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Gregersen, Trine A.; Birkelund, Regner; Wolderslund, Maiken; Steffensen, Karina Dahl; Ammentorp, Jette

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When life gives you no choice. Context of decision-making when offered an oncology clinical trial

When life gives you no choice

(iii) Authors
Trine A Gregersen RN, Cand.cur (PhD student)¹, ², ³,
Regner Birkelund MNSc, PhD, Dr.Phil. (Professor)², ³,
Maiken Wolderslund MHSc, PhD (Postdoc)², ³,
Karina Dahl Steffensen MD, PhD (Professor)¹, ³, ⁴,
Jette Ammentorp MHSc, PhD (Professor)², ³

(iv) Affiliations
¹ Department of Oncology, Lillebaelt Hospital - University Hospital of Southern Denmark, Vejle, Denmark.
² Health Services Research Unit, Lillebaelt Hospital - University Hospital of Southern Denmark, Vejle, Denmark.
³ Department of Regional Health Research, Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark.
⁴ Center for Shared Decision Making, Lillebaelt Hospital - University Hospital of Southern Denmark, Vejle, Denmark.

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Author contribution
TAG has made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data and drafting the manuscript. RB and JA have made substantial contributions to conception and design, analysis and interpretation of data and been involved in drafting the manuscript.
and critically revising it. MW and KDS have been involved in drafting the manuscript and critically revising it.

**Ethical approval**
The study was approved by the Danish Data Protection Agency. The Regional Committees on Health Research Ethics for Southern Denmark declared that no ethical approval was needed for this observational study.

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**Keywords:** Decision-making, treatment decisions, physician-patient communication, clinical trial, advanced cancer, observational study.
Abstract

Background
Patients with advanced cancer are faced with a wide variety of challenges and difficult treatment decisions made while in a vulnerable life-threatening situation, including decisions about clinical trial participation.

Internationally there is a great focus on shared decision-making as a way to help patients and health care professionals to make informed decisions together; nevertheless, research focusing on patient experiences show that information about clinical trials is insufficient in supporting patients to make trial decisions in the context of their course of disease and managing life with advanced cancer.

Aim
To explore where and how decisions about participation in oncology clinical trials are made and the role of the patients and health care professionals.

Methods
Participant observation was used as a qualitative research method to gain knowledge about decision-making in different clinical situations. Data were analysed using thematic analysis.

Results
Four themes were developed: 1) Preformed decisions, 2) Dissimilar perceptions of successful treatment, 3) Cues and concerns stated by patients, and 4) Creating common ground.

Conclusion
There are underexposed aspects to be aware of in the decision-making process for clinical trial participation. Preformed decisions made by the physicians before the encounter with patients seemed to narrow down the patients’ options and could have benefited from including the patients’ views. Cues and concerns stated by patients were often neglected. However, when physicians talked with the patients about truly difficult issues such as treatment expectations, hope, and death, it led to another kind of conversation about treatment decisions involving the patients’ preferences.

**Implications for practice**

Awareness of preformed decisions and an increased focus on picking up cues and concerns about existential issues in the clinical encounter may improve the quality of the decisions and increase shared decision-making.

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**Keywords:** Decision-making, treatment decisions, physician-patient communication, clinical trial, advanced cancer, observational study.

1. **Introduction**

Patients with advanced cancer are faced with a wide variety of challenges and difficult treatment decisions and very often one of the decisions is whether or not they want to participate in a clinical trial (1). Like all treatment options, there are benefits and risks of treatment in a clinical trial. Gaining access to a new treatment may induce new hope for a cure, which constitutes the primary advantage of participating in trials (2-8). However, among other potential downsides, the new treatment might be ineffective, and might have unknown side effects or side effects that are worse than those of the standard treatment (9). Moreover, new treatment may require additional visits and clinical tests (3).

The circumstances in which this decision has to be made is a vulnerable life-threatening situation, which makes it a particularly difficult decision (1). Initially, the concept informed decision-making was evolved within bioethics to improve informed consent and help patients understand the nature of the disease and the treatment options including benefits, risks, and alternatives (10). In recent years, more often, the term shared decision-making (SDM) has been used when making a treatment decision. The concept of SDM originates from general practice and takes informed consent a step further with the purpose of supporting patients in deliberation and determination around the decisions and match the patient’s preferences with the most appropriate treatment given the specific and individual preferences.
Both the concept of informed consent and the concept of informed decision-making are important in this context since the patients must receive adequate information to be fully engaged in the process of SDM and their consent to trial participation must be based on this information.

SDM is promoted internationally as a way to help patients and health care professionals (HCPs) make informed decisions together based on the best evidence, patient values, and preferences (13). Most studies about SDM have focused on single encounters and single decisions although it is known that often there are multiple decisions to be made in every encounter (14) and that decision-making is a process that should focus on the persons involved (15).

The HCPs are of great importance in the decision-making process because they are the ones responsible for informing the patients and their relatives about the possible treatment options. Furthermore, they are obligated to ensure the patients’ understanding of and willingness to participate in the clinical trial through written and orally provided informed consent (16, 17).

A review of qualitative observational research literature within decision-making in oncology clinical trials reveals that none of these describe the context in which the process of trial decision-making takes place. Nevertheless, a few other studies indicate that the setting in which these decisions are made impacts the decision-making process (18) and that recommendations made by the HCPs during the presentation of trials may influence patients’ decisions (19). In addition, other qualitative studies show that patients and relatives experience that the oncologists have more influence on the decision than experienced by the oncologists themselves (20). Furthermore, research focusing on patients’ experiences shows that information about clinical trials, including consent information, is not sufficient in supporting patients to make trial decisions in the context of their course of the disease and managing their life with advanced cancer (21).

The disparities between patients’ and HCPs’ experiences and the lack of knowledge regarding the entire decision-making process motivated us to explore how the decision-making process unfolds within clinical practice.

1.1. Aim

The study aimed to explore the context in which the decision-making process about clinical trials takes place by elucidating where and how the decisions are made, and how the role of the patients and HCPs unfolds.
2. Methods

2.1. Study design

We conducted a qualitative study in which data were collected through participant observation in different settings where decision-making about clinical trials took place, applying the observation approach described by James P. Spradley (22). Data were analysed using thematic analysis described by Braun and Clarke (23). The present study is part of a larger study in which qualitative interviews were conducted with some of the patients involved.

2.2. Study population

HCPs included in this study were all physicians or nurses employed in the Department of Oncology who attended the observed conferences, consultations or team meetings. Patients attending consultations were men and women, between 41 and 76-years old with different types of advanced incurable cancer. The palliative treatment they were offered were either life-prolonging or aimed at increasing their quality of life, e.g., by reducing pain. The patients were in different places of their life, some with small children, and others with adult children or grandchildren. Some of the patients were still working, whereas others were on sick leave or retired.

2.3. Setting

Observations of conferences and team meetings were carried out from September 2015 to February 2017 and observations of medical consultations from April 2016 to January 2019. Observations took place in a university hospital in Danmark. Overview of situations observed is presented in Table 1.

2.4. Data collection, registration, and organisation of data

Data were collected from passive participation observations, i.e. involvement of the researcher was avoided (22). Given the aim of exploring the context of decision-making processes, the field was at first approached by spending time at different places in the department, e.g. meetings and clinical events. This approach, described by Spradley (22), was initially carried out as “grand-tour observations” through which the most general features concerning the decision-making process like the place, persons present and activity were provided. After three months with these grand-tour observations (22), a review of the field notes revealed a need to explore more specific aspects of the decision-making process. Consequently, this led to formulation of more detailed questions for the “mini-tour observations” (22), for instance: which role do the physicians have in the consultations?
Registration of data consisted of handwritten field notes with descriptions of the social processes and the context in which they appeared. As former studies have suggested, the setting may impact the decision-making process (18), and special attention was therefore drawn to the communication and behaviour related to decision-making in the different settings observed. After observing, details were filled into the field notes recalling events that were not written down during observations (22). Thereafter, the field notes were transcribed and transferred into NVivo11 (24).

2.5. Qualitative analysis
Using thematic analysis, we analysed the field notes to discover patterns and characteristics. The process was iterative but followed six stages of the analysis, inspired by Braun and Clarke (23). NVivo helped us with an overview of the data, coding and thematization. The six stages are presented in Table 2 and illustrated in Figure 1.

2.6. Ethics
The study was approved by the Danish Data Protection Agency. The Regional Committees on Health Research Ethics for Southern Denmark declared that no ethical approval was needed for this observational study.

The head of the Department of Oncology at the hospital permitted the research study. The overall purpose of the researcher's presence was presented to the HCPs at several morning meetings in the department. Patients and relatives received information about the study both orally and in writing, and they were informed that participation was voluntary, anonymous and about their right to withdraw consent, and they consented to the research before the consultations.

3. Results
The thematic analysis revealed how patients’ and physicians’ understanding of the decisions to be made and the physicians’ approach to the decision-making influenced the conversation about whether or not to participate in a clinical trial. The nurses were recurring persons in the patient course of disease, and they were present at all the observed consultations. However, they appeared to play a minor or supportive role in the decision-making process. This came to light through the grand-tour observations, and for that reason, we choose to focus on the physicians.

The findings are presented in the following four themes, which will be elaborated below: 1) Preformed decisions, 2) Dissimilar perceptions of successful treatment, 3) Cues and concerns stated by patients, and 4) Creating common ground.
3.1. Preformed decisions

At the conferences, physicians discussed the patients’ treatment opportunities with other physicians. The main purpose was to let physicians discuss the patients with other, and sometimes more experienced, physicians. Nurses were not part of this discussion, but most often a nurse was present at the conference and could contribute with knowledge about the patients.

At first glance, the conversation at the medical conferences appeared to be strictly medical discussions about the patients’ disease and treatment plan. However, the mini-tour observations and the further analysis revealed that these discussions contained preformed decisions made before encountering the patient. Two types of preformed decisions were identified: medical decisions and personalised decisions. The first constitutes decisions that only physicians were able to make given their professional medical expertise. For example, at a conference, a physician presented a case with a patient whose cancer had spread. The physician decided that the patient was not going to have the opportunity to be offered experimental treatment because of poor kidney function.

The second type was personalised decisions which were identified based on observations of decisions containing elements that involved considerations about the patient’s life, values, and preferences, which the individual patient could have interest in being a part of. At several conferences, preformed personalised decisions were made despite the patient being absent, e.g., at one conference physicians were discussing two types of radiotherapy treatment for a patient. A physician lined up the pros and cons of the two treatments and concluded that in general, these treatments were equal because they would have the same outcome on cancer. However, the physicians also said that one of the treatments may produce a better mobilization outcome of the patient’s arm afterwards. This led to another physician commenting: “But that’s not what we usually go for”, referring to the primary focus being the treatment effect on the disease and not the personal preference about how important the mobilization outcome of the arm would be from the patient’s perspective. At the conference, the physicians did not mention that this part of the decision-making should be discussed with the patient, which indicates a risk of a preformed personalised decision being made without involving the patient.

In some cases, the treatment discussions at the conferences contained elements of both medical and personalised decisions and they often merged into each other, which made it difficult to distinguish between them. For example, at a conference, the physicians discussed a patient who might suffer a relapse. A physician stated that it was almost certain it was cancer and she considered treatment as a precaution. The physicians discussed further the different possibilities, including offering a new scan, giving treatment without a scan first, or the possibility of doing a new scan in three months to see if the
cancer would grow. After a while, the physician who brought up the case concluded: “In the end I think I will say that it looks calm”.

Sometimes the physicians did consider taking the patient’s view into account. An example was a conference where the patient up for discussion needed to have various examinations but was in a physically bad condition. In the discussion, the physicians took into account that the examinations and treatment could negatively affect the patient’s quality of life and agreed they would only refer the patient to further examinations if the patient wanted treatment for the cancer. At the end of the discussion, the physician said: “I can try to talk to him about what he wants”. In cases similar to this, the observed situations were characterised by discussions and less decision-making.

3.2. Dissimilar perceptions of successful treatment
Observations of the decision-making in the consultations and the role of the patients and HCPs revealed a great variation in their perception of treatment in terms of both information-giving and expected benefits.

The physicians’ focus was primarily on informing the patients about treatment opportunities, and the benefits and side effects of the treatment. Their emphasis was on the life-prolonging aspects of treatment. In contrast, the patients’ questions were focused on survival and treatment as a cure for cancer. This revealed that they had dissimilar criteria for successful treatment and consequently also a different understanding of the medical terms they used. An example of this was a consultation where the patient asked several times about the effect of the treatment, to which the physician answered: “This treatment will not cure your cancer”. The patient looks surprised. The patient said, (in a questioning tone): “I have heard that this is an effective chemo?” The physician did not respond to this question or comment on their different perceptions of “effective chemo” and continued talking about treatment and side-effects.

Another dissimilar perception to treatment effect appeared when physicians and patients talked about treatment options, including clinical trials. At the consultations, physicians often talked about treatment as “there is something to do”, and they presented clinical trials as an extra treatment option. However, when patients asked the physicians, “can something be done?” they talked about it with a hope for a cure. This became even more clear when some patients expressed a belief in trials as a chance to cure their cancer or a chance to gain time while new curative treatments were being developed.

Several patients talked about the decisions to enrol in a trial as “having no choice”, e.g., at a consultation, the physician explained the pros and cons of the different relevant treatment options. The
physician then recommended treatment as part of a trial. Both the physician and the nurse asked if the patient needed time to consider the opportunities and they emphasized that the patient could always change her mind. The patient answered: “No, there is no choice” (while crying and signing the consent form to participate in the clinical trial). Although there were other treatment options, the patient stated it as “having no choice”, which was an expression that reflected how many patients experienced the actual choice.

3.3. Cues and concerns stated by patients

In a majority of the consultations, there were cues and concerns stated by the patients that were not followed up by the Physicians. They often missed or avoided the patients’ cues to talk about the stage of the disease or life and death by moving on to treatment talk. At one consultation where the physician asked the patient if he was interested in chemo, the patient responded: “Yes, I have told my wife that I will live to be 80 years old.” The patient looked serious and questioning. The physician answered: “Unfortunately, this is not quite likely with this disease.” During the remaining part of the consultation, no one addressed that the patient might have unrealistic expectations of survival or at least hoped for a much longer life than expected by the physician.

There were also several consultations where both the patient and the physician focused on treatment opportunities. This led to situations where the patient’s concerns about existential issues may have been neglected, e.g. in one consultation where the patient came to be enrolled in a trial. During the consultation the patient was told she was no longer eligible for the trial. The patient was very sad about this because she really believed in the experimental treatment. The physician informed her about other treatment possibilities and the patient asked if these treatment options could reduce the disease. Without a pause, the patient continued: “My goal is to live ten more years.” The physician responded with a quiet laugh, then a short pause, and continued talking about the treatment options.

Another example of the missed opportunity to respond to cues and concerns was at a consultation with a mother of two young children. She was given multiple treatment options including two clinical trials, without the option of no treatment being proposed. She was very focused on treatment and decided to participate in a trial. During the consultation concerns about how much time there was left to live in and concerns for their children were mentioned by the patient and the relative. However, neither the patient and relative nor the physician addressed these issues concerning death in relation to treatment decisions. The patient died less than two months after the consultation and a discussion about treatment.
expectations and a no-treatment option might have led to a talk about existential issues which could have impacted her last months with her family.

Patients often expressed concerns about the clinical trial setup and in some cases perceived trials as an unnecessary risk. This was especially the case when the trial involved a randomisation procedure with the possibility of receiving a placebo or in cases with a longer enrolment period without treatment. An example of this was in a consultation where the physician explained the trial and the possibility of receiving a placebo instead of active treatment, the patient replied: “I cannot use that”. Then she cried and repeated that it felt useless. The patient's husband said: “We, on the other side, feel that you're just playing with us”. The physician listened to the patient, made a pause in the information-giving, and looked at them in an empathetic way. After a short while, the physician continued talking about the treatment options and recommended participation in a trial because the available standard treatment would be less effective.

3.4. Creating common ground

The data also revealed some examples of physicians picking up cues and concerns and using them to balance the discussion between choosing treatment with the risk of side effects and the impact of choosing no treatment with the possibility of gaining a better quality of life. An example of this was from a consultation with a patient who at the beginning focused on receiving treatment with a hope for a cure or at least many more years of life:

Physician: “Have you thought about that at some point this disease is going to take over?”
Patient: “Yes, but I don’t think about it all the time. I don’t suppose I'm that far yet?”
Physician: “What if that's what's happening now?” Patient: “Half a year, one or two years?”
Physician: “Maybe shorter.” Patient: “Then we need to figure out what we can do”.
Physician: “If you can do gradually less. What is then most important to you?” Patient: “I just want to be cured (crying). I would like us to make a plan! A treatment plan! That's all I can say”. Physician: “Some talk about life length and others talk about the quality of life. Have you thought about what is important to you?” Patient: “Yes. I just want to have it all, but I do not want to feel bad while I’m here. Then life is not worth living”.

As in the example above, and other similar cases, the physicians made room for existential issues as a basis for the decision-making. By doing so, they created a common ground for the patients and physicians to talk about treatment decisions and gave another direction for the decision-making process.
4. Discussion

Based on our observations, preformed decisions at the medical conferences were often made without the patient being involved. In the clinical meeting between patients and health care professionals, cues and concerns were often expressed by the patients, sometimes without any response. When physicians responded to cues and concerns related to difficult issues such as life expectancy and treatment effect, it created a common ground which was beneficial for the decision-making process.

Preformed decisions based on the physician’s clinical judgement appeared to be a significant part of the decision-making process. This is in line with a study by Ofstad et al. (12) showing that preformed decisions made before the encounter were conveyed to the patient as information and facts. Our study revealed that preformed personalised decisions were made at the conferences where the conversations among the physicians went from being medical discussions of the patients’ disease and treatment to being decision-making where the physicians made decisions about which information they were going to share with the patients. The fact that personalised decisions were made at the conferences without the patient being present might narrow down the treatment options discussed with the patients and point to a risk of important decisions being made without involving the patient.

The discussion of the patients’ treatment opportunities at the conferences allowed guidance of the younger physicians enabling them to have a treatment dialogue with the patient presenting validated options. According to the literature, the context in which the physicians perform their work is shaped by various professionals and organizational guidelines which can present barriers to the sharing of decisions with patients (25). Our findings indicated that the physicians might not be aware of some of these contextual barriers to sharing decisions, displayed by the difficulty to distinguish between discussion of treatment opportunities and treatment decision-making and medical and personalised decisions. This was displayed when both discussion and decision-making and the different types of decisions merged into each other; moreover, it became clear when the physicians made preformed personalised decisions in which it could have been beneficial to involve the patient’s view. These findings are supported by the literature, showing that preformed decisions led to particular courses of action and could have profited from patient input (12), moreover, existing research also shows that patients experience being offered a specific treatment course as opposed to being involved in the decision-making process (26).
According to the observations, treatment decision-making was also influenced by patients’ and physicians’ dissimilar perceptions of successful treatment. We found that patients often made treatment decisions accompanied by the feeling of having no choice, which was related to their treatment expectations. They felt that receiving treatment meant hope and choosing no treatment was equivalent to giving up on life. Consequently, patients made treatment decisions based on a hope to cure the cancer, whereas physicians focused on treatment and prolonging life. In relation to this, existing research literature discloses that patients accept experimental treatment with hope for therapeutic benefit (3, 4) and reveals a discordance between the patients’ and physicians’ perceptions of survival prognosis (27), which might also influence their different treatment expectations.

Our findings showed that in the consultations, physicians often missed patients’ cues to talk about life and death and related concerns. This finding is supported by existing research literature which reveals that physicians often miss most of the patient’s cues and concerns about existential issues (28). We found that addressing the patients’ cues and concerns to talk about death or other existential issues was significant for decisions about experimental treatment when diagnosed with incurable cancer. Talking about these difficult issues changed the conversation from solely focusing on treatment to being a more person-centred approach. The importance of addressing existential issues and concerns corresponds to findings in other studies (29, 30). Furthermore, these studies illuminated that the challenges in responding to the patients’ cues and concerns were associated with the HCPs’ ability to allow themselves to be mentally present as both a professional and a person. Interestingly, our findings revealed that the patients as well neglected their concerns about death by avoiding talk about existential issues in favour of a treatment plan. This might relate to the patients’ hope for a cure and could be explained by the fact that patients rarely have clear preferences when given treatment options (31). This opens up questions about how HCPs can help patients become aware of what matters to them and help translate this into treatment preferences and discloses that both physicians’ and patients’ attention to the patients’ existential issues is a highly relevant aspect of the decision-making, especially in this context of advanced cancer because of the life-threatening nature of the disease and the uncertain effect of the experimental treatment. In this context preferences in life become extremely important since patients may have to choose between treatments (including no treatment) that in different ways will have a significant impact on their final time. Examples of this were displayed in the consultations where physicians created a common ground for the decision-making. They addressed the patients’ existential issues and by doing so, brought forth the patients’ preferences and ensured treatment decision-making based on these preferences.
To understand how physicians’ roles unfold in the various settings, a narrative perspective can be used as it allows us to interpret their stories and therefore provide us with insights into their medical self-understanding, which forms the basis of their decision-making practice.

The observations show that the physicians’ focus was mostly on treatment and prolonging life at both the conferences and in the consultations. This issue has been brought up by Kathryn Montgomery in her book How Doctors Think (32), which not only takes a narrative approach but also examines and explains the physicians’ mindset. She describes how many physicians see curing disease or postponing illness and death as their most important task, which is challenged when curing the cancer is no longer a possibility. Our findings indicate that the physicians’ role of ‘saving lives’ is maintained by the way patient stories are used to be told and discussed at the conferences. Moreover, the physicians’ awareness of different types of decisions might be eclipsed by the importance of making the right medical decision. Nevertheless, in these particular cases where the cancer is incurable, the role of saving lives and an exclusive focus on treatment and medical decisions is not in line with the role required to establish a dialogue with the patients based on SDM (33). And as suggested by Atul Gawande (34), the physicians may benefit from working with other narratives than “the role of saving lives”, to unfold the many different roles they can take, for instance a more listening and supportive role.

4.1. Strengths and limitations

The strength of this study is the use of various observation sites, which provided an understanding of the entire process of decision-making. Although, parts of the decision-making process that patients might be engaged in outside the Department of Oncology are not covered. A limitation is the restricted number of HCPs being included. Consequently, in regards to the participating physicians their specific clinical judgement, awareness of existential issues and personality might have had a great impact on the results. Moreover, the focus was solely on physicians (excluding the nurses), which should be considered a limitation. The researcher has worked in the department as a research nurse, which has provided easy access to the field, an understanding of the patient group and how the department is organized. However, at the same time, this could have increased the risk of introducing observation-, observer expectancy effect-, or hindsight bias.

4.2. Implications for practice

Our study revealed that the conferences contained both discussions and decision-making. Consequently, it suggests the need for an increased awareness of the difference between discussing treatment opportunities and making treatment decisions that result in preformed decisions. Identifying the decisions that would benefit from patient input might increase patients’ involvement in treatment
decisions. Moreover, our study indicates a need for increased awareness among physicians on addressing cues and concern about existential issues as this may change the fundamental considerations of the decision to be made.

5. Conclusion
Our study shows that there are several underexposed aspects to be aware of in the complex decision-making process before entering a clinical trial. The physicians tends to make preformed decisions at the conferences which could have profited from the patients’ view and ultimately might narrow down the patients’ options. The decision-making process was also influenced by cues and concerns stated by patients which were often neglected. However, when physicians talked with the patients about existential issues such as treatment expectations, hope, and death it changed the conversation and created a common ground for the decision-making about trial participation.

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Figure 1:
Examples of chart notes and chart tools, codes and substituted
Markings on the theme: Inappropriate treatment by patients