BUNDESÄRZTEKAMMER

Bekanntmachungen

Statement

of the Central Ethics Committee at the German Medical Association

Medical responsibility at the limits of the appropriateness of medical measures. On dealing with "futility".

In the event of any discrepancies between the English and German versions, the German version shall prevail.

Preface

The question of what is meant by "futility" in the context of health care is being discussed internationally, not least in light of the SARS-CoV-2 pandemic and its implications. With its statement published in December 2021, the Swiss Academy of Medical Sciences most recently called for participation in the discussion of this complex topic. The focus of this discussion is on situations fraught with uncertainty in which there is no reasonable hope of cure or benefit despite continued medical care or treatment.

Therefore, the Central Ethics Committee at the German Medical Association (ZEKO) has decided to highlight the tasks of physicians, particularly in the shared decision making process with patients in such situations, and to formulate guidance for situations in which potential measures appear medically questionable or pointless. The aim is to eliminate uncertainties as well as the the associated possibilities for conflict. ZEKO differentiates between two futility constellations and, with this innovative proposal, shows, from the point of view of ZEKO, whether and when, in individual cases, physicians must or may refrain from certain measures from the outset. Further, the proposal discusses which considerations should, according to ZEKO, be included in the shared decision making discussion with the patient. Only if there is no reasonable doubt that a therapeutic strategy is ineffective or contraindicated, or has a very unfavorable benefit-harm ratio, the patient has to be informed of this only on request, according to ZEKO. In all other cases, the consideration, including the assessment of the probability of success of a therapeutic strategy for the individual patient, must be explained transparently.

As a visual aid, the medical considerations for the ethical evaluation of therapeutic strategies in the process of shared decision making, including the two futility types, have been represented in a flowchart.

Particularly with regard to the implications for medical practice as well as for the patients concerned and their relatives, the members of ZEKO have discussed the various aspects of "futility" in detail and evaluated them carefully. I am pleased that the following guidelines for the medical practice on dealing with the concept of "futility" were unanimously adopted by the members of ZEKO. I would like to take this opportunity to thank the members of ZEKO and all those involved for the sometimes controversial but always constructive discussions and for their commitment in the preparation of this statement.

Berlin, March 2022

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1. Introduction and problem definition

In light of constantly expanding medical possibilities on the one hand, and a broad range of treatment goals between curative and palliative approaches on the other hand, physicians are increasingly asking themselves when they may, or even should, refrain from using certain medical measures on their own initiative, and in which cases these considerations should be discussed with their patients.

At first glance, the answer to these questions seems simple: physicians should neither offer futile medical measures, nor do they have to discuss such measures with their patients. Rather, they must refrain from them.[1] However, what is meant by futility ("medical futility" or "futility" for short) and in which case a medical intervention is "futile" remains unclear and controversial despite a decades-long discussion on futility.[2] Accordingly, there is great uncertainty in medical practice.

Against this background, the present statement is intended to address the question of how to deal with the concept of futility in medicine [18], also recently discussed by the Swiss Academy of Medical Sciences, and to provide guidance for those situations in which possible measures seem questionable from a medical perspective. In addition, the statement intends to highlight the physician's tasks in the shared decision making process with patients in such situations. For this purpose, the ethical and legal aspects of these situations are elaborated upon and recommendations are given on how physicians should act in typical conflict situations.

Thus, ZEKO would like to contribute to a more precise understanding of the various constellations of "futility" and to contextualize them within decision making regarding medical treatment.

2. Background

The conditions under which a medical intervention can or should be judged as "futile", useless, or inappropriate have been discussed since the 1970s and are internationally considered controversial to this day [18; 13; 1]. A first line of discussion deals with the question of which criteria are to be used to determine so-called "futile outcomes". It has been shown that the approach of defining "futility" as an outcome which cannot be achieved under any circumstances – such as, for example, saving the lives of patients with transection of the entire spinal cord in the cervical region or without any physiological response to resuscitation attempts – is only applicable in rare cases and therefore falls short of the underlying problem [14; 6]. Thus, the discussion of "futility" has been broadened and attempts have been made to determine the criteria for identifying "futility" for qualitative states that occur with a certain probability. This refers to measures that, according to the current state of medical knowledge, are not, or are highly unlikely, suitable for achieving therapeutic success. However, it turns out that there is no ethical justification for setting a general threshold for the probability of effectiveness, and even a minimal probability can become part of a deliberation [14; 11; 6].

Another line of discussion addresses the question regarding the extent to which a physician's evaluation of a benefit-harm ratio is based on an understanding of the patient's benefit as an objective benefit, but not from the individual perspective of the patient. In the course of the debate, greater emphasis has been placed on the patient's perspective [20]. In the international "choosing wisely" initiatives, which emerged from an alliance of physician and consumer organizations, physicians and patients jointly address these questions with the aim of defining a catalog of measures of questionable usefulness.[3] It is recommended that the question of usefulness be carefully examined in each specific case and that it be jointly evaluated, in discussion with the patient, whether such a measure is worth considering.

From ZEKO's point of view, the fundamental question in the debate about "futility" is whether and when physicians must or may refrain from certain medical measures in individual cases in the first place, and which considerations should be included in the shared decision making process with patients. In the following, "futility" will therefore be used as a term to refer to these specific problems.

3. Normative analysis

3.1. "Futility" in the context of treatment decision making

The assessment of a measure such as "futile" is based on value judgments, for which physicians should be able to give reasons and, if necessary, make them transparent.[4] Assessments of a measure as "futile" take place against the background of the general goals of medicine and are embedded in a shared decision making process, which consists of interrelated but distinct steps: Physician and patient must jointly clarify the goal of medical activity[5] for the patient, i.e., the general treatment goals that are realistically medically achievable and desired by the patient are jointly elicited on the basis of the individual diagnosis and prognosis. The possible and medically-indicated measures (including the option of not carrying out any measure) are to be determined. The treatment goal and the selection of therapeutic measures are determined in a discussion between the physician and the patient. In the following, ZEKO uses the term therapeutic strategy to refer to the combination of one or more medical measures and the specific therapeutic goal to be achieved.

In the course of the shared decision making process outlined above, physicians must evaluate and decide which diagnostic or therapeutic strategies and measures should be included as options in the discussion with patients and which should not be included in the shared decision making process on the basis of ethical considerations. This decision-making process and the point at which strategies or measures are evaluated as "futile" are shown schematically in the following flowchart. The starting point is a patient who seeks medical help due to a medical condition. The representation of the decision making process focuses on the **physician's perspective** and, in particular, on those elements that are relevant for evaluations of "futility".

Furthermore, the flowchart, like the statement as a whole, focuses on considerations for selecting **therapeutic** strategies and measures. However, these considerations can also be applied to **diagnostic** measures, such as imaging or laboratory chemistry tests or invasive diagnostics (e.g., tumor biopsies or endoscopies).

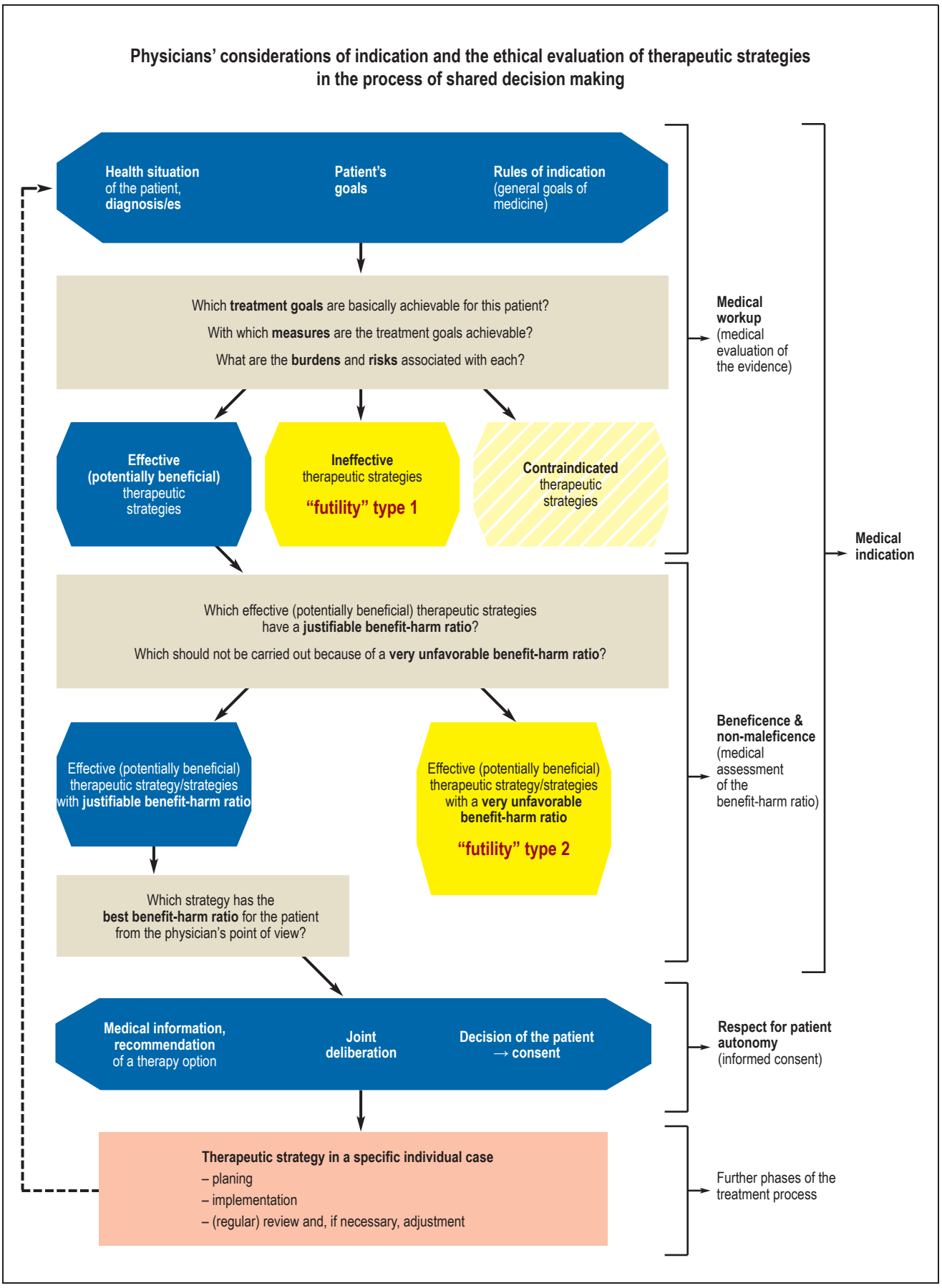
[1] Art. 11 (1) of the (Model) Professional Code for Physicians in Germany: "By undertaking to treat a patient, physicians commit themselves to their patients to conscientiously provide them with suitable examination and treatment methods."

[2] In a recent paper by John McMillan [13], it is even referred to as a "question of eternity".

[3] The German initiative "Gemeinsam klug entscheiden" is supported by the Association of the Scientific Medical Societies (AWMF). In Switzerland, medical societies, patient, and consumer organizations form the supporting association of the "smarter medicine" initiative (www.smartermedicine.ch).

[4] See now also SAMW [18], Sections 3.2. and 3.3.

[5] In law, the goal of medical activity for a patient is generally referred to as the "treatment goal", which is jointly defined within the framework of the "treatment contract" in the sense of § 630a of the German Civil Code (BGB). "Treatment", in this sense, therefore encompasses the entire treatment process, beginning with the initial contact, through diagnosis and therapy, to aftercare.



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(In)effectiveness, benefits, and harms of therapeutic strategies
The flowchart shows which aspects become relevant in medical considerations on indication and in the ethical evaluation of therapeutic strategies, and thus enables a localization of the questions that are discussed under the keyword "futility". It also illustrates how treatment goals, indication, and considerations of effectiveness, benefit, and harm are intertwined in the shared decision making of physicians and patients.

The general framework of possible and sensible **treatment goals** results, on the one hand, from the fact that the patient seeks medical advice because of a health problem and wants it to be cured or alleviated, and, on the other hand, from the corresponding **general goals of medicine**, such as healing, preserving life, alleviating suffering, preventing diseases, and rehabilitation. In addition, the patient's individual experiences of life and illness, as well as expectations of a possible therapy, must be taken into account.

Professional medical workup: Medical considerations on the therapeutic strategy start with the medical workup. On the basis of the diagnosis and an analysis of the medical situation, the **patient's goals**, and the general **rules of indication**[6] , the physician determines which treatment goals are basically achievable with the available therapeutic measures for the person concerned. This requires an **assessment of the effectiveness** of the available therapeutic strategies and the associated measures with regard to the respective treatment goals on the basis of the available evidence. In the process, physicians must also determine the burdens and potential harms associated with the identified effective therapeutic options in each case. Within the framework of these considerations, a distinction can be made between[7]:

Effective and potentially beneficial therapeutic strategies: Physicians must evaluate whether the scientific and medical evidence of effectiveness for the therapeutic option is sufficient in light of the treatment goals of the patient.

Ineffective therapeutic strategies ("futility" type 1): Examples of ineffective strategies are antibiotic therapy for an uncomplicated viral cold infection or the continuation of chemotherapy despite progression of the disease under this therapy. In these cases, this therapeutic strategy cannot be considered (any longer) under any circumstances since the measures do not contribute to achieving the treatment goal. Therefore, the physician must not offer them to the patient. In some cases, the treatment goal can no longer be achieved with any available strategy. In such cases, a change in the treatment goal is necessary from the medical perspective and must be discussed with the patient.

However, it must be considered that the interpretation of evidence of effectiveness is not value-free. In medical practice, for example, physicians place different requirements on proof of effectiveness for new therapies (e.g., phase 2 study versus meta-analysis of data from several randomized controlled trials). Such assessments should be reflected and, if relevant for the selection of therapeutic strategies, communicated.

Contraindications: If the harm potentially caused by a generally effective therapeutic option is so serious that its implementation – regardless of any potential benefit – is not justifiable (e.g., penicillin in the case of penicillin allergy), this measure is contraindicated. For this reason, this option must not be offered to the patient by the physician. If asked, the physician must provide adequate information about contraindications.

Process of determining indications on the basis of beneficence and non-maleficence: Another systematic element of the physician's considerations is the comparative evaluation of the **effective and potentially beneficial therapeutic strategies** identified in the previous step. The physician and if necessary, a multiprofessional team, assess, with due consideration of the potential benefits and harms, which of the available therapeutic strategies have a **justifiable benefit-harm ratio** for the patient when applying a perspective of medical care. The assessment includes both the probability of occurrence and the extent and intensity of benefits and harms, and requires evaluation in these respects as well. In some cases, a therapeutic strategy may emerge as the **"best" treatment option** from a medical care perspective.

During the process of establishing an indication, therapeutic strategies with a very unfavorable benefit-harm ratio for the respective patient may also be identified (e.g., the implementation of a high-dose multiple chemotherapy regimen with a very low chance of success and a high potential for harm in the case of a far-advanced, metastasized cancer). In these cases, careful consideration must be given to whether this option is considered unjustifiable from a physician's perspective due to its unfavorable benefit-harm ratio and is therefore not offered to the patient **("futility" type 2)**.

However, the assessments, if a measure is indicated, may diverge within a medical team both with regard to the evaluation of the available evidence and with regard to the benefit-harm ratio. The difficulty becomes particularly clear when there are two competing "equal" therapeutic strategies and there are good reasons to opt for one or the other. Here, the relevant value judgments should again be reflected in the treatment team. Particularly in the case of differing assessments of the benefit-harm ratio in the treatment team, the patient should be informed of the exclusion with the corresponding justification. This should give the patient the opportunity to reflect the underlying assessments of justifiable benefit-harm ratios and the risk propensity of the physician against their own preferences and assessment of the risk. This also includes, if necessary, the possibility of obtaining a second medical opinion for the assessment of the benefit-harm ratio of the therapy option.

Shared decision making and informed consent: The above-mentioned medical considerations are an expression of the physician's responsibility toward the patient and are framed by the physician's therapeutic freedom, which is, of course, committed to the patient and respects their autonomy. Their result is therefore incorporated into the **shared decision making process** where, on the basis of the medical information and recommendations from the medical care perspective, the options for action should be deliberated together with the patient. The decision is made by the patient, although this decision may also consist of entrusting the choice of action to the physician. While, for schematic reasons, shared decision making is shown in the flowshart as following from the physician's considerations, according to the concepts of Shared Decision Making (SDM), the shared considerations of physicians and patients ideally begin in the diagnosis phase [8; 12].

[6] Rule of indication: The rule of indication refers to measures that, given a particular diagnosis, are generally considered effective in achieving the general goals of medicine - healing, preserving life, alleviating suffering, preventing disease, and rehabilitation. In medical textbooks, the term indication is often used in this sense. Individual indication must be distinguished from this use of the term indication in the sense of a general rule of indication.

[7] The SAMW [18] proposes a different distinction: It distinguishes between ineffective or no likelihood of benefit (non-indicated), and probably ineffective or little likelihood of benefit (questionably indicated) measures, see Section 6.

With regard to the relevant questions concerning medical information, two basic constellations must be distinguished: On the one hand, situations in which there is no reasonable doubt that a particular measure is ineffective ("futility" type 1) or contraindicated or has a very unfavorable benefit-harm ratio ("futility" type 2). In these cases, the physician needn't provide information about the corresponding measure. On the other hand, this must be distinguished from situations in which – for whatever reason – there do exist justified medical doubts as to whether no effect can actually be achieved or whether the benefit-harm ratio is actually very unfavorable. In order to prevent patients from being denied potentially useful treatments from the outset, physicians must ensure that medical information also includes measures whose usefulness is medically disputed.

The information thus provided is part of a joint deliberation between the physician and the patient as to which therapeutic strategy the patient prefers in light of their individual preferences, i.e., which therapeutic goal should be pursued from their point of view in due consideration of the burdens and potential harm. In doing so, the patient can also exclude therapeutic strategies which, according to their subjective assessment, have an unfavorable benefit-harm ratio. This deliberation must also include the justified professional recommendation of a therapy option and, if necessary, the exclusion or non-recommendation of a therapy option with a very unfavorable benefit-harm ratio. The joint deliberation in the sense of SDM leads to the patient's decision on a therapeutic strategy and the implementation of the therapy measures.

3.2. Dimensions and framework conditions for the medical evaluation of therapeutic strategies

The selection and determination of therapeutic strategies has several dimensions that may become relevant to the discussion of "futility". They are outlined in the following.

Medical responsibility and therapeutic freedom

The practice of medicine is committed to the patient.[8] Considerations regarding the choice of therapeutic strategies must do justice to this medical responsibility. A physician's therapeutic freedom also serves the patient. In this context, this refers to a physician's free, patient-centered choice of treatment method, which is suggested to the patient. It includes three elements: First, the decision whether to carry out any treatment at all; second, the choice of the appropriate diagnostic or therapeutic method; and third, the right to refuse to carry out a method that contradicts the physician's conviction. The obligations to act with professional accuracy and provide information and education to patients constitute an essential correlate to therapeutic freedom [10].

Decision under uncertainty and handling of probabilistic knowledge

The evaluation of therapeutic strategies with regard to their effectiveness and the benefit-harm ratio involves various challenges. Medical knowledge about the (possible) success of a therapeutic strategy is based on statistical information, which itself may be subject to uncertainties. In addition, different study results on the likelihood of success of a therapeutic strategy need to be handled. The potential benefits and potential harms of a therapeutic strategy occur with a (known, only estimable, or potentially quantified differently in different studies) probability that must be weighted when choosing a therapeutic strategy. In this context, a physician's initial assessment is needed regarding which minimum requirements should be met by the available data or medical evidence with regard to the chance of achieving a therapeutic goal or the effectiveness of a therapeutic strategy or measure in order to offer it to the patient. The same applies to cases in which the physician, based on their clinical experience, comes to the conclusion that a therapeutic goal is highly unlikely to be achieved or that a therapeutic strategy is very unlikely to be successful for this patient.

On the one hand, it is clear that no definite statement about the success of a therapeutic strategy for an individual patient can be derived from statistical assertions about its potential success. Even if the chances of success can be determined and quantified with percentages, a therapy will ultimately either be successful or unsuccessful. On the other hand, it is clear that no percentages can be generically defined as a minimum level for minimum effectiveness. In this case, it is rather the task of physicians to communicate the medical information appropriately and comprehensibly to the patient, taking into account the existing epistemological difficulties.

The ethical assessment of benefits and harms in the course of the evaluation of therapeutic strategies does not stop at the comparison of probabilities, but includes personal values as they were introduced by the patient in the course of defining the treatment goal, and thus combines empirical and normative aspects. If physicians decide not to offer a therapy strategy because of ineffectiveness ("futility" type 1), contraindication, or a very unfavorable benefit-harm ratio ("futility" type 2), and if the evidence is uncertain or contradictory, or the probability of effectiveness with regard to the potential benefit is insufficient, the patients must be informed about this. This enables patients to share their own views and preferences (also) in the evaluation of chances of success within the framework of the shared decision making process with the physician.

Communication

The medical assessment of therapeutic strategies with regard to effectiveness, benefit, and harm is an expression of medical therapeutic freedom and must be carried out in a professionally responsible manner in the interest of the patient. The associated considerations, however, are often ambiguous and difficult. Moreover, not only are medical aspects relevant, but the patient's beliefs are as well. A reflected approach and, if necessary, open communication with patients (see Section 3.1. "Shared decision making and informed consent") about the assessment of therapeutic strategies as ineffective ("futility" type 1), contraindicated, or associated with a very unfavorable benefit-harm ratio ("futility" type 2) are therefore an essential basis for joint deliberation.[9]

SDM concepts envisage – as explained – that joint deliberation between the physician and the patient ideally begins in the diagnosis phase. Thus, the health problem is identified together, in-

[8] See i.a. Art. 2 (2) of the (Model) Professional Code for Physicians in Germany: "Physicians must practise their profession conscientiously and do justice to the confidence placed in them in practising their profession. In doing so, their medical activity must be in accordance with the welfare of the patient. In particular, they may not put the interests of third parties above the welfare of the patient."; German Medical Association (BÄK)/ZEKO [5], No. III, 1; ZEKO [24], Chap. 3.2 and 3.3.1.

[9] Art. 8 of the (Model) Professional Code for Physicians in Germany states: "The less medically necessary a procedure is, or the more significant its implications, the more comprehensively and emphatically patients should be informed of attainable results and risks."

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cluding the key message actively expressed by the physician that medicine often has more than one way of dealing with the problem. This is followed by the joint exploration and deliberation of therapeutic strategies and the final decision making meeting with a joint agreement on the further course of action.

It needs to be taken into account that individual assessments and evaluations on the part of physicians, such as risk aversion or willingness, also influence the assessment of treatment goals and therapeutic strategies. This must be considered within transparency-oriented counseling. The significance of individual assessments and evaluations in the context of shared decision making on the part of physicians fundamentally differs from that of patients. Physicians must reflect on these individual assessments and evaluations, which also influence the presentation of the medical situation, and disclose them to the patient in order to be transparent about their influence on the presentation and decision. Patients should be encouraged and supported to reflect on their own individual assessments and evaluations of the facts and to communicate these openly so that the decision is based in the best possible way on their own well-considered personal values.

In addition to legal questions concerning the scope of the physician's duty to inform the patient (see Section 3.1.), a number of further aspects – some of them professional, others ethical, others psychological – are relevant to consider for successful communication. For example, patients often wish for an evaluation of the fundamentally effective therapeutic measures presented to them in the course of the information session, as they feel unable to independently identify the best treatment strategy for them due to their limited medical knowledge. In view of their responsibility for the patient's benefit, physicians should not refuse such requests to evaluate generally effective alternative therapeutic strategies, but should actively contribute toward identifying the treatment option that is best suited for the patient's situation in light of the general medical goals and the individual value orientation of the patient, without restricting the patient's freedom of choice in any way in accepting the physician's preferred therapeutic option. Physicians should also always be aware that labeling an intervention as "ineffective", "contraindicated", or as having a "very unfavorable benefit-harm ratio" might not be received as purely factual information by the patient, but might pose a heavy existential and emotional burden. Recommendations have been developed for appropriately communicating "bad news" ("breaking bad news") in general, as well as for communicating a poor prognosis, which is also helpful for conversations in such situations.[10] The patient should be made aware of their individual prognosis in a sensitive way, without removing reasonable hope for possible treatments, and support and accompaniment should be assured.

Treatment situations in an intercultural context

Another ethically relevant area of conflict is decision making on treatment in an intercultural context.

For example, a Dutch study in which pediatricians were interviewed showed that parents with a migratory background were significantly more likely than native parents to express a wish for maximum therapy in hopeless cases [21]. Such attitudes may be caused by a fear of inadequate care due to the reactivation of experiences of discrimination, combined with overvalued ideas and hopes of feasibility in the highly technological medical system of the immigration country on the part of the relatives. Particularly in existential situations, language barriers, traumatic experiences of migration, and different, sometimes religiously influenced understandings of life and death, health and illness (e.g., ideas of God's omnipotence) can contribute to conflicts in treatment, which can be a very stressful experience for all involved.

A culturally sensitive and culturally responsive health care system therefore emphasizes the complexity of the importance of culture in medical-ethical conflicts and, also in this context, the uniqueness of each patient. In such difficult situations, intercultural competencies could be helpful for an adequate patient orientation and to prevent unnecessary and ineffective generalization and stereotyping [9].

Dealing with economic factors

The question of the "futility" of medical measures must also be discussed in terms of economic factors. Due to various economic conditions, such as care capacities and the remuneration system, there is a risk that medical measures with no potential benefit for patients or that are not wished for by a patient could be carried out for financial reasons. Overtreatment or inappropriate treatment should be corrected primarily by correcting the triggering factors, such as misaligned incentives in the DRG system or overcapacities in the care system. Physicians can, however, help to reduce economically-induced overtreatment if they carefully examine the effectiveness and the benefit-harm ratio in individual cases.

The critical examination of the effectiveness and benefit-harm ratio of therapeutic strategies must, however, be clearly separated from considerations of an efficient, demand-oriented, and equitable allocation of resources or a limitation of health care expenditures. Whether a therapeutic strategy should not be offered to a patient because of a lack of potential benefit should be determined exclusively based on the possible benefit gained by the person concerned. Interventions with a low potential benefit should not be considered futile and withheld from patients only because they incur high costs or represent a less efficient use of resources [22].

However, the question of the adequacy of an intervention with very high cost and low benefit may provide grounds to review the effectiveness and benefit-harm ratio of a therapeutic strategy for a patient. A careful consideration of the potential benefits of medical measures may well contribute to the judicious use of limited health care resources where therapeutic strategies are not offered following an evidence-based, patient-centered review, due to lack of effectiveness or a very poor benefit-harm ratio, or when less costly alternatives are available.

Therapeutic decisions in the case of individuals who may not be capable of giving consent[11]

Decisions about the treatment of a patient are made in a shared decision making process between the physician and the patient. The treatment goal, therapeutic strategies and their indications, the patient's individual goals and ideas, their assessment of benefits and harms, and willingness to take risks must therefore be discussed between the physician and the patient. Only after such a discussion can the patient form their ultimately decisive

[10] For the communication of bad news in general, see [2; 16; 19]; for the principles of "serious illness conversation" see [3; 17; 15]. An improvement in the setting of realistic therapy goals, even in seriously ill patients who are very attached to life, through specific communicative skills is also shown in [7].

[11] BÄK [4] under No. IV.

will regarding treatment and the question can then be asked and answered as to whether the patient has decisional capacity or not.

In the case of patients who are capable of giving consent, the physician must take into account the currently expressed will of the appropriately informed patient, even if this does not coincide with the therapeutic strategies required from the physician's point of view. This also applies to the termination of medical measures that have already been initiated. Physicians should help patients who refuse medically-indicated treatment to reconsider their decision.

In the case of persons who may be incapable of giving consent, the patient's representative, i.e., the representative authorized by a power of attorney issued by the patient or the representative appointed by the court of protection, or if there is no such representative the spouse (as of 01/01/2023), must be involved in the discussion at an early stage.[12] These are obliged to give effect to the wishes and ideas of the patient with regard to the treatment. This includes both the individual goals and ideas of the patient and their assessment of benefits and harms and willingness to take risks, as well as the desire for, or rejection of, certain therapeutic measures. For this purpose, the patient's representative can draw on previously written or verbally expressed patient wishes. If these are not known, the patient's representative must act as the person concerned would presumably have done (presumed will). In determining the patient's wishes and ideas, the patient's representative should involve the patient's relatives and other persons of trust, insofar as this is possible, without delay. If there are indications of abuse or an obviously wrong decision on the part of the patient's representative, the physician should contact the court of protection.

If there is no patient's representative, the physician should inform the court of protection and suggest the appointment of a representative, who will then make the decisions in question together with the physician.

Therapy decisions in emergency situations

Of course, physicians also have the obligation to examine the effectiveness and the benefit-harm ratio of the available therapeutic strategies in emergency situations. However, due to the acute pressure to act and the limited information available about the medical situation, this is often initially possible only to a limited extent. In most cases, therefore, the emergency measures required from a physician's point of view are taken, provided this does not contradict the patient's will. If, in the case of a person incapable of making decisions, the patient's will is not known and there is no time to consult with the patient's representative or to ascertain individual circumstances, the physician may assume that the emergency measures indicated from the medical point of view correspond with the presumed will of the person concerned.[13]

Based on the diagnostic and prognostic information obtained as the situation progresses, a more reliable assessment of the effectiveness and benefit-harm ratio of the therapeutic strategies can be performed. Such an assessment must be guided by the patient's stated or presumed wishes for treatment, which should be determined jointly with the patient and/or, if necessary, with the patient's representative.

With a view to a possible future emergency, it should be clarified in advance, particularly in the case of frail and chronically ill persons – for example, in the context of an advance care planning discussion, whether life-sustaining measures are likely to be effective and (still) desired by the patient. The result can be documented in an emergency form. Such a form should be documented by a physician to ensure that only measures with a certain likelihood of effectiveness and with an acceptable benefit-harm ratio are taken [23].

4. Selected problem constellations

Particular challenges arise in situations in which the parties involved in making decisions about therapeutic strategies, be it within the medical team or between physician and patient, have divergent assessments regarding the achievability of a therapy goal or the evaluation of the effectiveness, contraindication, or benefit-harm ratio of therapeutic strategies ("futility" types 1 and 2). In the following, the physician's responsibility in the context of such decision conflicts will be presented.

a) Divergent assessments within the medical team

Before discussing with the patient a difficult therapeutic strategy, especially one that is controversial, the courses of action that are realistic from the physician's point of view must be defined either by the physician in charge or, if several physicians are involved in the therapeutic decision, through a collegial discussion. This can lead to different assessments of whether a therapeutic strategy is effective and (potentially) useful or how the benefit-harm ratio should be evaluated.

In this context, different assessments often show that, in addition to objectifiable medical knowledge, individual professional evaluations factor into the assessment. Such disagreements should be clarified within the team prior to the patient interview, especially with regard to the reasons for the different assessments and the points of consensus within the assessment. In the interest of transparency in medical practice, these aspects should be disclosed in the patient interview. Ethics consultation can be helpful in this clarification process.

b) Low-evidence decision

Another difficulty may arise if the evidence-based knowledge does not allow any clear statements to be made for the given case (see 3.2. above). Here, too, the physician and the patient must discuss how the limited available evidence is evaluated by the physician with regard to the current situation and the desired therapeutic goal, and what uncertainties exist in this regard. A clinical example in which such considerations are typical is the implementation of an aggressive therapy based on guidelines for curatively treatable younger patients in the case of an older patient with a life perspective that is already severely limited by their general frailty. Against this background, the physician must carefully consider which measures can contribute to achieving the therapeutic goal in this specific case and what the benefit-harm ratio is, including possible side effects or risks, and then discuss all options for which evidence is available, even if it is limited, with the patient.

c) Dealing with patients' desire for "maximum therapy"

Another conflict constellation can arise when treating physicians are urged by their patients to continue to achieve survival by all

[12] If there is no authorized representative or guardian, the spouse can represent the patient in health matters for a maximum period of 6 months as of 01/01/2023 (§ 1358 BGB, new). The principles for patient representation outlined in the text also apply to the representing spouse. The same applies to registered civil partnerships.

[13] See also BÄK [4] under No. IV.

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means in a situation that is, in actuality, hopeless and patients demand measures for this purpose that have no benefit or a very unfavorable benefit-harm ratio. In practice, this can be expressed, for example, by the desire for "maximum therapy" and for "everything to be done".

Behind such statements there may be both the patient's wish for a measure to be implemented, which, in the physician's opinion, cannot achieve a therapy goal ("futility" type 1) or which is contraindicated, and the wish for therapeutic measures which have a very unfavorable benefit-harm ratio ("futility" type 2). In such cases, this should be addressed sensitively and appropriately by the physician in a detailed discussion.

The first step in the discussion is to clarify the extent to which the patient's considerations are based on false assumptions, and whether they are sufficiently aware of the medical options for palliative support and care.

However, such wishes may also be motivated by the fact that a patient has not yet been able to process the information that has been received in an emotionally appropriate manner. This applies, in particular, if the goal of the desired measure – e.g., a curative treatment – can no longer be achieved ("futility" type 1), with the result that the corresponding measures may no longer be offered. An example of this is a diffusely metastasized malignant tumor with resulting rapidly progressive liver function failure. In such constellations, the patient must be supported in an empathetic manner in successively developing a realistic understanding of their own health situation. If the patient continues to insist on such measures, the physician should refuse to carry out the measures due to their professional responsibility toward the patient.

In other constellations, the desire for certain therapeutic measures with a very unfavorable benefit-harm ratio ("futility" type 2) may be due to the fact that the patient, aware of this problem, still wants to achieve certain goals that are of existential importance for them personally (e.g., witnessing a certain family event, saying goodbye to or reconciling with a close person, etc.).[14] If the patient's assessment of the situation is realistic and the patient's divergent assessment is understandable, the patient's request should be complied with if possible.

d) Dealing with requests from patient representatives/relatives for "maximum therapy"

In practice, it may happen that the patient's representative and/or relatives – independent of the patient – urge the implementation of therapeutic measures that have no benefit or a very unfavorable benefit-harm ratio.

In the case of persons capable of giving consent, the will of the patient alone is decisive for the determination and implementation of the therapeutic strategy. In the case of persons who are no longer capable of giving consent, the patient's representative is bound by the declared or presumed will of the person concerned. This also applies to the common case in which relatives or other close persons represent the patient. They must also ascertain the patient's will to the best of their ability (cf. above "Therapeutic decisions of individuals who may not be capable of giving consent").

The considerations outlined under c) also apply with regard to dealing with requests from the patient's representative/relatives for "maximum therapy".

If the desired measures are ineffective (the desired therapeutic goal cannot be achieved or cannot be achieved with these measures, "futility" type 1) or are contraindicated, they may not (or no longer) be offered by physicians.[15] The patient's representative, especially if relatives or close persons are involved, must be informed about this in a sensitive manner and be made aware of the treatment alternatives that may be available. In individual cases, it may be justifiable to continue a measure that is no longer useful for the patient for a limited period of time in order to give the relatives time for the farewell process, provided this is not associated with unreasonable burdens for the patient and does not conflict with the patient's will.[16]

If the representative wishes to pursue a therapeutic strategy with a very unfavorable benefit-harm ratio ("futility" type 2), this should also not be offered as a rule. At most, it could be considered if there are clear and reliable indications that the patient has expressly desired or would desire the therapeutic procedure and has a clear understanding of the poor benefit-harm ratio. The determination of such a patient's will therefore requires special care.

In difficult decision-making situations, an ethics consultation may be useful. In the event of a persistent disagreement with the patient's representative that cannot be resolved in any other way, the court of protection must be involved in order to clarify which of the therapeutic strategies that are available and effective from the physician's point of view correspond to the patient's will.

If relatives or next of kin are not authorized to represent the patient, they do not have a legally protected right to make decisions when determining the therapeutic strategy. Nevertheless, they can be of great importance in terms of providing information when determining the patient's will. In this respect, their statements must be taken into account both ethically and legally by the patient's representatives and the treating physicians. Therefore, demands by these persons for "maximum therapy" can de facto lead to equally challenging situations. Physicians should then proceed in a similar manner, taking into account that providing support to relatives in keeping with the patient's wishes is also the task of the physician, provided that the involvement of the relatives does not contradict the will of the patient. In difficult decision-making situations, an ethics consultation may be useful, or the involvement of the court of protection may be necessary.

e) Dealing with the wishes of parents of underage patients for "maximum therapy"

In the case of underage patients, responsibility for medical treatment on the patient's side generally lies with the legal guardians, i.e., usually with the parents, who must decide in the best interests of their child. However, physicians must always actively involve their underage patients in the information and therapy planning processes, even if they are not regarded as capable of insight and judgment.

The parent-child relationship in the context of medical treatment is characterized not only by the special responsibility of parents for their child, but also by its usually high emotional intensity. This shapes another problem constellation. Parents' concern and their idea of parental responsibility to unconditionally care for their child can lead to their "not wanting to give up", even in

[14] See also BÄK/ZEKO [5] under III.2.
[15] See 3.1.
[16] See also BÄK/ZEKO [5] under III.2.

medically hopeless situations, and to oppose a physician's suggestion for a change of treatment goal and treatment limitation, and to demand measures that have no benefit or a very unfavorable benefit-harm ratio or that are contraindicated. For example, in a child with diffuse metastatic malignancy, after multiple recurrences and exhaustion of all oncological options, another change of therapy with a curative treatment goal may definitely be futile in advance ("futility" type 1). Furthermore, in the case of childhood neurodegenerative diseases with an undoubtedly unfavorable course, parents may want to take advantage of every opportunity to "do something" and demand a continuation of stressful therapies, even in cases in which only minimal treatment effects may be expected that do not relevantly improve the child's overall situation ("futility" type 2).

In discussions with parents, it is the task of physicians to enable the parents to make a decision in the best interests of the child. This includes, in particular, integrating other dimensions of the child's well-being into the consideration processes, in addition to life support, and discussing the potential benefits and harms of treatment for the child. In addition, the cultural and religious background and the resulting ideas of well-being and family responsibility must be given space in the discussion to enable a decision that integrates both the medical facts and their potentially differing assessments. In the case of ineffective and contraindicated therapies, as well as therapies with a very unfavorable benefit-harm ratio, particular clarity is necessary in the statements of physicians.

Especially in the case of older minors, conflicts may arise between them and their parents. For example, an adolescent oncology patient may refuse a new chemotherapy after several relapses of their acute leukemia, while the parents may insist on it. Conversely, however, the adolescent may also wish to receive "maximum therapy" even though it is ineffective from a medical point of view or has a very unfavorable benefit-harm ratio, while the parents, knowing this, may not be in favor of it. In these problem constellations, a solution should be sought in a discussion which particularly takes the parents' and the adolescent's attitude into account (mutual concern, "fighting/not giving up" for the other) and enables parents to continue to support their child in the course of the disease in the child's best interests. Whether the authority to decide ultimately lies with the parents and/or the adolescent must be determined on a case-by-case basis. The decisive factor is whether the adolescent, according to age and individual mental and moral maturity and capacity for discernment, can assess the significance and implications of undertaking or discontinuing medical treatment, weigh the advantages and disadvantages, and make a decision on this basis. But even if the adolescent is capable of making a decision in this sense, it is legally disputed whether the parents' consent to the treatment (e.g., to renewed chemotherapy) is also a legal requirement. In any case, physicians should endeavor to work toward a consensual solution that corresponds to the will of the adolescent and their parents. If this is not possible, and there is a risk to the child's well-being, physicians should involve the family court.

5. Summary and recommendations

With this statement, ZEKO would like to contribute to a more precise understanding of the various constellations of "futility" and to contextualize them within decision-making regarding medical treatment. It wants to offer orientation to physicians for situations in which possible measures appear medically questionable, and also point out the physician's tasks in the shared decision making process with patients in such situations.

- The unclear and controversial terms "futility of medical measures/medical futility" should be replaced by a more precise designation of the different constellations: Therefore, ZEKO recommends that a distinction be made between **ineffective** therapeutic strategies ("futility" type 1), **contraindicated** therapeutic strategies, and therapeutic strategies with a **very unfavorable benefit-harm ratio** ("futility" type 2).
- The medical assessment of therapeutic strategies with regard to effectiveness, benefit and harm for the individual patient is a legitimate medical task. While, as such, it is an expression of the physician's therapeutic freedom, it must, however, be carried out in a professionally responsible manner for the benefit of the patient. The associated considerations must be made carefully and should be transparent with regard to the evaluation standards.
- The assessment of a therapeutic strategy or measure must be carried out by the physician on the basis of available scientific evidence and with a view to the specific patient. Dealing with a lack of reliable evidence and with low probabilities of success in the assessment of effectiveness or the benefit-harm ratio is a challenge and requires special diligence.
- The treatment goals that are realistically achievable for a patient must be identified. This includes identifying the therapeutic strategies consisting of potentially effective measures together with the treatment goals that can be achieved by them, and distinguishing them from the ineffective ones. Clearly ineffective therapeutic strategies, as well as contraindicated measures, must not be offered. If such a measure is nevertheless requested by the patient, the physician should refuse to carry it out.
- A benefit-harm assessment must be carried out for the effective therapeutic strategies. The assessment of benefits and harms must be based on the treatment goal discussed with the patient and take into account the patient's preferences and values.
- Whether a therapeutic strategy should not be offered to a patient because of a lack of potential benefit should be determined exclusively based on the possible benefit for the specific patient. Therapeutic strategies with a low potential benefit should not be considered futile simply because they incur high costs or the associated use of resources is inefficient.
- In order to prevent patients from being deprived potentially useful treatments from the outset, physicians must ensure that medical information also includes measures whose appropriateness is medically disputed. Only if there is no reasonable doubt that a therapeutic strategy is ineffective or contraindicated, or has a very unfavorable benefit-harm ratio, does the patient need to be informed of this only on their request. In all other cases, the consideration, including the assessment of the probability of success of a therapeutic strategy for the individual patient, must be explained transparently in the discussion. This forms the basis for shared decision making.
- Communication about the assessments and considerations in the evaluation of effectiveness and the benefit-harm ratio should create transparency about the individual professional assessments used by physicians so that patients can develop their own attitudes and decisions.

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- If the treatment goal desired or hoped for by the patient is not (or no longer) achievable, this often represents bad news for the patient, which must be communicated appropriately in this difficult situation.
- The desire for maximum therapy in cases that seem medically hopeless can be motivated by different factors: e.g., by fear of medical undertreatment, various forms of coming to terms with one's own end of life, or even by certain religious beliefs. In intercultural contexts, additional difficulties may arise due to language barriers or concerns about becoming a victim of discrimination. In such cases, the development of intercultural competencies can be helpful in strengthening patient care, oriented toward individual needs.
- If a patient is incapable of giving consent, the considerations of ineffectiveness, contraindication, and the very unfavorable benefit-harm ratio must be discussed with the patient's representative as the patient's advocate. Communication with patient representatives and relatives requires special care in order to be able to determine the patient's will appropriately in these situations as well.
- Situations in which physicians consider not (or no longer) offering therapeutic strategies and measures because they are ineffective or contraindicated or have a very unfavorable benefit-harm ratio can lead to conflicts with patients and/or relatives. An ethics consultation can be helpful here. Therefore, ethics consultations should be as easily accessible as possible.
- Even in emergency situations, the ineffectiveness, contraindication, and very unfavorable benefit-harm ratio of therapeutic strategies and measures, as well as the patient's will, must be inquired after, albeit to an extent appropriate to the urgency of the situation.

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