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Value judgements that matter to patients remain implicit in oncology guidelines: an observational study

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ABSTRACT

Background: Clinical practice guidelines are often evidence-based. However, it is inevitable that there are value judgements in the practical recommendations contained in the guidelines. In order to see if patients are ultimately being supplied with sufficient information to help them make treatment decision, we determined 1) which value judgements influence the process of developing guidelines for palliative chemotherapy, and 2) whether these value judgements were made explicit in the final guideline report.

Methods: We studied the development process of six Dutch oncology guidelines in which palliative chemotherapy plays a substantial role. We observed the guideline development groups (GDGs), conducted semi-structured interviews with individual GDG members (including the chairs), and analysed the minutes of GDG meetings and subsequent versions of the guidelines. A value judgement was defined as a statement about the value of a patient outcome with regard to palliative chemotherapy.

Results: We identified the following value judgements in the process of guideline development: 1) consensus on what should be considered as valuable minimum patient outcomes, 2) preference for tailored treatment in situations where there is no evidence of treatment effect, 3) preference for 'doing something' even when there is sufficient evidence of no effect, and 4) the patient outcome of 'prolonging life'. These value judgements, however, were not reported in the final guideline.

Conclusion: At least the last two value judgements mentioned are relevant for patients with incurable metastatic cancer in making decisions whether to undergo chemotherapy and what kind. Value judgements should be made explicit in guidelines, so that clinicians can transparently discuss treatment options with individual patients.

KEYWORDS

Chemotherapy, ethics, guidelines, qualitative research

INTRODUCTION

Based on the best available research evidence, clinical practice guidelines aim to standardise and improve the quality of health care by rendering medical action more 'objective'.[1,2] Clinicians use these guidelines in making decisions on the best treatment for their patients. In the Netherlands, guidelines are developed according to the principles of evidence-based medicine, often with methodological support from the Dutch Institute for Healthcare Improvement (CBO).[3-5]

A guideline development process includes the following steps: 1) formulation of clinical questions based on an analysis of the most relevant problems in practice, 2) systematic collection, critical appraisal and grading of evidence, and 3) translation of evidence into practical recommendations. This third step includes considering factors other than evidence, such as safety issues, patient perspective, organisational barriers and cost.[6,7]

When formulating a recommendation, developers determine whether a certain treatment will be recommended as a standard of care. It is inevitable that value judgements are used in this process. For example, recommendations need value judgements about the value of life when health is impaired, the meaningfulness of aggressive treatment, and the acceptability of side effects and risks.[8] Although the same body of evidence is used both nationally and internationally, these value judgements account for many variations between clinical practice guidelines.[9,10]

It is particularly important to take value judgements into consideration when developing guidelines for the treatment of metastatic cancer. Because no curative options are available, metastatic cancer patients are facing death. For these patients, guidelines may recommend offering chemotherapy as an option for prolonging life or reducing symptoms. Chemotherapy, however, can also cause serious side effects and may burden the patient with visits to the hospital. According to principles of shared decision-making, the patient and his or her physician need to weigh up the pros and cons of different treatment options, including the possibility of 'watchful waiting'.[11] One patient's value judgements may differ from those of another patient, which may differ from those of a physician, which may in turn differ from those of another physician. Nowadays, physicians tend to be less paternalistic and to share decision-making with their patients. Therefore, both physicians and patients should be aware of the value judgements in these cancer guidelines in making decisions on treatment.

It is unknown how value judgements are incorporated into guidelines for 'optimal care' for metastatic cancer patients. The purpose of our study was to answer the following questions: 1) Which value judgements were used in developing guidelines for palliative chemotherapy? and 2) Have these value judgements been made explicit in the final guideline report?

METHODS

Between January 2005 and January 2008, we conducted a longitudinal observational study of the development process of six national oncology guidelines in the Netherlands. We selected cancer guidelines for areas in which palliative chemotherapy plays a substantial role: lung cancer, oesophageal cancer, breast cancer, prostate cancer, 'cancer with pain,' and colorectal cancer.

Data collection

Different methods were used to collect data: 1) observing guideline development group (GDG) meetings as an auditor;[12] 2) in-depth, semi-structured interviews (of one hour in length) with the members of the GDGs;[13] and 3) text analysis of meeting minutes, draft and final guideline documents.

GDG meetings were observed at crucial stages in the guideline development process: at the start (scoping and defining clinical questions), halfway (formulation of recommendations), and the end (endorsement of the final guideline). In addition, meetings were observed when palliative chemotherapy was on the agenda. At the start of our study, one guideline (lung cancer) had already been completed and another guideline (oesophageal cancer) was nearly ready. For these guidelines we could not observe their GDG meetings (*table 1*). One guideline meeting concerned the update of a guideline (just one meeting). We observed three to five meetings for the other three guidelines. In total, 14 meetings were selected for observation.

All chairs of the GDGs were asked for an interview. Key members of all GDGs were identified and asked for an interview, also if they were involved in metastatic cancer care. In total we selected 20 professionals (including chairs) from different disciplines, including medical oncologists, a palliative care physician, a radiotherapist, a urologist, methodologists and also a patient representative (see also *table 1*). Two professionals, one chair and one radiotherapist, declined due to time constraints.

The results of text analysis were used as input for the GDG observations and interviews. If available, GDG observations were also used as input for interviews. Analysing the next versions of guideline documents allowed us to trace the changes that resulted from the GDG meetings we observed.

Observations and interviews were recorded on tape and transcribed. The interviews included open questions related to the specific guideline documents and relevant events during observations (*table 2*).

Table 1. *Guidelines selected and data sources used*

Guideline (time of start and time of publication of final report)	Documents analysed	Number of GDG observations	Number of interviews
Non-small cell lung cancer (2002 - Oct 2004)	Minutes, final guideline text	None	3 (Jan 2005)
Oesophageal cancer (2002 - Dec 2005)	Minutes, final guideline text	None	5 (Jan - Mar 2005)
Breast cancer (2002, revision 2004, update 2006)	Minutes, final guideline text	1 update (Mar 2006)	4 (Jan - Feb 2005)
Prostate cancer (Jan 2003 - Jul 2007)	Minutes, drafts and final guideline text	5 (Mar 2005 - Oct 2006)	3 (Jan - Feb 2007)
Cancer with pain (Sept 2005 - Sept 2007)	Minutes, drafts, and final guideline text	5 (Sept 2005 - May 2007)	2 (Dec 2006)
Colorectal cancer (Jan 2005 - Jan 2008)	Minutes, drafts, and final guideline text	3 (Sept 2006 - Apr 2007)	3 (Jan - Feb 2007)

Table 2. *Interview topics*

Subjects	Examples of questions
Ethical aspects	What do you consider to be an ethical aspect of guideline development? Do you agree with our definition of value judgements?
Process	How did you determine what should be the standard of care? Could you provide examples of statements about the value of a patient outcome in the GDG discussions? How did the different specialties work together in the GDG?
Specific	Why did you say ... during that meeting ...? Although it was discussed in the GDG meetings, why didn't you mention ... in the guideline document?
General	Do you believe recommendations for curative conditions should be distinguished from non-curative conditions? In what way?

Analysis

Based on the findings from other studies,[3,22] we defined a value judgement as a statement about the value of a patient outcome with regard to palliative chemotherapy. As an example, the aim of prolonging life with two months could be considered as a value judgement in recommending a treatment for patients with metastatic cancer. The research questions were guiding in the analysing process. MAXqda® software was used for open coding and identifyiwng themes in the transcripts of observations and interviews.[14] The codes were categorised by sorting the data by theme. Text analysis of draft and final guideline documents supported refining the categories. We compared categories of different value judgements with the guideline text[15] and examined the presence or absence of arguments supporting the value judgements. We excluded judgements on the availability of resources, cost and organisational issues.

RESULTS

Nine out of fourteen observed GDG meetings had palliative chemotherapy on the agenda, but the subject was discussed at only five meetings. During these meetings, most discussions about palliative chemotherapy dealt with patient quality of the individually evaluated studies related to the overall evidence. We seldom encountered explicit statements on the value of a certain patient outcome. *Table 3* illustrates how we identified a small number of value judgements while observing the prostate cancer GDG.

In the interviews, the 20 respondents did not spontaneously mention value judgements as being important to the guideline development process. Evidence-based medicine and guidelines were primarily associated with scientific research and empirical studies. Most of them also assumed that the strength of the recommendations is determined by the strength of the evidence. According to respondents, the GDG's expert opinion would only be needed if there was non-inclusive evidence or inconsistent findings.

The meeting minutes mentioned organisational issues but no value judgements. Drafts and final guideline texts included a few statements about the perceived value of evidence-based outcomes. However, no details were provided about the background of these statements. For example, no motivation or further specification was provided for the recommendation 'Benefits and burdens of docetaxel in metastatic hormone-refractory prostate carcinoma should be considered'. Based on observations and interviews, it appeared that GDG members were in doubt about the best moment to start docetaxel and about whether to offer this palliative chemotherapy to frail, elderly men.

Value judgements in developing guidelines for palliative chemotherapy

We identified four value judgements in the guideline development process that influenced final recommendations.

Consensus on what should be considered as minimum patient outcomes

If there is sufficient evidence available on the effectiveness of palliative chemotherapy, the GDGs often agreed on a 'valuable minimum' for deciding whether the treatment should be recommended. There seemed to be consensus about the minimum results on certain patient outcomes:

Table 3. *Examples of observational notes and implicit value judgements*

Observational notes	Value judgements
In the discussion on the value of docetaxel, one GDG member questioned whether docetaxel should become the standard treatment, because prolonging life by two months could be considered to be a very marginal outcome in patients who have had this disease for years.	Considering disease-specific patient outcomes is important.
Another GDG member replied that the studies were the first to show a significant increase in survival time. Obviously, the benefits of the treatment should be weighed against the burdens.	Prolonging life is important.
The treatment could be offered to younger patients who are in good condition, have an aggressive tumour, and want to be treated.	Tailored treatment is important.

I believe that palliative chemotherapy can only be considered a standard if the response rate is at least 30%. Some people would say 20%, but, obviously, if the response rate is lower you cannot recommend this as standard therapy. (respondent Breast 4)

Some respondents referred to the PASKWIL criteria developed by the Medicines Evaluation Board in the Netherlands (*Beoordeling Oncologische Middelen* in Dutch) (*table 4*). For example, for the outcome 'survival' in metastatic disease, these criteria set a minimum of prolonging life by at least six weeks.
A valuable minimum patient outcome specified per disease (rather than a consensus on what should be considered as valuable minimum for all diseases) was rarely used. However, some respondents highlighted the specific disease context:
Patients with metastatic prostate cancer are often frail and elderly and have known for years that they have cancer. For them, a few extra months would not be as important as for patients with colorectal cancer who are younger and asymptomatic. (respondent Colorectal 1).

Table 4. *PASKWIL criteria for metastatic disease*

Criteria	**Fulfilled/satisfied (difference between standard or best supportive care)**
Palliative:	
• Response rate	>20%
• Time to treatment failure	>6 weeks
• Time to progression	>6 weeks
• Survival (median, after 1 year)	>6 weeks, and >20%
Side effects:	
• Lethal	<5%
• Acute, serious (admission)	<25%
• Chronic (restrictive)	<10%
Impact of treatment:	
• Clinics	<5 days
• Outpatient	<3 days
Quality of life:	
• Performance status (PS), WHO/Karnofski	>20% improvement
• Stabile PS, Time to progression to PS	>6 weeks
Level of evidence	One or more phase III study/ meta-analysis
Costs	No criterion

Preference for tailored treatment
In situations without evidence of treatment effect (which should be distinguished from 'evidence of no effect') or in the case of equal treatment options, GDGs preferred to tailor the treatment to the individual patient, weighing up the benefits and harms. For example, one member of the prostate cancer GDG proposed during an observed GDG meeting only offering palliative chemotherapy (docetaxel) to young patients who had an aggressive tumour and an explicit preference for treatment. Respondents in the interviews mentioned different criteria used in practice, such as a drop in haemoglobin or a rise in lactate dehydrogenase or prostate specific antigen (PSA) (respondents Prostate 2 and Prostate 3). However, these criteria were not mentioned in the guideline because of lack of evidence. Nevertheless, the strong conclusion in the prostate guideline (level 1, two randomised controlled trials (RCTs) with positive results) was translated into a weak recommendation ('...might be offered to patients', instead of: '... should be offered') because the GDG wanted to allow professional freedom in tailoring the treatment to the individual patient.
In the colorectal guideline, the GDG decided to describe different treatment options and leave the actual treatment decision to the physicians, for instance whether to use mono-chemotherapy or combination-chemotherapy, or choosing between oxaliplatin and irinotecan. One of the respondents explained how he tailored the therapy for certain patients (and groups of patients):
...you can make a 'tailored decision'. If the patient needs to be progression-free in six months, it would be better to give combination chemotherapy, and if the patient doesn't want to go bald you shouldn't give irinotecan. (respondent Colorectal 2) However, only options were provided in the guideline text. Considerations how to weigh these options were not mentioned.

Preference for 'doing something'
We found that physicians in the GDGs preferred to offer at least some kind of intervention to patients with metastatic cancer, even if there was sufficient evidence of no effect. For example, estramustine was a standard therapy for patients with metastatic, hormone-resistant prostate cancer (HRPC) before docetaxel became a standard therapy (in an earlier guideline that is not evaluated in this study).
At that time estramustine was the only drug available and therefore at least 'something' could be offered. (respondent Prostate 1)

Physicians also believed patients attached value to 'doing something'. One guideline developer told about patients' preferences with regard to the best moment in time to start docetaxel:
The patient wants to start as soon as possible because he finds it hard to do nothing. (respondent Prostate 2)

However, there was no evidence available that showed that an early start in patients with raised PSA but no other symptoms was better than a later start once other symptoms of metastasis had occurred. The recommendations of the final guideline just mentioned that: 1) Patients with HRPC can be offered docetaxel, and 2) in asymptomatic HRPC patients who do not prefer

docetaxel, a symptomatic treatment is recommended. No background information was given to support decision making.
We found one clear exception to the tendency to value 'something' over 'nothing'. The oesophageal carcinoma guideline (2005) clearly stated in the conclusion that:
(...), chemotherapy cannot be considered to be a standard of care. It is preferable to use chemotherapy exclusively in studies.

Although chemotherapy was not considered to be a standard of care, in fact again 'something' was offered in the form of chemotherapy in the context of research.

Prolonging life
We found that GDGs often considered prolonging life to be the most important patient outcome:
What you notice is that a working group is focused on 'curing' the disease, with quality of life getting less attention. Apart from those treatments, the side effects of treatments could be a focus too, to see how you could treat them and what evidence there is for this. (respondent Oesophagus 5)

Several respondents stated that this tendency could be explained by the difficulty in measuring quality of life and also the average patient's preference to live as long as possible. For example, prolonging life was the only decisive patient outcome when docetaxel became the standard of care.
Palliative chemotherapy was considered for potential chemotherapy-sensitive tumours in the 'cancer with pain' GDG. Although two respondents emphasised that palliative chemotherapy would never be administered only for pain reduction, prolonging life should also be attempted if possible (respondents Pain 1 and Pain 2). The fact that prolonging life is mentioned even in an area where pain reduction is the main goal underlines how highly this is valued.

Value judgements in the final guideline report
Although we encountered different value judgements during guideline development, often they were not reflected in the final guideline text. In the interviews, respondents gave several reasons for the lack of explicitness:

1. The treatment of a metastatic disease depends to a great extent on the preferences of the individual patient. This conflicts with a guideline that should be applicable for all patients. Therefore, respondents said that GDGs limited their job to summarising the statistically significant effects.
2. The section in the guidelines about palliative chemotherapy was often drafted by medical oncologists. As the interest of GDG members is often limited to their own field of expertise, the value of chemotherapy was not always discussed in detail in the GDG meetings: *Although surgeons might think that chemotherapy is terrible for the patient, they will leave the decision up to medical oncologists because it is our profession* (respondent Breast 4)
3. The GDGs aimed to limit the length of the guideline. Detailed considerations were not included for reasons of readability.

DISCUSSION

In this study, we determined several value judgements used in developing guidelines for palliative chemotherapy. However, often these value judgements were not explicitly mentioned in the final guideline report. As a consequence, patients with incurable metastatic disease may not be aware of relevant value judgements. We believe that for patients in the process of making decisions about their treatment, at least two of the four encountered value judgements are important: the preference for 'doing something' and for prolonging life. A patient should know that chemotherapy could be offered because physicians find it hard to 'do nothing' and believe that patients value 'doing something' and prolonging life above 'watchful waiting'. Such value judgements are not mentioned in the guideline but play an important role in determining the standard of care as expressed in the final recommendations in oncology guidelines.
We believe that the lack of explicitness about value judgements may be due to broad consensus between medical oncologists about routine care and the widespread association of evidence-based clinical practice guidelines with objectivity, thus excluding value judgements. However, value judgements about patient outcomes are inevitable in guideline development. These value judgements distinguish a guideline from a review of literature. In the guideline text the conclusions are based on scientific literature, which are graded using a scale from level 1 (one systematic review or two or more RCTs) to level 4 (expert opinion). Beyond the evidence, 'other considerations', including the value judgements that we found, can play an important role in translating the conclusion to recommendations. The wording of recommendations (for instance using terms as 'must', 'should', 'could') reflects *both* the level of the conclusion and the weight of the other considerations. One might argue that if the considerations and value judgements were more explicitly described, the length of the guideline could hamper the implementation of the guideline. This would not be a problem, however, if summary guides and tools for application (such as patient leaflets) are provided to facilitate the guideline's use in practice.
As far as we know, this is the first study on value judgements in oncology guidelines. We studied the process of the development of six oncology guidelines in the Netherlands. Our analysis of a sample of evidence-based

oncology guidelines developed in other countries confirmed our findings: recommendations for palliative chemotherapy are rarely explained and value judgements have not been made explicit in these guidelines.[16-20] Berg *et al.* studied value judgements in guidelines on depression and angina pectoris and came to the same conclusion.[8]

Strength of our study is the use of three different methods of data collection. We know from the literature that the process of guideline development is influenced by group dynamics and the composition of the GDG.[21-23] By using semi-structured interviews as a data source (in addition to observations and text analysis), we used 'triangulation' to increase the consistency of findings.[24]

A limitation of our study is that we observed plenary GDG meetings and might have missed small group discussions and discussions via email. Even if we did miss certain value judgements, these were not reflected in the final guideline reports. Furthermore, we excluded costs and other organisational issues. We report on different opinions for including/excluding cost issues in guidelines in another paper from this project.[25] We also excluded value judgements that had already been made in evaluated studies during guideline development. In a separate paper for this project, we report on the importance of prolonging life compared with quality of life in interpreting randomised controlled trial results on palliative chemotherapy.[26]

The quality of guidelines for the treatment of metastatic cancer could be improved by making value judgements explicit and by providing tools for weighing up the pros and cons of different treatment options.[27] Then, the guideline user (the physician) will be able to discuss the relevant value judgements with his or her patient.[28] A checklist of potential values could support this process (*appendix 1*). Both physicians and patient representatives involved in the development of guidelines should be trained in making value judgements more explicit. Guidelines should ultimately focus on improving individual patient care, and being explicit about value judgements is essential to this.[29]

Appendix 1. *Checklist to support explicit use of value judgements in guidelines (for example, in considering a palliative chemotherapy for metastatic, hormone-refractory prostate cancer)*

What are preferable outcome measures?
Is (are) the main outcome(s) large enough to consider the treatment as standard? Yes/No. Why?
Does (Do) the main outcome(s) involve a representative part of the patient population?
What would be the best moment in time to start the treatment?
Have other (non-)treatment options been proposed?
Imagine that your father/partner has metastatic cancer.

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