# “SpezPat”- common advance directives versus disease-centred advance directives: a randomised controlled pilot study on the impact in physicians’ understanding of patients’ end-of- life decisions

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# Abstract

**Background:** The advance directive holds patients' health care choices and fosters the patients' autonomy. Nevertheless, understanding the patients' wishes based on the information provided in advance directives, remains a challenge for health care providers. Based on the ethical premises of positive obligation to autonomy, an advanced directive that is disease-centred and features problems and complications of the disease the patient has, should help the health care providers to understand the patients' wishes correctly. To test this hypothesis, a pilot-study was conducted to compare if physicians could make the correct end-of-life decision for their patients when patients used a disease-centred advance directive versus a common advance directive.

**Material and Methods:** A randomised, controlled, prospective pilot study was designed, that included patients with NSCLC stage VI from the Department of Haematology and Medical Oncology, University Medical Centre, Goettingen. Patients were randomised into intervention and control groups. The control group received a common advance directive and the intervention group a disease-centred advance directive. Both groups filled out their advance directives and returned it. Subsequent, patients were asked to complete nine medical scenarios with different treatment decisions. For each scenario the patients had to decide whether they wanted to receive treatment on a 5-point-Likert scale. Four physicians were given the same scenarios and asked to decide on the treatment, according to the patients' wishes as stated in the advance directive. The answers by patients and physicians were compared whether the physicians had made the correct assumptions.

**Results:** Recruitment was stopped prematurely. 15 patients completed the study, 9 patients were randomised into the control group and 6 patients in the intervention group. A total of 135 decisions were evaluated. Concordance of physicians' and patient's answers, was 0.83 (95%-CI 0.71-0.91) in the intervention group, compared to 0.60 (95%-CI 0.48-0.70) in the control group and the difference between the two groups was statistically significant (p=0.005).

**Conclusions:** This pilot study showed that disease-centred advance directives help physicians to understand their patients' wishes more precisely and make treatment choices according to their wishes.

**Trial registration:** The study is registered at the German Clinical Trial Register (no. DRKS00017580, registration date 27/08/2019)


# Introduction

Cancer plays an important role in palliative care, because of its often still fatal course of the disease[1,2]. Due to the increasing number of treatment options in cancer care and their effects on the patients' quality of life, it also presents a challenge to advance care planning[1]. Therefore, advance directives as part of the advance care planning need to be adapted to that challenge and incorporate the changes in the dynamics of cancer treatment.

Autonomy is one of the four principles of bioethics that guide modern medicine [3]. To foster and preserve autonomy presents a challenge in every physician-patient's relationship, which is aggravated when patients can no longer make decisions themselves, because they lack the capacity to do so. To rise to this challenge, the concept of advance directives was introduced [3]. The advance directive is a legal document that holds a patient's health care choices and therapeutical wishes to ensure medical treatment according to those wishes and through that foster the patient's autonomy. Nevertheless, the concept of advance directives has met with insightful criticism on different levels. A major concern were problems with implementation that were successfully addressed with the introduction of advance care planning in many important scientific studies [4,1,5]. Ethical questions remained [6–9]. Among them are questions about the nature of understanding, choice and decision making in health care[10,11]. One of those questions is how physicians can empower patients to make autonomous choices about end-of-life-decisions. What kind of information do patients need, what are the important decisions to make, how can they be related to the life the patient is living right now and how can those decisions made be in accordance with the patient's own values? Based on the premises of positive obligation to autonomy, the health care system is obliged to provide patients with the information they need to make autonomous choices [3]. If the premises of positive obligation to autonomy is transferred to the concept of advance directives, the content of the advance directives needs to be adapted to the facts and complications of the disease the patient is in. A broad document that covers different complications without regards to what is likely to happen in the course of the disease that patients are suffering from, does not rise to the premise of positive obligation to autonomy. In theory an advanced directive that is disease-centred should foster patients' autonomy and help the health care providers to better understand the patients' wishes. To test this hypothesis, we conducted a pilot-study to compare disease-centred advance directives with common advance directives.

# Material And Methods

We designed a randomised, controlled, prospective pilot study. The study was conducted at the Department of Haematology and Medical Oncology, University Medical Centre, Goettingen with support of Academy of Ethics in Medicine and the Department of Medical Statistics, University Medical Centre, Goettingen. A prospective randomised interventional design was used. The study was approved by the local ethics committee (no.14/11/18).

The study aimed to show if a disease-centred advance directive helped physicians to understand their patients' wishes more precisely than a common advance directive.

Compilation of the disease-centred advance directive

We developed a disease-centred advance directive for patients with non-small cell lung cancer (NSCLC) stage VI. To assess the relevant information that patients with NSCLC stage VI need to be provided with, we made a list of commoncomplications known associated with NSCLC stage VI and their therapeutic options. The outline of the disease-centred advance directives approximated to the outline of common advance directives. It started with an introduction, followed by a declaration of validity, a general passage

about how to reflect on one's values, an explanation of all relevant terms used in the advance directive, a section featuring relevant medical scenarios and was concluded with the appointment of a health care proxy. Each medical scenario included a bullet-point list of medical treatment options. Patients could exclude treatments they did not prefer by marking them on the bullet-point list. All listed medical scenarios were derived from the list of complications associated with NSCLC stage VI and their therapeutic options.

Recruitment and Intervention

The study included all patients with NSCLC stage VI who were older than 18 years, capable of understanding the study design, the advance directives and giving consent. A sufficient proficiency of the German language was required, as well. Exclusion criteria were a second type of malignancy. As baseline characteristics we documented gender, if patients had already completed an advance directive prior to the study, if they had children and whether they thought themselves to be of religious belief. Duration of NSCLC disease was not part of the inclusion criteria. Patients were recruited from January 2019 until December 2020 at the wards and the outpatient clinics of the Department of Haematology and Medical Oncology, University Medical Centre, Goettingen. Eligible patients were contacted at the outpatient clinic and were asked to participate in the study after its purpose and aim of the study was explained to them. After giving informed consent, patients were randomised into intervention and control groups (1:1 allocation). The control group received a common advance directive (the advance directive of the Bavarian state ministry of justice) and the intervention group a disease-centred advance directive. Both groups were asked to fill out their advance directive and return it. Once the advance directive was returned, patients were asked to complete a questionnaire. The questionnaire contained nine medical scenarios with different treatment decisions. For each of the nine scenarios the patients had to decide whether they wanted to receive a treatment in the nine described circumstances and mark their decision on a 5-point-Likert scale. The nine scenarios included different complications that commonly arise during treatment and disease of NSCLC (see Table 1).

After all questionnaires were returned, the returned advance directives were distributed among four physicians. The four physicians were given the same scenarios and asked to decide, what treatment the patients wanted, according to the patients' wishes as stated in the advance directive. Only physicians who were trained more than two years and had experience in intensive care were eligible to perform the evaluation. To ensure an even evaluation, it was aimed that the physicians received the same number of advanced directives from the intervention and the control group. The answers on treatment decisions by patients and physicians were compared to evaluate whether the physicians had made the correct assumptions.

Table 1
Content of medical scenarios

| Scenario no. | Description |
|---|---|
| 1 | Ongoing treatment, moderate side effects, stable disease<br>Complication: infection and delirium<br>Decision: intensive care, yes or no |
| 2 | Ongoing treatment, moderate side effects, stable disease<br>Complication: infection and delirium<br>Decision: resuscitation, yes or no |
| 3 | Ongoing treatment, moderate side effects, stable disease<br>Complication: infection and delirium<br>Decision: antibiotic treatment, yes or no |
| 4 | Ongoing treatment, moderate side effects, progressive disease<br>Complication: infection and delirium<br>Decision: intensive care, yes or no |
| 5 | Ongoing treatment, moderate side effects, progressive disease<br>Complication: infection and delirium<br>Decision: resuscitation, yes or no |
| 6 | Ongoing treatment, moderate side effects, progressive disease<br>Complication: infection and delirium<br>Decision: antibiotic treatment, yes or no |
| 7 | Ongoing treatment, severe side effects<br>Complication: infection and delirium<br>Decision: intensive care, yes or no |
| 8 | Ongoing treatment, severe side effects<br>Complication: infection and delirium<br>Decision: resuscitation, yes or no |
| 9 | Ongoing treatment, severe side effects<br>Complication: infection and delirium<br>Decision: antibiotic treatment, yes or no |

Sample Size Assessment

The required sample size was calculated prior to the trial to confirm a clinically relevant effect. With a sample size of 60 patients (30 per group), assuming the true concordance between patients and medical doctors of 50% in the control group, a significant difference between groups can be observed with a 81.9% power (two-sided significance level of 5%) if the concordance is at least 62% in the intervention group. Calculations were performed by 1000 simulation runs using generalized linear models (logistic regression) in R Version 4.0.2.[12]

Data Management and Statistical analysis

Data collection and management was performed in SecuTrial® via web-based electronic capture report forms. The primary endpoint, concordance between physician's and patient's treatment decisions, was compared between groups using generalized linear mixed models (logistic regression) with random intercept and treatment group as factor. Concordance rates were reported group-wise with 95%-Confidence Intervals (CI). Baseline characteristics are reported using descriptive summary values (mean, standard deviation, quartiles, minimum, maximum and range) or by tables and banners, for categorical data. All analyses were planned prior to data base lock in a statistical analysis plan and were performed in R version 4.0.2.

# Results

Recruitment was stopped prematurely as the planned sample size could not be reached. 51 eligible patients were contacted (Fig. 1). Of those contacted, 31 patients gave informed consent and were randomized. However, only 15 completed the study. Of those 15 participants 9 were randomised into the control group and 6 in the intervention group. Baseline characteristics were distributed as presented in Table 2.

Table 2
Descriptive data showing absolute numbers or mean and standard deviation (SD) and Median and Minimum/Maximum (Min/Max)

| | | Control | Intervention |
|---|---|---|---|
| Gender | Male | 4 | 4 |
| | Female | 5 | 2 |
| Age | Mean (SD) | 67.1 (7.3) | 69.5 (8.1) |
| | Median (Min/Max) | 68 (52/75) | 71.5 (58/80) |
| Do you have children? | Yes | 8 | 6 |
| | No | 1 | 0 |
| Are you religious? | Yes | 6 | 5 |
| | No | 2 | 1 |
| | Missing | 1 | 0 |
| Do you already have an advance directive? | Yes | 5 | 4 |
| | No | 4 | 2 |

[insert Fig. 1 here]

*Figure 1: Recruitment flow chart*

As each participant made a treatment decision in nine medical scenarios, a total of 135 decisions were evaluated. The primary endpoint, concordance of physicians' and patient's answers, was measured to be 0.83 (95%-CI 0.71–0.91) in the intervention group, compared to 0.60 (95%-CI 0.48–0.70) in the control group (Fig. 2). The difference was shown to be statistically significant ($p = 0.005$). Sensitivity analysis, to assess the influence of the physicians' rating and specific scenarios, could not be performed due to low sample sizes. Four physicians (two from the Department of Haematology and Medical Oncology and two from the Department of Cardiology and Pneumology) performed the evaluation. Even distribution of control and intervention advanced directives was not possible due to the uneven number of participants. Concordance with the patients' wishes was higher in the intervention group for each physician, except for one who evaluated only advanced directives from the control group. Descriptive analysis showed that concordance probabilities only differed between intervention group and control group and did not reveal any evidence of unequal rates between physicians (Fig. 3).

[insert Fig. 2 here]

*Figure 2: Comparison of concordance probability between control and intervention group*

[insert Fig. 3 here]

*Figure 3: Comparison of concordance probability between the four physicians in intervention and control group; due to the uneven number of participants physician no. 4 evaluated only advance directives from the control group*

When comparing the different scenarios, concordance probabilities were higher in the intervention group that in the control group in all scenarios except 3, 6 and 8 (Fig. 4). In scenarios 3 and 6, control and intervention both had a concordance probability of 1, suggesting that these scenarios are less difficult to decide upon. Scenario 9 showed a concordance rate of 1 in the intervention group. In scenario 8, the control had a concordance probability of 0.88 and intervention had a concordance probability of 0.83. (Fig. 4). Therefore, the physicians had more difficulty in interpreting the patients' disease centred advance directive in this scenario.

[insert Fig. 4 here]

*Figure 4: Comparison of concordance probability in intervention and control group between the different medical scenarios*

# Discussion

Limitations

The study had some limitations. The sample size was low with only 15 patients completing the pilot study. Initially a much larger sample size was planned, which could not be reach because of unexpectedly low recruitment rates and was therefore stopped prematurely. This might be due to the data collection method. Patients received and returned the documents via mail. Mail-surveys in general have response rates around 60% [13]. Another reason could be the emotional reactions that are connectedwith considering end of life and end of life decisions. As this was a concern when the study was designed, explaining that participation could trigger anxiety and depression was part of the informed consent process. Furthermore, the Department of Psychooncology, University Medical Centre Goettingen was informed about the study and their contact details were placed in the informed consent form. After consultation with the local ethics commission, we did not assess the reasons for drop-out as to refrain from triggering emotional reactions again.

Another limitation is that participants were diagnosed at different stages in their history of treatment. Some were newly diagnosed with stage IV NSCLC and had just started treatment, as others had received treatment for years. Initial study design only included patients that had been newly diagnosed with NSCLC stage IV and had just started treatment. As recruitment rates were very low, the inclusion criteria were adapted to include patients who had NSCLC stage IV and were already treated. The initial concern was that a bias would be introduced as participants with a long history of disease and treatment might be more precise in their advance directives, as they are more familiar with complications and course of disease.

The disease-centred advance directive was tested only against the advance directive of the Bavarian state ministry of justice. Therefore, results are only limited to the difference between those two advance directives. To put the results into a broader perspective the results need to be validated in lager studies following this pilot.

### Discussion of results

This data suggests that disease-centred advance directives might help physicians to understand their patients' wishes more precisely and make treatment choices according to their wishes. Even though the sample size was not large enough to perform a sensitivity analysis, descriptive analysis showed that, when physicians made treatment decisions with the help of the disease-centred advance directive, decisions were more likely to be according to the patients' wishes than when they made decisions with the help of the common advance directive in this pilot study.

Those results need to be confirmed in a larger sample size, but these results suggest that there was no underlying confounder. A disease-centred advance directive might indeed help physicians to better understand their patients' wishes.

Furthermore, the results show that in most scenarios, physicians made the same treatment decisions as patients when a disease-centred advance directive was used. Exceptions were scenario 3 and 6, where there was no difference between the treatment decisions of physician and patient in control or intervention and scenario 8 were there was a minor difference. From a statistical point of view, scenario 3, 6 and 8 do not provide discriminatory power to answer the question which advance directive is more suited to translate the patients' wishes to the physician. Therefore, these scenarios should be eliminated or altered in a larger study. From a medical care point of view, it is interesting that scenario 3 and 6 dealt with the question of receiving antibiotic treatment under stable disease (scenario 3) or progressive disease (scenario 6). Almost all patients wanted treatment in those scenarios, except a few who were indecisive. Scenario 8 described reduced capability to participate in daily life (severe fatigue) due to the side effects of treatment and asked if participants wanted to be resuscitated in the case of a cardiac arrest. Most participants decided against treatment. These data suggest that those wishes seemed to be communicated well and independent of which advance directives are used.

### Integration into current research

With the rise of advance care planning, advance directives became a small part in fostering patients' autonomy regarding end of life decisions [14–16, 2,17]. Drafting and completing an advance directive is only a small part of advance care planning. Advance care planning aims to transform the act of writing down one's treatment wishes into a continuing process that includes structures and procedures to keep conversation about treatment wishes going. It The process of advance care planning ensures that changes of heart are regarded and added to an already existing advance directive. Furthermore, advance care planning rises general awareness on end-of-life decision making and its importance for patients' autonomy [18]. Even though the advance directive is only a small piece of advance care planning it still

plays an important role. Studies suggest that advance directives may help to reduce overtreatment and hospital admissions at the end of life [4,19,20]. Still, it remains unclear, if that also means that treatment is in concordance with the patients' wishes. Most studies use ICU or hospital admission as end points [4], without comparing it to the instructions given in the advance directive. Even though it can be assumed that most patients who possess an advance directive drafted it, because they do not want life-prolonging treatment, that is not necessary the content of every advance directive. Up to this point, only a few studies evaluated if the advance directive actually help health care providers to understand the patients' wishes [21]. Therefore, there is little data on how well health care providers understand patients' treatment preferences and choices after reading their advance directive. Still, it remains an important question when it comes to end of life decision making, especially when it is not possible anymore to ask patients about their preferred treatment. Especially as there are many types of advance directives that differ greatly in their content and their approach on preserving the patients' autonomy [22–25]. Yet there is no validation process that shows that the advance directive indeed reflects the patients' wishes and values and is correctly understood by health care providers.

Data from the acute care setting shows that advance directives remain an important tool to assess the patients' wishes and foster their autonomy in acute care [26–28]. Unfortunately, acute care providers often describe them as unclear, not applicable to the situation and unhelpful [26]. This underlines the importance of implementing and validating advance directives that help health care providers to understand the patients' treatment wishes. In this study we showed that an advance directive that is disease-centred might be more helpful.

## Conclusions

Advance directive still play an important role in end-of-life decision making. In this pilot study, we showed that a disease-centred advance directive can help health care providers to understand the patients' wishes more precisely. Due to the low sample size, the results may need to be validated in a larger prospective study.

## Declarations

# a. Ethics approval and consent to participate

The study was approved by the local ethics committee (Ethikkommission der Universitätsmedizin Göttingen; approval no.14/11/18). The study is registered at the German Clinical Trial Register (no. DRKS00017580; registration date 27/08/2019). All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was obtained from all subjects and/or their legal guardian(s).

# b. Consent for publication

Not applicable as this manuscript does not include details, images, or videos relating to an individual person

# c. Availability of data and materials

The datasets used and analysed during the current study are not publicly available due to their relationship with privacy matters and health, but are avaliable from the corresponding author on reasonable request.

# d. Competing interests

The authors declare that they have no competing interests.

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# f. Authors' contribution

J.K. designed the study with the help of T.A., T.R.O., A.S. and A.B.. The study was managed by J.K., who also carried out the data collection. T.A. and J.K. led the data analysis and writing of the manuscript. A.B., T.R.O., A.S., L.T. and G.W. critically reviewed and contributed to significant revisions of drafts of the manuscript. All authors read and approved the final manuscript.

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# Figures

### Figure 1

Recruitment flow chart

### Figure 2

Comparison of concordance probability between control and intervention group

## Figure 3

Comparison of concordance probability between the four physicians in intervention and control group; due to the uneven number of participants physician no. 4 evaluated only advance directives from the control group

## Figure 4

Comparison of concordance probability in intervention and control group between the different medical scenarios