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Inequalities in oncology care: Economic consequences of high cost drugs

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ABSTRACT

The expenditures for hospital drugs are continuously increasing, and grow much faster than the global hospital budgets do. This explosive growth is caused mainly by a few so-called 'expensive drugs' of which the oncolytics form the main part. The global budgets should stimulate more effective provision of care ('technical efficiency'), however the room for technical efficiency is decreasing. Hospitals thus have to make impossible choices, so that eventually equal access can no longer be guaranteed. If no other policies are applied, health care goals will no longer be met. This paper tries to map the contours of the current problem and its possible solutions. It is time governments take up their responsibility and take back control.

1. Introduction

The expenditures for hospital drugs increase approximately 10% per year, and grow much faster than the hospital budget does. Between 1996 and 2000 the expenditures increased approximately 8% per year in the Netherlands. An even steeper upward trend is predicted for the future: a 20% yearly increase in expenditures for hospital drugs is considered plausible.[1] The introduction of new, expensive hospital drugs is causing this; examples are the oncolytics trastuzumab (Herceptin®) and oxaliplatin (Eloxatin®). To finance hospital care most countries apply the traditional system of fixed global budgets, or the more modern variant of allotted amounts at a specific diagnosis-based level (e.g. in prospective payment systems based on case mix). The costly drugs also have to be paid for out of these budgets. Hospitals or hospital departments thus have to find the resources to purchase newly introduced expensive drugs. It is clear that expensive and innovative drugs exert a great pressure on the hospital pharmacy budget, or on the allotted amounts at the level of specific diagnoses. Examples of regional differences between and within countries in the use of these expensive cancer drugs show that inequalities are increasing and that hospitals are no longer able to pay for these expenses from the allotted budgets.[2–4] The question therefore is whether we can expect hospital managers to deal adequately with this problem, or does the financing system force them to make impossible choices.

This paper argues that today's governmental policies do not adequately handle the unsustainable and exponential growth of expensive drugs such as oncolytics. In the majority of western countries, hospital finance has been based on global budgets to stimulate more effective provision of care (also called 'technical efficiency'). This strategy shifted a social

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problem to hospitals, but with a good reason: the perceived overcapacity in the health care system. The advantage of a budgeting system then is that it offers hospitals an incentive for efficiency, and it enables managers to make decisions on structural issues that have greatly improved technical efficiency of the health care system. For example, efficiency of hospitals can be improved by reducing staff size, reducing the number of hospital beds, or by cutbacks in the number of casualty departments. This financing system, however, has in the Netherlands been operational for more than two decades now. As a consequence, room for improvement of technical efficiency is decreasing; hence the chance increases that health care goals will no longer be met if no other policies are applied. For that reason, we cannot leave it up to the hospitals to deal with the budget pressure exerted by expensive drugs. Sooner or later it will become a social problem again, a financial problem, a quality problem, or an ethical problem related to increasing treatment inequalities.

This paper discusses some of the current policy strategies to deal with this problem, as well as their limitations as they occur in the Netherlands. Nevertheless, this paper will not offer solutions but will try to map the contours of the current problem and its possible solutions.

2. Expenditures for hospital drugs

Drugs dispensed in hospitals are part of the entitlement to hospital care, which is financed out of a global budget (see Section 3). That this budgeting system is problematic for the finance of hospital drugs becomes clear when one looks at Fig. 1. Fig. 1 depicts the development in volume of and expenditures for hospital drugs over the last 15 years in one (anonymous) Dutch, non-university teaching, regional hospital (about 900 beds). The figure shows a sustainable yearly growth rate of about 5% in the volume of hospital drug use, which is more or less in line with the rate at which the allowed annual growth of hospital expenditures in the same period. However, the cost of hospital drugs grow about twice as fast, increasing 300% over 15 years and 150% in the last 5 years. Growth rate of drug costs is thus outpacing the growth of the hospital budget.

The growth of expenditures for hospital drugs can be attributed to the introduction of new drugs that are very costly. Indeed, the percentage the hospital budget spent on new and expensive drugs increased from 6.2% in 1996 to 11.7% in 2000.[1] Especially for this group of drugs the financing is perceived as problematic as it leads to large variation in the availability of certain expensive drugs across hospitals and to referral of 'expensive' patients to specialised centres, which are then confronted with much higher patient costs than other regional hospitals (something that the central budgeting system does not automatically control for). Since 1996, the costs for so-called 'expensive drugs' have increased 500%. In Fig. 2 the purchasing data of the 'expensive medicines' according to the Regulation Expensive Medicines of the hospital pharmacy are depicted for the same anonymous hospital as mentioned before.

A large share of these costs relate to few drugs. Especially, the introduction of some oncolytics (e.g. cytostatics and monoclonal antibodies) has contributed to the growth in expenditures (see Figs. 3 and 4). The introduction of the first few expensive drugs mid-ninetees was then heavily debated. For example, when paclitaxel (Taxol®) was registered, the debate about the high costs was very intense. Taxoids were considered to be not cost-effective, but the general opinion was that hospitals could not withhold this therapy from severely ill patients only because of a cost-argument. The government even decided to contribute towards the costs of taxoids, by subsidising the costs of this treatment. The taxoids' case seems to have created a precedent. First, in later years, even more expensive oncolytics have been introduced without public debate about their financial implications. Second, the possibilities to receive additional resources for provision of high cost treatments were expanded (see Section 3).

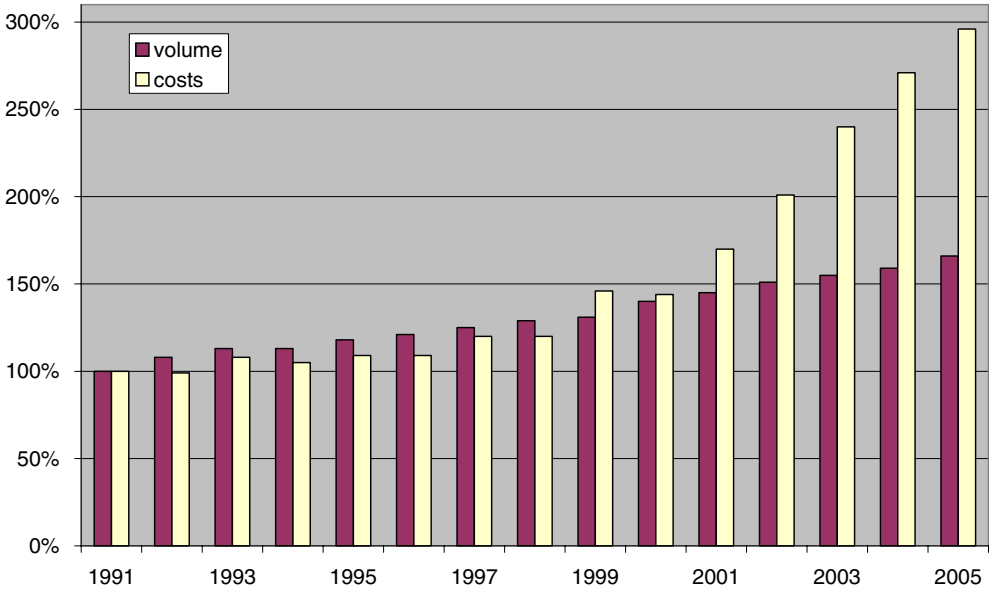

Fig. 1 – Hospital drugs: development in volume and expenditures since 1991 (1991 = 100%).

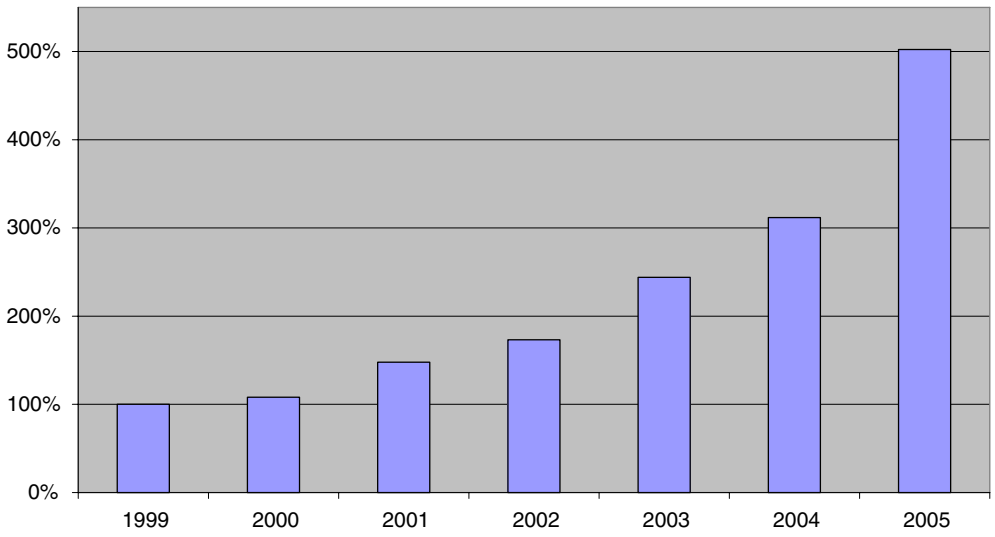

Fig. 2 – Development in total expenditures for 'expensive drugs' since 1999 (1999 = 100%). Expensive drugs are those drugs that have been listed since 2002 on the 'Regulation Expensive Medicines'.

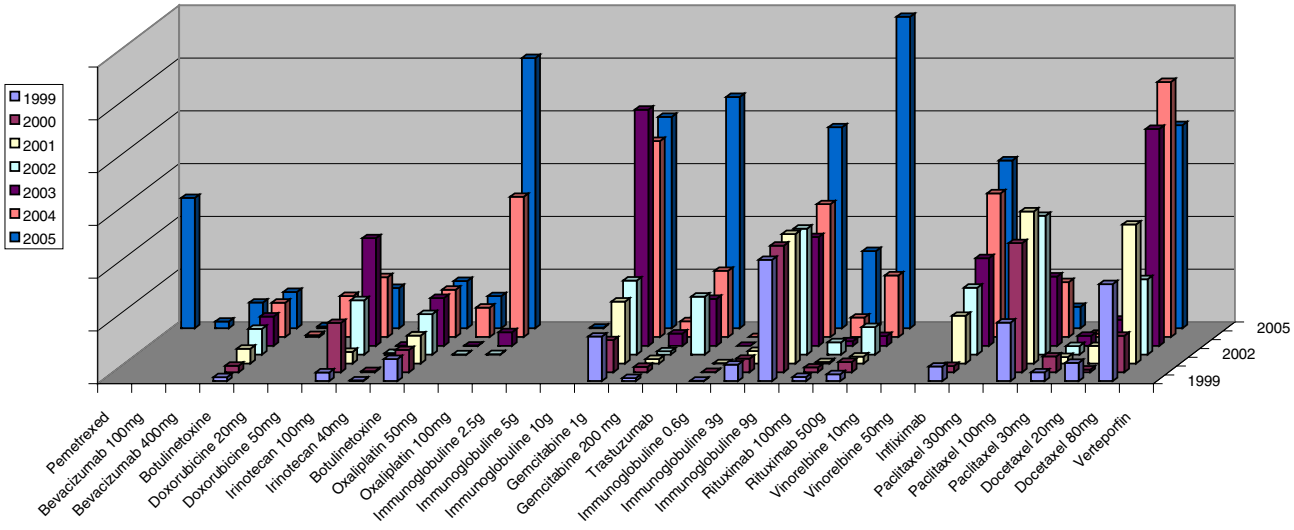

Fig. 3 – Relative expenditure levels for expensive drugs by year and product.

3. Dutch policy

Hospitals received, until 2005, a lump sum budget annually, which was determined by the National Health Tariffs Authority (CTG). This hospital budget had to finance all delivered care and cover all other expenses. A similar system applies in many western countries.[5] Based on the modern belief that health care can be managed more efficiently when the system offers hospitals incentives for competition and patients more freedom of choice,[6] a new financing system was introduced. As of January 1, 2005, hospital care is financed using diagnosis and treatment combinations (diagnose behandeling combinaties – DBCs). A DBC defines the whole of the hospital and medical specialist activities and services arising from the demand for care by a patient consulting a specialist in a hospital. This new financing system, based on case-mix, introduces more transparently defined hospital products covered by prices reflecting costs. Because of this direct link between provided care and available resources, it may become easier to prevent discrepancies between budget and expenditures. However, resolution of the current budgetary problems caused by high cost hospital drugs should not be expected on a short notice. The DBC finance system applies only to 10% of hospital expenditures; for other expenditures the traditional budgeting system still applies. The percentage of expenditures covered in the DBC system will likely be expanded over the following years, but as yet it is not known if or how this will include costs of hospital drugs. The reason is that not all hospitals can deliver sufficiently detailed costs data to attribute the costs of hospital drugs to different DBCs. Moreover, the dynamics of the hospital formulary may require more flexibility than the DBC system can offer.

Recognising the problem of financing expensive drugs like oncolytics and the increasing risk of practice variation in

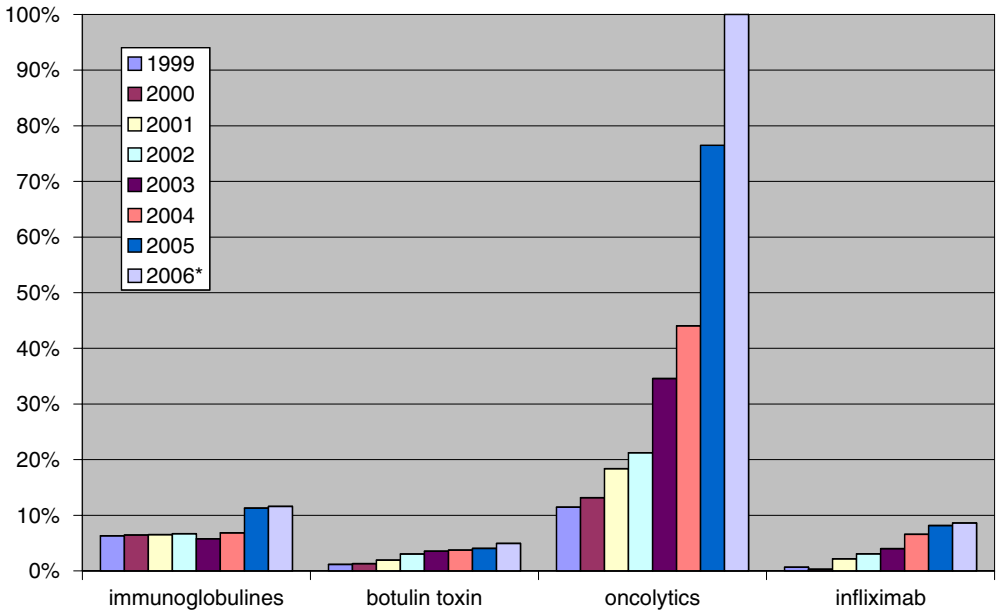

Fig. 4 – Relative expenditure levels for expensive drugs by year and drug group.

hospital care, in 2002 the Dutch government implemented a law that forced health insurers to contribute to the costs of some expensive drugs.[7] For all drugs listed on the 'Regulation Expensive Medicines' separate reimbursement should be offered. Until 2005 hospitals had to pay between 25% and 100% of expenditures;[5] the reimbursement percentage was variable and was determined after negotiation with insurers. In 2006 the reimbursement rate was fixed at 80%. Reimbursement for the 'expensive drugs' is limited to specific (sub)indications and conditions, which are decided by the minister on the basis of an advisory report drafted by the Commission Pharmaceutical Care (CFH) of the Dutch Health Care Insurance Board (CVZ) which assesses the drugs for their therapeutic value. Drugs are included on the list when the prognosis is that they will consume at least 0,5% of the total pharmaceutical expenses of hospitals. By March 2006 sixteen drugs were listed (see Table 1, oncolytics in bold). Three years after listing a decision will be made about the continuation of the subsidy based on a cost-effectiveness analysis using daily practice data collected in these three years. If the cost-effectiveness ratio is favourable, the temporary measure will become permanent; if negative, the medicine is removed from the list and is no longer eligible for additional subsidy.

In spite of the additional funds for expensive drugs, their expenditures still increase rapidly. Obviously the measure has not fully resolved the problem. Unless reimbursement rate is at 100% it is therefore unlikely that treatment inequalities can be prevented.

Table 1 – Drugs included on the Regulation Expensive Medicines, March 2006

- **Docetaxel**
- **Irinotecan**
- **Gemcitabine**
- **Oxaliplatin**
- **Paclitaxel**
- **Rituximab**
- Infliximab
- Immunoglobine IV
- **Trastuzumab**
- Botulinetoxine
- Verteporfin
- **Doxorubicine** liposomal
- **Vinorelbine**
- **Bevacizumab**
- **Pemetrexed**
- **Bortezomib**

4. Problems

Because of the central budget an artificial scarcity was created which aimed to improve a technical efficiency. Hospitals were stimulated to cut redundant costs. Fact is, however, that possibilities for shifting budgets vary across hospitals, e.g. small hospitals typically have less room to manoeuvre than large hospitals, so they may seek other solutions. One of the easiest ways to resolve the problem is simply not to purchase expensive products and to refer patients to other hospitals. Therefore, the budgeting mechanism created a large variation in the availability of certain expensive drugs across hospitals. This, in turn, resulted in a disproportionate stream of 'expensive' patients to specialised centres. These specialised centres were thus confronted with a disproportionately high cost of specific drugs, so that their scarcity problem became more pronounced and they were disadvantaged vis-à-vis other hospitals. In these circumstances it is not surprising that some patients do not receive the care they are entitled to. A recent study into the use of trastuzumab (Herceptin®) shows that this drug is not as often prescribed as was expected on the basis of clinical guidelines and demographic data. The differ-

ences across regions are pronounced, as is depicted in Fig. 5. Policies have thus not been able to prevent postcode prescribing.

In the Netherlands, hospital treatment qualifies for reimbursement when that particular treatment is considered 'usual care' for that specific patient group. In the trastuzumab case, patients thus may not get the treatment they are entitled to, which is undesirable and even against the law. The previously mentioned 'Regulation Expensive Medicines' aimed to ensure that patients can validate their entitlements. The example shows that this regulation does not have the desired effects. This could have been expected. The Regulation describes the conditions under which a hospital receives extra budget (80% of the total costs) for expensive drugs. Nevertheless, the hospitals still have to cover 20% of the costs. This may seem a relatively small amount, but declining possibilities to cut in other hospital expenditures makes it a large financial gap to bridge The Dutch Federation of Hospitals estimates the cost increase caused by new expensive drugs to be €200 million for 2006.[8] Just to indicate what the consequences are, let's say that an average hospital is confronted with a €2 million cost increase. If the hospital has to finance this from its own resources, it could imply that about 45 people lose their jobs. However, this is not a sustainable solution, since hospitals already have a shortage in personnel.

Likely, the finance of hospital drugs will become even more problematic in the future. Clinicians expect a continued increase of average drug prices. A reason is that drugs become more expensive because of new production technologies, e.g. biotechnology. What is more, the new drugs often target relatively small patient subgroups, creating a downward pressure on revenues and hence an upward effect on prices. Trastuzumab is an example of this new group of so-called personalised drugs; it is only effective in women with breast cancer who have an amplified HER2/neu gene.[9] More and more of such products are registered, so that average drug price increases. The threshold of 0,5% gets more difficult to reach. Since the total budget does not sufficiently increase to compensate for inflation and innovation, the Regulation Expensive Medicines does not improve financial viability of hospitals. From that point of view, the Regulation primarily offers a solution for practice variance in the treatment with (listed) expensive drugs, but this may come at the cost of increasing practice variance in other treatment areas. The reason is that now a part of the budget is earmarked as the Regulation explicitly states, what care should be delivered. Moreover, it does not indicate how priorities should be set in the allocation of remaining resources.

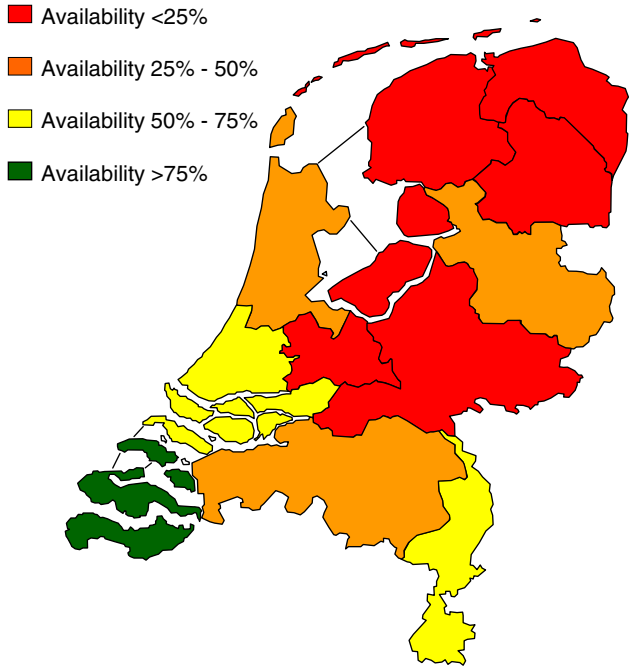

Fig. 5 – Estimated availability of trastuzamab (herceptin®) in Dutch regions (Figure reproduced from[2]).

5. Future directions

To solve current problems, changes to the financing system of hospitals are required: we need to search for a new balance between central budgeting and fee-for-service financing. The introduction of a case-mix financing system may help to resolve the problems, especially when this system is expanded to all hospital care and to include expenditures for hospital drugs. An implication of this policy change, however, is that the system loses incentives for technical efficiency, because this case-mix system is in theory open-ended. Typically, control over the total level of expenditures in open-ended financing systems is maintained through tighter control of the benefit package. This means that more emphasis is put on productive efficiency, and that more outcomes research is performed to make sure that the use of health care technologies at the practice level is evidence based.

In many countries, reimbursement decisions of outpatient medication are made at the national level, based on evaluations of (cost)-effectiveness. In contrast, local hospitals are responsible for meeting the health care needs of their populations, but they are free to make decisions concerning the use of new technologies. It is not exactly known how these local managers decide on the content of the hospital formularies. Do they consider therapeutic value? Do they consider cost? Do the new drugs meet the expectations in daily practice? And when are costs considered to be too high? There is increasing awareness that more openness in the decision making process is required. If we expect all patients to receive high quality care, different hospitals would have to answer such questions in a similar way. Also the recognition that some of the newly implemented interventions proved not effective in retrospect has increased awareness of the need for more scientific evidence before introduction of new health technologies into hospital care. In improving the decision making process the government should play a role: it would be helpful if they promote research into efficient use of resources in hospitals by evaluating new and existing services from medical, economic and ethical point of view and establish organisational structures for dissemination of the results to local decision makers. In that respect it is a good development that Dutch policymakers recently accepted some responsibility for promotion of evidence based decision-making regarding hospital treatments. This becomes apparent

from the change in the policy rule for expensive drugs stating that three years after listing, the medicine should be re-assessed to see if the drug meets its expectations and to decide if the particular drug still deserves its place in the Regulation.

But, does this type of outcomes research really solve the problem? Maybe we should not expect too much. If outcomes research shows that a medicine meets all common requirements for effectiveness and cost-effectiveness, it does not necessarily mean that the hospitals or Dutch government are able to fund this medicine. Outcomes research can be used to prioritise which drugs are in- or excluded from the hospital formularies by demonstrating which drugs represent added value for each additional euro spent. But it does not resolve the problem that it may not be affordable to fund every medicine that meets all requirements for effectiveness and cost-effectiveness. The introduction of new (cost-effective) drugs means that health outcomes can be improved at reasonable cost, but it also means that total resource consumption has to increase. There is no guarantee that the hospital is able to meet the additional resource requirements.[10] Certain flexibility of the total budget or of the applied assessment criteria is required to make the system work.

The question then is not just whether or not a hospital is able to use its pharmaceutical budget as efficient as possible, but also if the total budget for health care is used in an optimal way. A comprehensive approach would include transparency of resource use and outcomes for the entire hospital and also in other health care sectors, and the flexibility to reallocate available budgets. In the end, under this approach, comparisons may be made between expenditures for health care and other public goods (e.g. education), so that benefits associated with possible expansions can be related to the question whether or not the health care budget should be increased to meet the health needs of the population.

6. Discussion

The social problem of expensive drugs is new and enormous in the Netherlands, and likely also in other western countries. If the current policy is not changed, the 16 medicines now classified as 'expensive' will cost approximately up to €600 million in about 5 years. This amount is comparable with the current turnover of all drugs in all hospitals.[11] This is not just a problem of hospitals; sooner or later it will become a social problem again. Governments should intervene before the problem gets out of control, as a financial problem, a quality problem, or an ethical problem related to increasing treatment inequalities. This paper has pictured the development of the problem and identified fundamental issues that need to be resolved. Will budget impact be allowed to overrule cost-effectiveness? And, does this give legitimacy problems? These questions are a signal that reflection on the value of health is necessary and the available budgets have to be reconsidered. In answering these questions we need to hurry, because of the enormous speed with which the cost explosion is developing. The current lack of political action is worrisome, especially in the field of oncology since many expensive drugs are used in this field. The transparency of its high expenditures may make this field vulnerable to budget cuts.[12] On the other hand, the severity of many types of cancer also stimulates discussion about fairness. Hopefully oncologists will be able to use this discussion to their advantage and stimulate a public debate about the real issue that system changes are needed to guarantee that patients get the treatment they need.

Conflict of interest statement

None declared.

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