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Cost issues in new disease-modifying treatments for advanced cancer: In-depth interviews with physicians

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SUMMARY

Background: The high costs of new disease-modifying, but non-curative, treatments in advanced cancer are increasingly regarded as problematic. Little is known about oncologists' beliefs regarding their ethical obligations for cost considerations about these types of treatments.

Participants and Methods: This study used in-depth interviews to explore how physicians in The Netherlands view their role regarding the cost of potentially beneficial but expensive drugs, especially for new disease-modifying treatments in advanced cancer. Thirty-six physicians, 19 physicians caring for patients with advanced cancer and 17 physicians participating in four national oncology guideline committees, were interviewed.

Results: Physicians identified cost considerations on three levels: individual patient care, hospital policies and national guideline development. Generally, physicians were reluctant to consider costs in individual patient care, believing this compromised their ethical obligations. They did consider costs relevant at the level of hospital policies regarding coverage for drugs. They were divided regarding the role of cost considerations in national practice guideline development.

Conclusions: The distinctive levels of decision-making were understood to be morally relevant as physicians separated their role as direct care provider from that of taking part in decisions about coverage. Because of the fundamental tension between the physician obligation to act in the best interest of the individual patient, the vulnerability of having a life-threatening illness and the inevitability of sharing resources in modern health care, cost considerations will always be problematic for physicians. The roles physicians play at different levels, especially at the levels of hospital policies and national practice guidelines, should further be developed and explicated.

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1. Introduction

The debate about whether physicians should consider costs in treatment decisions is a recent one. In the Hippocratic tradition, the ethical obligations of the physician are defined exclusively in terms of the potential benefits to each individual patient. That central commitment is still a crucial consideration. However, modern health care operates in complex systems of funding and health care delivery. The physician is no longer responsible for all resources necessary for provision of the patient's well-being and benefit. These resources are now shared not only by the other patients of a physician but by the other patients of other physicians as well. Moreover, there are many different types of funding for necessary care, both public and private, for profit and many different forms of physician payment. Some payment schemes provide financial incentives to reduce the number of tests, treatments, referrals and use of expensive drugs. The Hippocratic tradition offers no clear direction as to doctors' duties in this complex environment.

The growing literature in this area identifies two competing conceptions of physician duty: physicians should adhere to the Hippocratic ideal of clinical loyalty to each individual patient,[1,2] or physicians must balance obligations to the interests and wishes of patients with those regarding the health care system in which they practice.[3–7] According to the first ideal, physicians should promote the well-being of every patient regardless of costs. According to the second ideal, however, physicians need to recognise these shared resources and balance their duty to specific patients with that to at least some (potential) other patients. Concern has been expressed about the erosion of patient trust in physicians as a result of issues of payment and funding.[2]

Physicians are the gatekeepers to health care and healthcare expenditures. The financial consequences of their treatment decisions may be enormous.[8,9] Physicians are caught in policy and practice decisions that mirror both understandings of their ethical obligations. Dutch physicians have little personal financial incentives for prescribing treatments. In The Netherlands all patients have a compulsory insurance that provides for a standard package of essential healthcare. The package provides essential curative care tested against the criteria of demonstrable efficacy, cost-effectiveness and the need for collective financing (http://www.minvws.nl/en/themes/health-insurance-system/default.asp). However, insurance companies are not obliged to cover costs of very expensive new disease-modifying drugs, especially when coverage agreements are not yet available.

Little is known about how physicians themselves view their role and ethical obligations regarding expensive treatments and cost-control obligations and arrangements. In this qualitative study, we have explored this issue in the complex and value-laden area of physician attitudes toward the costs of new, expensive chemotherapy with limited benefit for patients with advanced cancer such as gemcitabine (Gemzar®), irinotecan (Campto®), and monoclonals such as cetuximab (Erbitux®) and trastuzumab (Herceptin®) (all active cancer treatments together will be called: disease-modifying treatments). The cost issue in advanced cancer treatment is urgent for at least three reasons: firstly, these new drugs are usually very expensive. For example, an eight weeks treatment (biweekly fluorouracil plus leucovorin in 48-h infusion with biweekly irinotecan with weekly cetuximab) for metastatic colorectal cancer costs 30.675 dollars in the US.[8,10–12] Secondly, financial agreements for the coverage of these new drugs by both public and private insurance schemes are not yet generally available; and thirdly, the use of disease-modifying treatments with palliative, rather than curative intent at the end of life is increasing.[13,14] In addition, the emotional and ethical considerations for 'last chance therapies' make this area an especially problematic one for physicians.[15] Our research question was "how do physicians in The Netherlands view their role regarding the cost of potentially beneficial disease-modifying treatments in advanced cancer?"

2. Materials and methods

2.1. Study design

The present study is part of a research project examining treatment decision-making processes concerning chemotherapy in advanced cancer at both the level of the individual patient and guideline development in The Netherlands. We used a qualitative design and performed semi-structured in-depth interviews with two groups of physicians:[16] one providing direct care to patients with advanced cancer; another group of physicians involved in the development of national oncology guidelines (who were also directly providing cancer care to patients). We were particularly interested in how participants viewed their role and responsibilities regarding recommendations to patients and the costs of expensive treatments in advanced cancer. All participants were assured that the interview data would be used anonymously and confidentially. The Medical Ethics Committee of the Academic Medical Center in Amsterdam granted a waiver.

2.2. Participants

All 36 physicians who were approached for an interview were informed that the interview concerned treatment decisions in advanced cancer. Attending physicians were selected via the medical oncology department of an academic medical centre (see Table 1). Physicians involved in guideline development were selected from three national oncology guideline committees at the CBO (Dutch Institute for Healthcare Improvement) and at the BOM (a national medical oncology committee: Committee for Evaluation of New Drugs in Oncology). We purposefully sampled for guideline developers who worked in academic as well as in non-academic hospitals because of the leading position of academic hospitals with regard to new treatments.

2.3. Interviews and data collection

The interviews were conducted in a confidential 1:1 setting leaded by a physician–interviewer (SdK). The topic list (see Table 2) used was adapted per respondent and included examples of individual patients or specific guideline texts on the basis of which questions about decision-making were asked. The interviewer introduced the cost subject (which

Table 1 – Characteristics of physician respondents

Respondents	Coded as
Attending physicians	
Oncologists (medical oncologists, oncology surgeons, radiotherapists)	Respondent 1–11
General physicians	Respondent 12–19
Guideline developers	
CBO (guideline of treatment of breast, lung and oesophagus carcinoma)	Respondent 20–31
BOM	Respondent 32–36

constituted, as a whole, about 25% of the total interview) by stating that health-care costs are increasing, followed by open questions, such as 'Can you tell me how you think these high costs should be dealt with?', 'What should the decision-making process look like?', and 'How do you feel about talking about costs with your patient?'

2.4. *Coding and analysis*

All interviews were audiotaped and transcribed. Analysis and data collection were performed simultaneously as is usual in qualitative research. For the initial analysis, SdK and DW conducted multiple readings of the interviews. MAXqda® software was used for open coding of relevant parts of the interviews and then categorising these open codes by constantly comparing the codes in the different interviews.[17] Examples of codes were 'avoiding waste', 'comparison with other expenses (of a fighter jet)' under category 'distribution'; and the codes 'physician' and 'patient' under category 'responsibility'. SG, PD, NK and DR reviewed the provisional analyses; disagreements were discussed and used to sharpen the analysis process.

3. Results

3.1. *Is the cost of expensive chemotherapies with palliative rather than curative intent a problem for physicians in the Netherlands?*

The physicians we interviewed said that for them cost was never an issue when prescribing the best-perceived treatment. However, they also said that for colleagues in other hospitals cost sometimes did pose a problem in the sense that they were forced to prescribe sub optimally.

> 'Until now we have been in the reasonably luxurious position of being able to prescribe what we think is best. Fortunately we don't have to give people inferior treatments because of cost considerations. Apparently that is not the case in all hospitals.' (Respondent 31, oesophagus carcinoma guideline, about his own clinical practice)

This comment refers to recent attention to regional inequalities in treatments in the Dutch media after the publication of a survey about the use of certain medical treatments in breast cancer.[18] One respondent said that the problem of inequality in treatment access is a very delicate matter because of the fear of potentially negative publicity which, in

Table 2 – Interview topics

Topics	
General	
Guideline developers	• Can you give examples of ethical discussions during the guideline developing process/evaluation of a drug? • In the … guideline text was written: 'it can be considered to use… as a therapy' How did you come up with this recommendation? Why did you decide so?
Attending physicians	• What determines a good treatment (decisions)? Can you give an example? • I remember a case from my observation in which… happened. How did this develop? What were your considerations?
Cost considerations	• Can you tell me how you think these high costs should be dealt with? • What should the decision-making process look like? • Do you consider costs in setting protocols? Why and if so, how? • Does scarcity affect your acting/treatment? In which way? Can you give an example? • How do you feel about talking about costs with your patient? • To what extent will you inform the patient about cost considerations? • Do you have any clue about what a 'gained month of life' might cost? What about 15,000€? • How does oncology relate to other disciplines? Is the problem of expensive treatments with modest/small benefits specific for oncology? • Why do many doctors don't like to speak about costs? What can they do?
Guideline developers	• Were cost considerations involved in developing the guideline and how? • Do you think cost-effectiveness needs to involved? • There are people who believe that the judgments of the BOM become more trustworthy if costs are involved. What do you think?
Probing questions	• Can you tell a bit more about that issue? Why? How? What do you believe is important?

his opinion, might be a reason why some physicians said that colleagues were having problems and they themselves did not (respondent 35).

Although respondents said that the scarcity problem had not yet affected them, they said they expected problems in the future. Factors such as the ageing of the population, the development of increasingly expensive medicines, public expectations and cancer's transformation to a chronic disease for many were considered relevant developments. Physicians said they needed to think about the scarcity problem because *'If we, as professionals, don't regulate things amongst ourselves, they will be forced on us by politicians'* (respondent 32, BOM). This physician pointed to the importance of the use of physicians' substantial medical knowledge in the decision-making about cost.

3.2. *At what level of decision-making should the cost of expensive drugs in disease-modifying treatments for persons with advanced cancer be considered?*

Respondents' comments could be categorised into three levels of cost consideration: individual patient care, hospital policies and national guideline development.

3.2.1. *Individual patient care*

Physicians felt that cost considerations do not belong in the consultation room. They referred to the Hippocratic Oath saying it is always their duty to do everything possible in the patient's best interest.

> 'I will always refuse to judge how much one gained year of life might cost. I think it is an obscene question to a physician because it is our duty to help a patient. It is not our duty to say that a certain treatment would be very good for the patient but is a bit too expensive. In that case you will no longer be able to do your job with the conviction that you are doing the best you can for your patient.' (Respondent 33, BOM)

Some physicians indicated they had problems with expensive, marginally effective drugs.

> 'If there is a possibility for treatment, patients often want it. That is difficult with a drug that is very expensive and hardly works. So you always have to wonder whether the things that are possible are also obligatory.' (Respondent 19, general practitioner)

The 'rule of rescue' was another argument mentioned by one respondent: *'If someone has fallen into a well and calls for help, you will try to save him, no matter what the cost'* (respondent 35, BOM). He clarified that as long as there is no societal agreement about cost restrictions, it will be virtually impossible for a physician to refuse a patient an expensive treatment that he needs.

Some respondents felt that all possible treatments should be discussed with the patient even if they were not reimbursed, while others felt that expensive treatments should not be discussed if they could have important financial consequences for the patient.

> 'If a treatment is expensive and will not be reimbursed you should not inform a patient about this possibility. The treatment could improve the quality of life of the patient, but the rest of the family might no longer have anything to eat.' (Respondent 1, medical oncologist)

3.2.2. *Hospital policies*

Hospital policies regarding expensive treatments are the result of discussions among physicians and physicians with their hospital administrators, about the proportion of the total budget which goes to each department. Respondents gave examples of agreements among colleagues to not prescribe certain expensive marginally effective treatments.

> 'Topetecan is registered for the treatment of ovarian cancer after other therapies have failed. It is a toxic and also an expensive drug. We do not give this treatment in our hospital because we think that the costs and toxicity really do not outweigh the benefits – I mean, if the treatment would cost only 1.5 euro, I would think about it. So this is an example in which costs are absolutely considered.' (Respondent 2, medical oncologist)

> 'Through hospital budgets you are forced to work within certain margins. And of course you can choose between 5-FU or Gemcitabine in combination with radiation.[g] Maybe it has been an unconscious process, because 5-FU is a lot cheaper than Gemcitabine and in this combination is almost as effective, which made us decide to take 5-FU as the chemotherapeutic in our study design. Evidence that you need the most expensive treatment is often not that strong. Although I can imagine that this is harder for medical oncologists whose budgets are spent entirely on chemotherapeutics. For example, if they have one expensive new medicine their budget will already be spent by April...' (Respondent 9, radiotherapist)

None of the physicians indicated having financial restrictions imposed by the hospital administration. In one example toxicity was mentioned and in another example, the fact that the most expensive drug was almost as effective as a cheaper drug was mentioned as reason to not use it. The following quote refers to the interaction between physician and hospital management, which also illustrates that the hospital management did not restrict the physicians in their expenditures.

> 'Our director told us that as oncology is the spearhead of our hospital, we more or less have a carte blanche. He said that the costs spent by the department of oncology are his responsibility. Because of this I feel responsible and want agreements with my colleagues about what we offer patients and what we won't offer them.' (Respondent 36, medical oncologist)

[g] This example of a research design may not be a realistic issue in clinical practice, but illustrates that the motivation for using a very expensive treatment is not always that convincing and leaves room for other considerations like cost-effectiveness.

3.2.3. *National guideline development*

CBO and BOM are national practice guideline development bodies which have different approaches to cost benefit and cost-effectiveness in their policy development. CBO sometimes considers the cost issue, whereas BOM explicitly disregards cost as irrelevant to their decision regarding standard of care.

> 'In the section 'remaining considerations' we want the working group to not just look for effectiveness but to also weigh side effects, costs, and involve the health-care system in the Netherlands in the decision-making process. As a guideline committee you can prescribe something, but if it is not practicable at all, there's nothing more to be said.' (Respondent 23, breast carcinoma guideline CBO)

> 'We want to take our responsibility about what we feel to be reasonable results from a therapy. But we have never refused a treatment that met our criteria because we thought it was too expensive. We have decided that it is not up to us to judge about the value of a certain treatment in terms of costs.' (Respondent 36, BOM)

The views about the goals of a good guideline turned out to differ substantially among guideline developers. Some guideline developers who did not consider cost as a decisive issue felt that only the best possible treatment should be included in a guideline.

> Respondent (R): 'Trastuzumab is terrifically mild stuff.'
> Interviewer (I): 'But very expensive.'
> R: 'In the guideline we'll say that every HER2-positive metastatic breast cancer patient ought to get Trazucimab somewhere in the disease course. That's it.'
> I: 'No matter what the health-care budget? Is that a consciously made decision?'
> R: 'Yes, it is wonderful stuff and if it works, and you can find that out quickly, it works for a longer period of time. We indeed try to break stand up for this mild treatment. No one in our group questions this.'
> I: 'No one asks whether this recommendation is realistic in terms of the possibility to apply it in practice?'
> R: 'Whether it is affordable? That is not our problem. The issue is that if something turns out to be unaffordable in health care – and if this is the case in the future, I can live with it – physicians are not the ones to decide about these issues. Politicians are the ones who need to decide about health-care expenditures.' (Respondent 26, breast carcinoma guideline CBO)

Other guideline developers, however, felt that a guideline should be realistic and applicable in practice and therefore affordable.

> 'In the BOM committee people quickly say that costs are not an issue. However, if drugs are becoming very expensive I think that, as a committee, you are no longer credible if you hold on to this principle.' (Respondent 35, BOM)

3.3. *Additional findings*

We want to report two additional results. First, at least some physicians assume that patients want a treatment regardless of cost. Second, physicians did not want to give an estimate about cost per treatment because they said that others should decide about this kind of issues.

4. Discussion

This study offers insights into how physicians viewed their role in considering costs of expensive oncology treatments with limited benefit for patients with advanced cancer in The Netherlands. Physicians are active at three levels of cost-containment: individual patient care, hospital policies and national guideline development. They do not want to consider costs when they are face-to-face with individual patients. However, as soon as there is a little more distance between physician and patient, e.g. at the hospital policies level, costs often are understood to be important considerations. At a national guideline level, opinions differ regarding the role of cost-effectiveness and cost benefit analysis in determining standards of care. These findings mirror those from the few other studies in this area.[19–21] Generally, physicians do not discuss the cost of expensive treatments with their patients because of their sense of ethical obligation and their reluctance to judge about the value and the quality of life of their patients.[22,23] However, the situation in the US is different from most countries in Europe because of the very different health care system in which even patients with good health insurance have substantial co-payments. Schrag and Hanger found that in the US there is heterogeneity in medical oncologists' attitudes towards discussing chemotherapy treatment costs with patients.[24] They found that 42% did so always or most of the time, 33% did sometimes and only 26% rarely or never did.

The strength of this study is that physicians' views regarding cost are assessed in the context of questions about treatment decision-making in general in advanced cancer. By doing so we explored the subject in a way that was consistent with the physicians' day-to-day experiences and judgments. We were aware of the political sensitivity of the topic of financial considerations with patients facing life-threatening disease. We ensured a confidential face-to-face interview setting to facilitate honest answers. A potential disadvantage of interviewing one person at a time could be difficulty in recalling problems. It would be interesting to repeat this study in, for example, focus groups or with observations of the actual practice. Another limitation is that exploration of cost considerations of expensive treatments is dependent on the local context of public or private funding and delivery of care as well as societal expectations. As we showed already findings may be different in other health care systems, and also across other specialties and practice settings.

Physicians feel that distinctions should be made among the different levels of cost consideration. We believe that these distinctions are morally relevant. In a Dutch vignette study about the opinions of physicians on cost issues, the authors reported a discrepancy between the physicians' idea

that rationing should be done by politicians, whereas the same physicians were not always willing to work within the imposed limitations.[25] We believe that this 'discrepancy' is not strange and can be explained by the different roles physicians play at different levels of cost considerations. Playing different roles fits in with the concept of being a good doctor. However, we believe that physicians need conceptual tools to assist them in identifying their ethical obligations in their different roles and decision-making processes. Doctors should not be required to do bedside rationing. Because of their primary obligation, they should recommend what they believe to be in the patients' best interest. Even if the preferable drug is not subsidised, they should discuss it with the patient and they should be patients' advocates towards hospital management and insurance companies. The issue of potential restrictions in using expensive drugs with limited benefits should be explicit at the level of hospital policies and national practice guidelines. At these levels physicians are able to balance patients' interest with the welfare of the health care system in which they practice. In considering costs, 'Dunning's funnel'[26] might be a useful tool, except for the last criterion. The funnel, which was originally meant for the government to assess the coverage of treatments, works with four criteria: necessity, efficacy, cost-effectiveness and the extent to which patients could pay for treatments themselves. The risk of considering costs at a hospital policies level is that money issues may generate inequalities in treatments between different hospitals. With regard to equal treatment access we believe that it is advisable to consider costs on a national guideline developing level rather than on a hospital policies level, as is already the case in the United Kingdom.[27] It is, however, questionable whether we can still talk about a *medical* practice guideline if allocation decisions become part of national guideline development.[28,29] However, this is where physicians may bring in their medical knowledge as one of the parties involved in national guideline development.

In general, we were surprised at the little explicit reflection of the respondents on the goals of medicine, and, more specifically, on the goals of disease-modifying cancer treatment.[30,31] The tendency of patients, and more strongly, families to believe in expensive treatments rather than the acceptance of the limits of medicine has unfortunately not been fully explored by us. Because of the fundamental tension between the physician's obligation to act in the best interest of the individual patient, the vulnerability of having a life-threatening illness and the inevitability of sharing resources in modern health care, cost considerations will always be problematic for physicians. This study demonstrates that physicians are confronted with cost considerations at the three distinguished levels of cost considerations. The roles physicians play at different levels, especially at the levels of hospital policies and national practice guidelines, should further be developed and explicated.

Conflict of interest statement

None declared.

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