Abstract
Rising costs of cancer care and the growing burden of cancer in a world of finite resources seem to make rationing in oncology inevitable. Information is currently lacking about oncologists’ strategies in responding to resource constraints and the prevalence of withholding costly treatments. An online survey was offered via e-mail to physician members of the German Society of Hematology and Oncology. Those actively practicing were asked to complete an online questionnaire asking how limited resources were currently affecting their clinical practice. Two-thirds of 345 participating oncologists reported withholding costly treatments in at least some instances. Regarding their rationale, 70% stated that evidence for costly intervention was not convincing enough, and 59% said that they rationed approved treatments because of an unfavorable cost/benefit calculation. Only 29% reported being explicit about their rationing decision if the patient did not know or inquire about the respective intervention. Withholding expensive procedures from individual patients was widespread among the respondents. Oncologists withheld treatments not only if they perceived the scientific evidence to be questionable but also if they perceived reimbursement prospects or the cost/benefit ratio to be unfavorable, a behavior that could be called rationing. Currently this mostly refers to costly procedures with limited additional benefits. Although this result may be interpreted as indicating that oncologists assume responsibility for spending the resources in a justified way, more transparency and an open discussion on cost-effectiveness and the just allocation of costly treatments is needed. (JNCCN 2013;11:658–665)

Oncology, with its numerous expensive therapies and increasing number of patients, contributes considerably to increasing health care expenditures. The benefit of these new cancer treatments varies from highly relevant improvements in outcome to effects of which the relevance for clinical practice has been a subject of controversy within and outside oncology. In fact, the field of oncology has been criticized for its spiraling costs that exceed the financial scope even of health care systems in high-income countries. The oncology community and society in general are, therefore, called on to confront the questions of what should count as a benefit in cancer care and how to set limits in a fair and justifiable way. Setting limits also means to withhold beneficial care (ie, ration treatments). If rationing is inevitable, a broad consensus exists that an explicit, rule-based rationing process is preferable to implicit, case-based rationing at the bedside.

In Germany, tight budgets have been imposed on the inpatient and outpatient sectors. In short, inpatients of both statutory and private health insurances are reimbursed per case according to a system of diagnosis-related groups, with extra payments for some expensive procedures or drugs. Furthermore, the total budget of a hospital is limited and must be negotiated with the insurers. Outpatients in oncology are treated either in private practice or in outpatient clinics. In both cases, reimbursements are mainly per procedure. Reimbursements of costs for medicaments are compared...
with benchmarks according to the respective medical specialty. Moreover, in case of “off-label” use (a frequent situation with new cancer drugs), reimbursement either must be negotiated with third-party payers in advance, or remuneration may be endangered and redemption may be claimed from the prescribing physician. Explicit measures of rationing have only been adopted for a limited set of procedures and medications, none of them of high relevance for the therapy of life-threatening diseases (e.g., limitations of coverage in dentistry and for over-the-counter drugs).

Empiric studies in the fields of cardiology and intensive care report actual bedside rationing in Germany. However, to the authors’ knowledge, no data exist from quantitative studies, and only few data are available from qualitative studies that analyze bedside rationing in oncology. Moreover, review of the international literature indicates that, although a few studies analyzed the views and attitudes of oncologists about costs and cost/benefit, data are scarce on the prevalence of bedside rationing, with no special focus on oncology.

This article presents data obtained from a survey of German Society of Hematology and Oncology (DGHO) members, which had the goal of acquiring information about the prevalence of withholding expensive treatments, typical examples, and rationales behind these decisions.

**Methods**

**Questionnaire**

The authors designed and pretested a 36-item, self-administered, online questionnaire to obtain data on 1) the prevalence of different rationing strategies (e.g., premature discharge, postponing or withholding of treatments); 2) the impact of specific reasons for decisions against costly treatments (e.g., level of scientific evidence, market approval, cost/benefit ratio); 3) information about perceived effects of limited resources in general; 4) self-reported knowledge of physicians about the cost-effectiveness of their decisions; 5) opinions about potential approaches to resource restraints; and 6) personal information (e.g., demographics, practice setting, professional status). Data on items 1, 2, and 6 are reported herein.

The prevalence of decisions to withhold expensive treatments was surveyed by registering the frequency of these decisions using a 4-step Likert scale (at least once a week; at least once a month; less than once a month; never). To avoid different interpretations of “rationing,” the authors did not use this term, but rather the definition “withholding a medically beneficial intervention for cost reasons.” Questions in this section were asked twice: one set was tailored to inpatient care and one to outpatient care. Participants caring for both types of patients were asked to answer both sets of questions. Participants were also asked to provide examples in a free text section if they approved having withheld procedures. The authors evaluated the validity of the examples in the free text section using a score from 0 to 4 (0 = not related to the question; 1 = response unclear or not a costly procedure; 2 = no clear indication for the procedure or indication unclear, and therefore no example of rationing; 3 = example comprehensible but imprecise; and 4 = well-defined and sound example for the specific question). Plausible examples for the respective rationing scenarios (score 3 or 4) are listed for every question.

The authors developed the questionnaire based on a survey about rationing in cardiology and critical care medicine. They adopted 11 items, constructed additional items for section 2 using specific rationing scenarios, and tailored sections 1 and 2 to the inpatient and outpatient setting, because reimbursement differs between these settings.

The questionnaire was pretested among a sample of 10 physicians. This University of Erlangen Institutional Review Board designated the study exempt from ethics committee review.

**Data Collection**

In February 2011, a personalized contact e-mail was sent to all members with a valid e-mail address containing an explanation of the survey and an Internet link to the electronic questionnaire. Only members of the society who were actively practicing as physicians were asked to reply (not scientists or retired doctors), but were not preselected, because this information was not available in the member database in 2011 (in the 2012 database the percentage of active physician members was 82%). The link was protected so that each respondent could complete the survey only once. Alternatively, members could send the printed version of the questionnaire via mail.
Technical realization was performed by a commercial provider (Linequest, Unterhaching, Germany).

**Statistical Analysis**
Replies were separated from the personal data for complete anonymization. Descriptive statistical analysis was performed on items of sections 3 through 6. Descriptive analysis in sections 1 and 2 were first calculated separately for participants answering the inpatient or outpatient section. This article presents the separate results only for one item (question 9) in which answers differed significantly between the inpatient and outpatient settings, and for 2 items that are only relevant for the inpatient setting. The inpatient and outpatient data sets were merged to calculate the overall prevalence of rationing in the scenarios described in the other questions. If participants had answered both sets of items, the response from the dominant field of activity was counted.

Statistical significance of differences in the frequency distributions of replies between different cohorts was compared using the $\chi^2$ test for trend after exclusion of respondents without a reply to a particular question. Statistical analyses were performed with GraphPad Prism (GraphPad, La Jolla, CA, USA).

**Results**

**Respondents**
Respondents (n=345; 17% of DGHO members with a valid e-mail address) were predominantly male (83%) and board certified in hematology and oncology (72%). Many respondents reported having cared for inpatients and outpatients in the previous 6 months. Table 1 summarizes the respondents’ characteristics and practice settings.

**Prevalence, Rationing Strategies, and Rationales for Withholding Costly Treatments**
Of the oncologists caring for inpatients, 68% reported having withheld medically beneficial care and waited to see if the patient would get along without it, compared with 51% of oncologists in outpatient care (Table 2). Furthermore, 63% of oncologists in inpatient care reported having discharged patients to outpatient care prematurely. Although two-thirds of respondents approved having withheld beneficial care, most of them did so less than monthly (Table 2 lists the prevalence and frequency of different scenarios).

The frequency of withholding treatments and the rationale behind the respective decisions was explored through depicting 4 additional scenarios; 70% of oncologists report that costs play a decisive role in deciding against interventions that are not based on strong evidence. Moreover, 69% reported that they also withheld treatments that were supported by evidence and international guidelines if the intervention had not yet been approved for the situation in question in Germany, a scenario in which the physician must apply for reimbursement and thus invest extra paperwork and/or may encounter reimbursement problems. More than half (59%) of the oncologists said that they withheld approved treatments because they regarded the therapeutic advantage too small compared with the price difference, and 22% reported that they did so merely because the intervention was expensive. The frequency of withholding treatments in all of these scenarios did not differ between the inpatient and outpatient settings.
Most oncologists (73%) said that they negotiated reimbursement with third-party payers in situations in which they felt pressured to withhold costly treatments, and 54% reported that dealing with questions of costs consumed a considerable part of their working time. Oncologists were more likely to communicate their decisions regarding withholding costly treatments if patients specifically inquired about the respective intervention (48%). Only 29% of oncologists reported being explicit about their decision if the patient did not know nor inquire about the intervention.

**Examples for Withheld Costly Interventions**

Respondents who approved withholding interventions gave free-text examples of the respective interventions in 30% to 50% of the responses (Table 3). The authors assessed the validity of those free-text responses using a scoring system from 0 to 4, as described earlier. A high percentage (86%-91%) of free-text examples for questions 4 through 7 were valid (score of 3 or 4), whereas only a minority (38%) of examples for question 8 supported the validity of the respondents’ answers.

In inpatient care, respondents reported more frequently delaying costly supportive therapy (eg, antifungal drugs, granulocyte colony-stimulating factor, immunoglobulins) to see if the patient got along without it, whereas in the outpatient setting, antibodies were the most frequently reported examples of rationing by delay. In all other scenarios, no marked difference was seen between inpatient and outpatient care.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>At Least Weekly</th>
<th>At Least Monthly</th>
<th>Less Than Monthly</th>
<th>Never</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1: I refrained from using an indicated but costly procedure in the first place and waited to see if the patient could get along without it.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a: Inpatient care</td>
<td>3</td>
<td>21</td>
<td>44</td>
<td>29</td>
<td>3</td>
</tr>
<tr>
<td>b: Outpatient care</td>
<td>3</td>
<td>16</td>
<td>32</td>
<td>47</td>
<td>2</td>
</tr>
<tr>
<td>Q2: I discharged patients to outpatient care, although further inpatient care had been medically sensible.</td>
<td>11</td>
<td>20</td>
<td>32</td>
<td>34</td>
<td>2</td>
</tr>
<tr>
<td>Q3: I have referred patients to other hospitals, because expensive procedures were necessary.</td>
<td>0</td>
<td>5</td>
<td>21</td>
<td>73</td>
<td>2</td>
</tr>
<tr>
<td>Q4: I have referred patients to other wards within the hospital, because expensive procedures were necessary.</td>
<td>1</td>
<td>7</td>
<td>15</td>
<td>75</td>
<td>2</td>
</tr>
<tr>
<td>Q5: Scenario: Published data on a therapeutic procedure have convinced you only in part. If it were cheap, you would try it for your patient. I abstained from this procedure due to cost reasons.</td>
<td>4</td>
<td>30</td>
<td>36</td>
<td>24</td>
<td>7</td>
</tr>
<tr>
<td>Q6: I abstained from expensive therapeutic procedures, although they were superior to cheaper alternatives according to published data and/or national or international guidelines, because these procedures were not licensed for the indication in question in Germany.</td>
<td>6</td>
<td>26</td>
<td>37</td>
<td>28</td>
<td>3</td>
</tr>
<tr>
<td>Q7: I abstained from therapeutic procedures due to cost reasons, although they were licensed and demonstrably superior to cheaper alternatives, because the therapeutic advantage was too small compared to the price difference.</td>
<td>5</td>
<td>22</td>
<td>32</td>
<td>37</td>
<td>4</td>
</tr>
<tr>
<td>Q8: I abstained from a procedure, although it is considerably superior according to published data and is also licensed, due to mere cost reasons.</td>
<td>1</td>
<td>4</td>
<td>17</td>
<td>76</td>
<td>3</td>
</tr>
</tbody>
</table>

All numbers are a percentage of replies. The total number of replies is 337, except for Q1a, Q3, and Q4 referring to inpatient care (192 replies), and Q1b referring to outpatient care (257 replies).

Abbreviation: NA, no answer to this question.
The most frequently given examples of treatments withheld on the grounds of unconvincing evidence and based on an unfavorable cost/benefit analysis were erlotinib, bevacizumab, and other antibodies (Table 3, Q5 and Q7). Typical examples for withholding treatments because of pending approval for the respective indication in Germany were lenalidomide, rituximab, and other expensive drugs, such as cabazitaxel and bortezomib.

**Attitudes to and Determinants of Rationing**

Slightly more than half (54%) of the oncologists endorsed the view that it is justifiable to avoid very expensive medications and resort to somewhat less-effective alternatives under conditions of scarcity. Oncologists who supported this view were more likely to report rationing in question 1 ($P<.01$, $\chi^2$ test for trend), question 5 ($P<.01$), and question 7 ($P<.001$), but not question 6.

In bivariate analyses, regional differences in cost coverage, hospital owner being for-profit or non-profit, and dissatisfaction because of cost pressure were not associated with the frequency of reported rationing.

**Discussion**

Four key findings resulted from this survey. First, withholding costly treatments from individual patients was reported by two-thirds of the responding oncologists at least in some instances. Second, although most oncologists tried to negotiate coverage for expensive beneficial care with third-party payers, reimbursement problems was an important reason to withhold beneficial interventions not yet approved in Germany. Third, most respondents reported withholding treatments based on their individual cost/benefit calculations, which constitutes a behavior that the authors call *bedside rationing*. Fourth, these decisions are largely made without informing the patient. The following sections focus on the interpretation of data against the framework for health care allocation in Germany, and the current debate about adequate ethical and empiric foundations of rationing decisions.

**Rationales Behind Decisions to Withhold Costly Treatments**

The prospects for reimbursement play an important role in decisions against costly treatments. More
than two-thirds of respondents abstained from interventions of proven benefit if these had not yet been approved for the respective use in Germany (ie, off-label use). In these situations, reimbursement must be negotiated with the third-party payer. Two-thirds of oncologists reported negotiating reimbursement, and many also said that these negotiations consumed a considerable amount of their time. Berry et al showed that oncologists may go to great lengths to access cancer drugs they feel would benefit their patients. Still, these negotiations may not always be successful or are too time-consuming for an individual patient to receive the respective treatment.

More than two-thirds of respondents withheld treatments because of cost reasons if they considered the available evidence not sufficiently convincing. The marginally superior effects of treatments mentioned in many of the respondents’ free-text replies are also the subject of current debate about the spiraling costs of cancer care, with erlotinib in pancreatic cancer and bevacizumab the most frequently mentioned examples. Arguably, approval of these substances is based on trials that provide statistically significant results, but whether these translate into meaningful clinical benefits for the respective patients can be questioned.

The perceived cost-effectiveness of interventions was important in oncologists’ decisions even if the respective substances had already been approved. Half of the respondents withheld approved beneficial care because they determined the therapeutic advantage to be too small compared with the additional costs. This result is surprising, because in most situations oncologists do not encounter negative financial effects of single prescriptions if the treatment has been approved in Germany.

**When Does Withholding Costly Treatment in Clinical Practice Meet the Definition of “Rationing”**

Rationing is commonly defined as “withholding beneficial care for cost reasons.” The results of this survey show that different reasons may factor into the decision not to offer a costly treatment, such as extra efforts required to obtain/uncertainty about reimbursement, weak evidence, or unfavorable cost/benefit ratio. From an ethical perspective, these reasons for withholding expensive treatment differ in the way and degree they constitute rationing. Although the reimbursement argument does not question the benefit of the intervention, the argument of weak evidence and unfavorable cost/benefit do. If beneficial care is withheld because of pending approval in Germany, this does not constitute bedside rationing, but rather rationing on the state level if approval is delayed. These data show that oncologist feel compelled to make up for procedural delays but may be overchallenged.

Insufficient evidence of a clinical benefit would count as a sound reason against offering an intervention regardless of whether it was cheap or expensive. However, respondents would have offered the intervention if it were inexpensive (question 5). Hence, they expected some clinical benefit that would justify offering the treatment if it were inexpensive. The authors would therefore argue that these interventions are perceived as beneficial, even though the extra benefit is marginal, and are withheld because of cost considerations. All the more, this applies for the argument of an unfavorable cost/benefit calculation of approved medications. Certainly, good reasons exist to question the value of the procedures described in the free-text examples, and thus to question approval of those treatments. Still, as long as those marginally beneficial treatments have been deemed to provide enough of a benefit to pass approval and obtain coverage by insurers, withholding it for cost reasons constitutes bedside rationing.

Nonetheless, the major ethical concern about bedside rationing is that similar patients are treated differently and that they are deprived of beneficial care. Although some surveyed oncologists deviated from the path described as optimal in clinical guidelines, they mostly rationed care with a marginal benefit. Hence, rationing did not pertain to core procedures that are essential for thorough patient care in oncology.

Still, the reporting of rationing costly treatments stands in some contrast to the long row of political statements that claim no rationing occurs with regard to health care in Germany. Moreover, the courts have repeatedly emphasized that rationing should not occur, at least not in life-threatening diseases and when costs are the only limiting factor, and not in tangibles such as donor organs or intensive care beds. However, although Germany is a wealthy country with a comparatively well-funded universal health care system, budgets have been imposed to control the rising health care costs. Against this
background, the findings of this survey indicate that German oncologists make decisions at the bedside that reflect the current climate of scarce resources and not just the health care needs of patients with cancer.

This survey has the shortcoming of a low response rate of 17%. Because retired physicians and nonphysicians were included in the e-mail list, but were not invited to respond and accounted for 18% of the sample, the calculated response rate among the invited members is 21%. Still, this means that the viewpoints of the participants may not necessarily be representative of all oncologists. However, the high percentage of oncologists with a board certificate, the plausibility of free-text examples, and the good accordance of these data with those of Strech et al. from the field of cardiology and intensive care medicine increase the credibility of these results.

Conclusions

German oncologists reported that they withheld expensive beneficial treatments if reimbursement was uncertain. They rationed interventions if the benefit was not supported by good evidence or the marginal benefit was not worth the costs in their perception. Thereby, they enact some of the principles that have been suggested for controlling costs of cancer care. However, as long as those rationing decisions are neither guided by a consensus on what should count as dispensable benefit nor shared with the patient, the great likelihood exists that patients in similar clinical situations will receive different care solely because of the physicians they encounter in the course of their illness. More research is needed to obtain insights into the types of decisions against costly treatment and their impact on patient outcomes. These first data hopefully support an open discussion about the limits of affordable cancer care.

Acknowledgments

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