Priority-setting criteria in the Norwegian health services

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.

Torbjørn Wisløff
twisloff@gmail.com

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 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-effectiveness in Lønning II is primarily quality and length of life. Quality Adjusted Life Years (QALYs) are an indicator which cap-

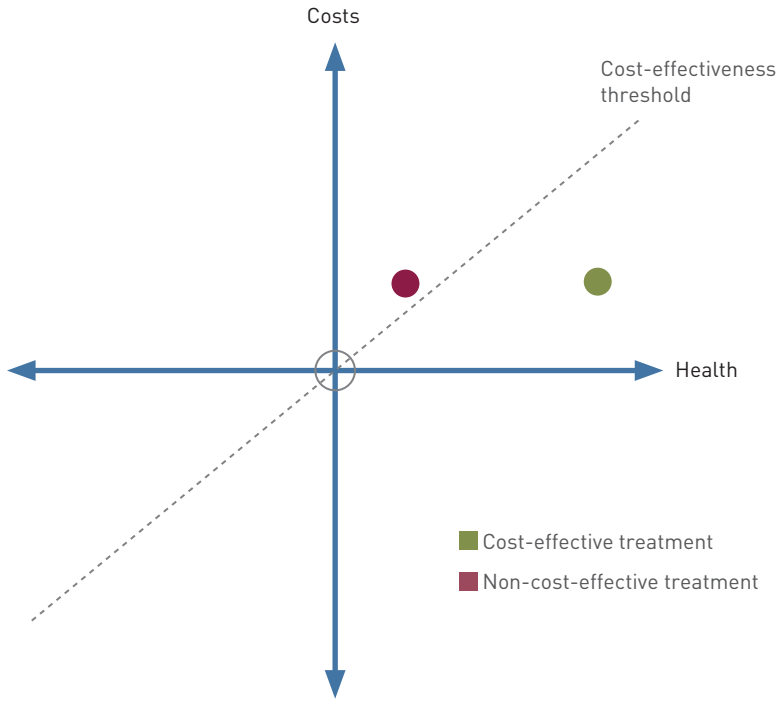

Figure 1 *The cost-effectiveness plane. Health is measured on the x-axis and costs on the y-axis. The current treatment is the standard point of comparison, and is therefore placed in the centre (origin). Treatments with higher costs compared with existing treatments are placed above the x-axis and those 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*

tures 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).

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

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

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

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).

As earlier stated by Wang & Høymork 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.

Torbjørn Wisløff (born 1976)
is a statistician and health economist, researcher at Oslo Centre for Biostatistics and Epidemiology (OCBE), Oslo University Hospital, and associate professor at the Department of Health Management and Health Economics (HELED) at the University of Oslo. He supervises researchers and PhD scholars in South-Eastern Norway Regional Health Authority who conduct health economic evaluations.
The author has completed the ICMJE form and reports no conflicts of interest.

References

1. Husom N. Prioritering – politisk likhetsideal gir medisinsk ubehag. Tidsskr Nor Lægeforen 2000; 120: 2.
2. Meld. St. 16 (2010–2011). Nasjonal helse- og omsorgsplan (2011–2015). www.regjeringen.no/no/dokumenter/meld-st-16-20102011/id639794/ (21.5.2015).
3. Holm AM, Leuckfeld I. Hvem skal få nye lunger? Aftenposten 22.4.2014. www.aftenposten.no/meninger/kronikker/Hvem-skal-fa-nye-lunger-7542035.html (21.5.2015).
4. NOU 1987: 23. Retningslinjer for prioriteringer innen norsk helsetjeneste. www.regjeringen.no/globalassets/upload/kilde/odn/tmp/2002/0034/ddd/pdfv/154646-nou1987-23.pdf (21.5.2015).
5. NOU 1997: 18. Prioritering på ny – gjennomgang av retningslinjer for prioriteringer innen norsk helsetjeneste. www.regjeringen.no/no/dokumenter/nou-1997-18/id140956/ (21.5.2015).
6. LOV-1999-07-02-63. Lov om pasient- og brukerrettigheter (pasient- og brukerrettighetsloven). https://lovdata.no/dokument/NL/lov/1999-07-02-63 (21.5.2015).
7. FOR-2000-12-01-1208. Forskrift om prioritering av helsetjenester, rett til nødvendig helsehjelp fra spesialisthelsetjenesten, rett til behandling i utlandet og om klagenemnd (prioriteringsforskriften). https: //lovdata.no/dokument/SF/forskrift/2000-12-01-1208 (21.5.2015).
8. FOR-2010-06-23-957. Forskrift om endring i forskrift om legemidler (legemiddelforskriften). https://lovdata.no/dokument/LTI/forskrift/2010-06-23-957 (21.5.2015).
9. McKie J, Richardson J. The rule of rescue. Soc Sci Med 2003; 56: 2407–19.
10. Wisløff T, Norheim OF, Halvorsen S et al. Kostnader og leveårsgevinster ved medikamentell primærforebygging av hjertekarsykdom. www.kunnskapssenteret.no/publikasjoner/kostnader-og-levearsgevinster-ved-medikamentell-primaerforebygging-av-hjertekarsykdom (21.5.2015).
11. Helsedirektoratet. Økonomisk evaluering av helsetiltak. https://helsedirektoratet.no/retningslinjer/veileder-i-okonomisk-evaluering-av-helsetiltak (21.5.2015).
12. Drummond MF, Sculpher MJ, Torrance GW et al. Methods for the economic evaluation of health care programmes. 3. utg. Oxford: Oxford University Press; 2005.
13. Statens legemiddelverk. Helseøkonomiske rapporter. http://legemiddelverket.no/Blaa_resept_og_pris/Helseoekonomiske%20rapporter/Sider/default.aspx (21.5.2015).
14. Mørland B. The history of health technology assessment in Norway. Int J Technol Assess Health Care 2009; 25 (Suppl 1): 148–55.
15. Helsedirektoratet. Nasjonalt system for innføring av nye metoder i spesialisthelsetjenesten. www.helsedirektoratet.no/helse-og-omsorgstjenester/system-for-innforing-av-nye-metoder/Sider/default.aspx (12.8.2014).
16. Nilsen L. Ut mot Støres forskningsstudie. Dagens Medisin 4.10.2013. www.dagensmedisin.no/artikler/2013/04/10/ut-mot-stores-forskningsstudie/ (21.5.2015).
17. Storvik AG. Mener ipilimumab-studien er feil ressursbruk. Dagens Medisin 14.10.2013. www.dagensmedisin.no/artikler/2013/10/14/mener-ipilimumab-studien-er-feil-ressursbruk/ (21.5.2015).

>>>

18. Sæterdal I, Ringerike T, Odgaard-Jensen J et al. Legemidler til røykeslutt. www.kunnskapssenteret.no/publikasjoner/legemidler-til-roykeslutt (21.5.2015).
19. Hagen G, Wisløff T, Klemp M. Cost-effectiveness of varenicline, bupropion and nicotine replacement therapy for smoking cessation. http://evalueringsportalen.no/evaluering/cost-effectiveness-of-varenicline-bupropion-and-nicotine-replacement-therapy-for-smoking-cessation (21.5.2015).
20. Legemiddelverket. Legemiddeløkonomisk vurdering. Ipilimumab (Yervoy) til behandling av avansert malignt melanom hos voksne som er tidligere behandlet. www.legemiddelverket.no/Blaa_resept_og_pris/Helseoekonomiske%20rapporter/Documents/2012-2011/Yervoy_malignt melanom_2012.pdf (21.5.2015).
21. Hagen G. Nye vaksiner mot omgangssyke er sikre og effektive. www.kunnskapssenteret.no/publikasjoner/nye-vaksiner-mot-omgangssyke-er-sikre-og-effektive (21.5.2015).
22. Samdal K, Hagen G, Flem E et al. Kostnadseffektivitet av å inkludere vaksinasjon mot rotavirus i det norske barnevaksinasjonsprogrammet. www.kunnskapssenteret.no/publikasjoner/kostnadseffektivitet-av-a-inkludere-vaksinasjon-mot-rotavirus-i-det-norske-barnevaksinasjonsprogrammet (21.5.2015).
23. Kristiansen IS, Wisløff T. Grønn resept – effekt og kostnadseffektivitet. SMM-rapport nr. 7/2003. Oslo: SINTEF Unimed, 2003.
24. Wisløff T, Abrahamsen TG, Bergsaker MA et al. Cost effectiveness of adding 7-valent pneumococcal conjugate (PCV-7) vaccine to the Norwegian childhood vaccination program. Vaccine 2006; 24: 5690–9.
25. Lauvrak V, Norderhaug I, Hagen G et al. Tidlig ultralyd i svangerskapsomsorgen. www.kunnskapssenteret.no/publikasjoner/tidlig-ultralyd-i-svangerskapsomsorgen (21.5.2015).
26. Kristiansen IS, Falch JA, Andersen L et al. Bruk av alendronat ved osteoporose – er det kostnadseffektivt? Tidsskr Nor Lægeforen 1997; 117: 2619–22.
27. Wang H, Høymork SC. Prioritering–er alle gode ting bare tre? Tidsskr Nor Legeforen 2014; 134: 1260–2.
28. NOU 2014: 12. Åpent og rettferdig – prioriteringer i helsetjenesten. www.regjeringen.no/no/dokumenter/NOU-2014-12/id2076730/ (21.5.2015).

Received 19 February 2015, first revision submitted 21 April 2015, accepted 21 May 2015. Editor: Hanne Støre Valeur.