveness have been key criteria for priority setting in the Norwegian health services since the government commission on priorities in health care (the Lønning II Commission) submitted its recommendations in 1997. This article discusses some examples of how the principles have been interpreted in practice and what we may expect in the future.

Equality is one of the underlying principles of the Norwegian health system – the right to equal access to health services (1). An alternative principle is that of maximising benefit – priorities should be set in such a way as to achieve maximum (health) benefit in society. In the National health and care plan, this objective is reiterated in the phrase «the maximum good years of life for all» (2).

Both equality and maximisation of health obviously have their appeal, and both these principles are considered pivotal for the Norwegian health services. In order to achieve these two objectives, it may be tempting to say that all patients should receive every possible treatment as rapidly as possible. However, we have limited resources. Perhaps it may be strange for some to hear that we have limited resources in Norway, but if we look at organs for transplant, it is evident to most people that this resource is limited (3). It is possible to find solutions for many of the resource limitations by simply spending more money, but the money has nonetheless to come from somewhere – such as through higher taxes.

The Lønning Commissions
A desire for criteria on how resources should be distributed within the health services lay behind the first Lønning Commission, appointed on 24 May 1985 (referred to here as Lønning I). The commission proposed five levels of priority setting to be applied at a superordinate level in the health services when new interventions or treatments were introduced (4). These were graded according to the severity of the disease and the efficacy of the intervention or treatment. When grading severity in this manner, it was to be assumed that the most severe conditions and the most effective treatments should be the first priority.

Although the Lønning I Commission’s recommendation had a certain degree of influence on practice, there was dissatisfaction with the fact that the criteria lacked clarity and thereby allowed for too much discretion in practice (5). A new Lønning Commission was appointed in 1996 (referred to here as Lønning II), which submitted its report one year later (5). The criteria on severity and efficacy were retained in this report, and the criterion on cost-effectiveness was introduced. However, efficacy was replaced with a new word, benefit, which allowed for several interpretations. The three criteria have since been embodied in law and regulations, for example in the Patients’ and Users’ Rights Act (6), the Regulation on Priority Setting (7) and the Regulation on Medicines (8). In all these documents, a precondition for priority setting is that all the criteria must be fulfilled in order for a treatment or drug to be adopted, even though it is also mentioned that adjustments can be made if one criterion is particularly well fulfilled. For example, a somewhat lower requirement with regard to efficacy and cost-effectiveness might be considered if the disease was of great severity.

The criteria according to Lønning II

The severity criterion was relatively well described in Lønning II, but has not been equally well described in the above-mentioned Act and regulations. There has been some uncertainty with regard to how severity should influence priority setting in practice. One purpose of using severity of disease as a criterion is to place extra emphasis on those who are, or are expected to be, the least healthy. It is therefore a way of aiming to reduce health inequalities, and thus may be said to be based on the principle of equality, in this case related to equality of outcome. For persons with life-threatening conditions (the top priority according to Lønning I), it is rather the principle of assistance for the most acutely ill (rule of rescue) (9) which is the underlying principle (4).

The criterion of efficacy of the intervention may be interpreted in different ways. The reason for possible confusion here is that in the Lønning II Commission’s recommendation, the second criterion is referred to as «the benefit of the intervention». Considering that in most places Lønning II refers to therapeutic effect (clinical outcome) as being the criterion that matters, the implication is probably that this is what they meant. So what is the problem with using «benefit» rather than «efficacy» – in everyday speech, is this not more or less the same thing? For economists, benefit is based on valuation of the outcome. This can be achieved by measuring quality of life, for example. The Lønning II recommendation explicitly states that quality of life shall not be used as an indicator of clinical outcome because it was considered that the existing methods were not sufficiently mature to be used as an alternative to efficacy in practice. In other words, it appears unlikely that they intended us to use anything other than clinical efficacy as measured in randomised controlled trials.

Cost-effectiveness was a criterion which was introduced with the Lønning II Commission. The wording from 1997 has in no way lost its relevance: «Increased budgets do not necessarily make priority setting easier. Even with significant increases in resources, we have to undertake the same type of ranking and selection of those patients who should receive treatment. The principles will be the same, but the threshold for receiving treatment will be lower» (5). In health economic evaluations, the idea is to weigh up the

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costs of an intervention against the effectiveness to see whether «the costs are reasonable compared to the effectiveness of the intervention» (6). The objective here is health maximisation; we want the best possible health for each Norwegian krone already allocated to the health budget. The proposed indicator for health in relation to cost-efficiency in Lønning II is primarily quality and length of life. Quality Adjusted Life Years (QALYs) are an indicator which captures both the proposed dimensions, and it is probably this measure that the Commission had in mind. However, the Lønning II recommendation was somewhat unclear, and other objectives, for example (unadjusted) years of life, have also been used (10) and are even recommended as an alternative to QALYs in the Norwegian Directorate of Health’s guidelines for economic evaluations of health care (11).

The Lønning II Commission introduced the criterion of cost-effectiveness, but a long-standing problem has been the Commission’s failure to specify a reasonable relationship between costs and effectiveness, that is, what is the cost-effectiveness threshold. Without this being specified, the criterion is difficult to apply in practice. In Figure 1 I have illustrated what we often refer to as the cost-effectiveness plane (12).

**Figure 1** The cost-effectiveness plane. Health is measured on the x-axis and costs on the y-axis. The current treatment is the standard point of comparison, and is therefore placed in the centre (origin). Treatments with higher costs compared with existing treatments are placed above the x-axis and those with lower costs are placed below. Treatments to the left of the y-axis have lower effectiveness and those to the right have greater effectiveness. Treatments in the lower right quadrant are thus obviously cost-effective, and those in the upper left quadrant are obviously not cost-effective. In the remaining two quadrants of this plane we need the described threshold in order to know which treatments are cost-effective.

**Practical application**

As has been mentioned, the criteria proposed by the Lønning II committee have been implemented in law and regulation. The criteria have also been a guiding reference for the priority areas we have had, for our work with health technology assessments and for applications for inclusion of drugs in the prescription reimbursement scheme («blue prescription»). The severity criterion has been less widely used, in the sense that...
prioritisation has rarely been refused on the basis of insufficient severity. The efficacy criterion has in practice been closely tied to statistical significance, perhaps more so than was indicated by the Lønning II Commission, which was more concerned with the size of the effect. In order for cost-effectiveness to be a criterion in practice, a threshold is required regarding the extent to which society should be willing to pay for one year of life. The cost-effectiveness threshold which has been applied in practice, has often been close to the annual GDP per inhabitant.

Using these criteria in practice has proven to be difficult: The Norwegian Medicines Agency has used the criteria actively, as evidenced by the reimbursement reports published on the Internet, although it is sometimes unclear how the severity criterion has been dealt with (13). However, until 2013 it was primarily the reimbursement of drugs for «blue prescriptions» that was subject to a system in which the three criteria were used systematically. Since 1998, the Norwegian Centre for Health Technology Assessment (SMM) and later the Norwegian Knowledge Centre for the Health Services (NOKC) have prepared health technology assessments which have contained a thorough review of the efficacy and cost-effectiveness criteria (14). The severity criterion has not generally been directly evaluated in these reports.

Costly cancer drugs have been widely discussed in the mass media in recent years. The reason for this is the new system for introduction of new methods in the specialist health service (15). The system was officially launched in 2013 and entails that in practice there will now be a system for the introduction of new methods in the specialist health service. By this is meant a review of «efficacy, safety and costs», which indicates that the severity criterion is presumably not evaluated as systematically.

Examples

A cancer drug that created much public outcry was ipilimumab, used to treat advanced skin cancer. The new drug clearly fulfilled the severity criterion, nor were there any great objections with regard to the efficacy criterion (statistically significant reduction in mortality). The key question was whether the high cost of the drug was «reasonable compared to» the effectiveness. The Norwegian Medicines Agency and the Norwegian Directorate of Health found that the cost was too high and proposed that it should not be introduced. However, Jonas Gahr Støre, the Minister of Health, was approaching a parliamentary election and chose to introduce the drug through what he termed a «research project». The research project was severely criticised on several grounds by the professional community (16, 17).

Drugs for smoking cessation were evaluated in 2010 by the Norwegian Knowledge Centre for the Health Services, commissioned by the Norwegian Directorate of Health (18, 19). The Knowledge Centre concluded that drugs for smoking cessation were both effective and cost-effective. Although the follow-up time for the randomised controlled trials of efficacy was insufficient to be able to conclude on «hard endpoints», it is my opinion that the association between smoking cessation and such endpoints may be said to be so well established that the efficacy criterion is fulfilled in this case. Whether it may be said that the severity criterion is fulfilled depends on how it is interpreted. Smoking alone is obviously not a «severe disease», but it is proven beyond any doubt that it entails a significantly increased risk of severe disease. Since this increased risk is far higher than, for example, the increased risk associated with exceeding the treatment thresholds that are generally accepted for blood pressure and serum cholesterol, in my opinion there should be little doubt that smoking cessation drugs fulfil all three of the criteria.

Thus ipilimumab does not fulfil the criteria, but is funded through government budgets, while drugs for smoking cessation fulfil the criteria without being refunded. In recent years there have been many examples similar to those of ipilimumab and smoking cessation
drugs where I consider that either interventions have been introduced that do not fulfil the criteria, or interventions are deemed to fulfil the criteria but are not funded through government budgets. Table 1 provides an overview of some interventions in recent years (18)-(26).

### Table 1

Some interventions whose introduction has been considered in the last 20 years and deviation from the criteria. The assessments of whether the criteria have been fulfilled and whether there has been media pressure are based only on my personal impressions and do not represent absolute fact, but are intended as an illustration.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Severe</th>
<th>Effective</th>
<th>Cost-effective</th>
<th>Used</th>
<th>Subject to media pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking cessation (18, 19)</td>
<td>Probably</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Ipilimumab (20)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Rotavirus vaccine (21, 22)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>«Green prescription»– fee-for-service lifestyle advice (23)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Pneumococcal vaccine (4 doses) (24)</td>
<td>Rarely</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Pneumococcal vaccine (3 doses) (24)</td>
<td>Rarely</td>
<td>Not tested</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Early ultrasound (25)</td>
<td>No</td>
<td>No</td>
<td>Not evaluated</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Fosamax (26)</td>
<td>Probably</td>
<td>Yes</td>
<td>Probably</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

As earlier stated by Wang & Høymark in this journal (27), the reasons for accepting interventions have gone far beyond what the Lønning II Commission intended with regard to the three criteria. However, the explanation as to why interventions that fulfil the criteria are not introduced is less clear.

### The road ahead

The fact that the three Lønning II criteria have not been fully operationalised represents a problem for the evaluation of priority setting in the health services. What should be considered severe? When is an intervention effective and cost-effective? These questions were among those that the Norheim Commission was tasked with answering. The Norheim Commission proposes health loss as a criterion instead of severity and has suggested a possible way to operationalise this (28). The Commission also proposes to replace the efficacy criterion with health gain and cost with resource use. New in the Norheim Commission’s report is that all three criteria together shall be weighed against the opportunity cost when introducing new interventions. Efficacy and severity shall not be distinct criteria to be evaluated separately, as is the case today, and cost shall now rather be weighed against health gain through cost-effectiveness. The definition cost-effectiveness is now suggested to be dependent on the assumed health loss. The Norheim Commission
therefore opts for an explicit combination of the equality principle and the health maximisation principle when it now proposes the slogan «more good years of life for all, fairly distributed». In the literature this is termed the prioritisation principle.

In the last 10–15 years, the slogan «more good years for all» has set the tone for the legislative framework which underlies decision-making processes for the introduction of new interventions in Norway. However, it has not been applied consistently in all types of decisions. Whether the newly launched «more good years of life for all, fairly distributed» will be applied more consistently remains to be seen.

LITERATURE


