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Assessment of value for resource allocation in cancer care

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ABSTRACT

There has been an increased interest in ways of measuring the value of new therapeutic options in oncology. An example of this in a European context is the ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS). The purpose of this study is to analyse how the value scales, exemplified with ESMO-MCBS, developed mainly to assist decisions by physicians, relate to other measures of clinical benefit and value used by reimbursement agencies.

We undertook a comparison of ESMO-MCBS with three different approaches to measure value; the patient benefit scale (AMNOG) used in in Germany, the assessment of ASMR (Amélioration du Service MédicalRendu) used in France and estimates of gain in quality adjusted life years (QALY) used in several countries such England and Wales, Scotland and Sweden. The criteria and metrics, as well as the purpose and decision making processes differs between the agencies, which makes it possible to study both differences and similarities between the three different approaches compared to the ESMO-MCBS value framework. Correlations between the scales were formally tested using the Spearmans rank test.

There was reasonable agreement between ESMO-MCBS and the AMNOG. Although there was a statistically significant correlation between the scale and ASMR scores overall there is very little agreement between the two categories in the middle of the scale. The link between ESMO-MCBS and QALYs appears to be very weak with very little differentiation between drugs receiving a ESMO-MCBS of 2, 3 or 4.

1. Introduction

New cancer medicines are granted market authorization in the EU based on an assessment of efficacy and safety by the European Medicines Agency (EMA). While evidence about efficacy and safety indicates potential benefits for the patient, this measure does not provide any estimate of the relative effectiveness (RE) of the new medicine compared to available therapeutic alternatives. In a private market, where the patient pays for the drugs, the assessment of expected benefit and value can be left to the prescribing doctor, acting as an advisor and agent for the patient. The same model for assessment and decision-making can be used in a publicly funded health care system if the cost and effectiveness of the drug are insignificant in relation to other factors considered in the choice of treatment.

However, as new cancer medicines accounts for a significant share of public spending on cancer decisions about their use cannot be left solely to the patient and to the treating physician. There is a need for a complementary mechanism for the evaluation of relative effectiveness and cost-effectiveness (CE). This is not only necessary in controlling costs in making the health care system financially sustainable, but also to provide incentives for efficiency, both in the short run and in the long run.

With the introduction of an increasing number of new cancer medicines, which are also used in combination and sequence, the number of available alternatives for treatment with different costs and outcome creates a decision problem. Information about both costs and effectiveness is necessary to provide the best possible outcome within available resources. Efficiency in allocation of resources, including cancer drugs, becomes an increasingly important issue in cancer care; not primarily because resources are limited (that is and has always been the case) but because there are an increasing number of alternatives that differ in costs and outcome.

In the short run health care systems aim at optimizing the use of resources to provide best possible quality and outcome in can-

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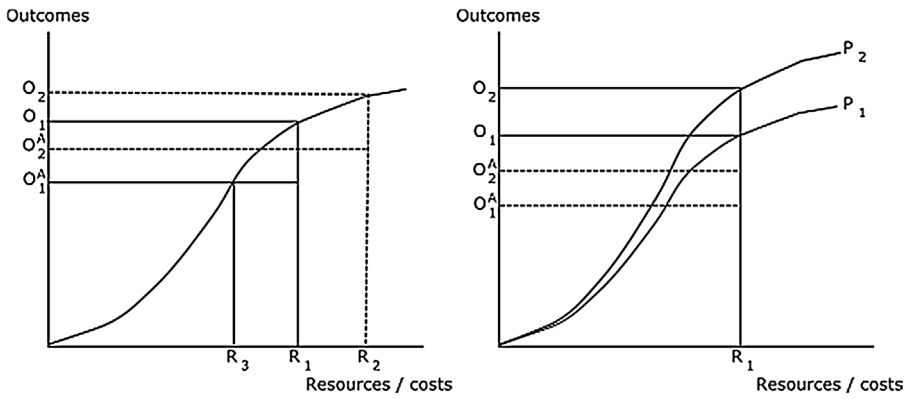

Fig. 1. Potential production of outcomes under a resource constraint.
The production function (P) shows the maximum outcome that can be achieved at different levels of resource input (left figure). Actual outcome (O1A) for a given resource constraint (R1) can be less than optimal (O1), or could have been produced with less resources (R3). Improvements in efficiency can be used for cost savings and/or better outcomes. An increase in resources (R2) gives a potential increase in outcome to (O2), but the actual increase may only be to (O2A).
An increase in productivity through innovation (right figure) is illustrated by, a shift in the curve (from P1 to P2). Potential outcome increases from O1 to O2) at the given level of resources. Actual outcome (O2A) may move closer to the new production frontier if the innovation triggers reallocation of resources.

cer care. Wasting resources on ineffective or suboptimal care is not acceptable when resources are scarce. Efficiency is not the only goal for health care systems. It is also important that resources are allocated equitable, with a priority for patients with the greatest need. Thus, it is important to keep all relevant objectives in mind when assessing alternative ways of allocating scarce resources. Health care systems are seldom operating at the "efficiency frontier" as described in the figure below. We should therefore be looking for opportunities to improve both efficiency and equity in the allocation of resources for cancer care (Fig. 1).

How resources are used influence the quality, outcome and equity of cancer care for patients. But the budget for cancer in a given year and the spending patterns will also have long-term consequences. Spending on cancer drugs provides incentives to develop new cancer drugs, and thus the availability of new treatment options in the future. Spending patterns do not only provide financing of research and development, but also information about how the health care system value different types of new drugs. Spending patterns are therefore important for the dynamic efficiency as well as the static efficiency of the health care system, and what we get today as well as tomorrow, meaning that there is a trade-off between static and dynamic efficiency.

2. Formal assessment of value for resource allocation

If the health-care system strives for value, it is crucial how value is assessed and how payments to providers are linked to value. With the growing focus on value-based health care [1], focusing on best possible outcome rather than provision of services, it is not surprising that assessment of value of new cancer drugs has gained a growing interest. This interest is, for new medicines, primarily linked to the pricing, since the dominating model for public payment for new drugs is through a decision about reimbursement. A positive decision about reimbursement means that the drug, if prescribed under certain conditions, could be paid for by a third party payer. There may be restrictions by the payer in order to control total spending.

The decision on reimbursement is –in most countries- not directly based on the price even if price plays a role for the reimbursement decision. The decision is mainly determined by assessments of effectiveness or patient benefit. In some countries the decision on reimbursement is based on formal assessments of cost-effectiveness, where the price comes in as an important determinant. However in the US, where recently a number of initiatives have been launched to assist in determining the value of new cancer drugs, public payers are not allowed to explicitly considering cost-effectiveness as a criteria for reimbursement [2]. These initiatives include the ASCO Value Framework [3], the Memorial Sloan Kettering Cancer Center DrugAbacus [4] and the National Comprehensive Cancer Network (NCCN) [5]. In all cases, the high price and questionable cost-effectiveness of many new cancer drugs have been mentioned as one of the rationales for developing tools to assess the value of new drugs.

In Europe, the ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) has been inspired by the US development, but with no direct relation to price or reimbursement decisions [6]. However, it is obvious that the scale aims at addressing an efficiency problem, i.e. the allocation of resources towards more valuable new cancer drugs, and away from less valuable drugs.

As can be seen in Table 1, the scales are triggered by the same concern about price and costs, but the specific objectives of the scales vary. Whereas the ASCO Value Framework is intended for use by oncologists in discussions with individual patients, ESMO-MCBS intends to give a single measure of the clinical benefit of a new drug for the communication of its potential value. DrugAbacus focus directly on prices, providing an estimate of a price based on how the user values different characteristics of the drug. The NCCN Evidence Blocks finally graphically illustrates different components of the NCCN Guidelines. Despite the different objectives, they use a similar core set of information with some minor variations

The purpose of this study is to analyse how the value scales, exemplified with ESMO-MCBS, developed mainly to assist decisions by physicians, relate to other measures of clinical benefit and value used by reimbursement agencies.

3. Material and methods

We undertook a comparison of ESMO-MCBS with three different approaches to measure value; the patient benefit scale used in the AMNOG (Arzneimittelmarkt-Neuordnungsgesetz) process in Germany [7], the assessment of ASMR (Amélioration du Service Médical Rendu) by HAS (Haute Autorité de Santé) in France [8] and estimates of gain in quality adjusted life years (QALY) used in several countries such England and Wales (National Institute for Health and Care Excellence, NICE), Scotland (Scottish Medicines Consortium, SMC) and Sweden (Tandvårds och Läkemedelsförmånsverket, TLV) [9,10]. This comparison is used as the basis for a discussion on the challenges of developing a value scale, which can be used

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