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PAPER

# Evaluating a patient's request for life-prolonging treatment: an ethical framework

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## ABSTRACT

Contrary to the widespread concern about over-treatment at the end of life, today, patient preferences for palliative care at the end of life are frequently respected. However, ethically challenging situations in the current healthcare climate are, instead, situations in which a competent patient requests active treatment with the goal of life-prolongation while the physician suggests best supportive care only. The argument of futility has often been used to justify unilateral decisions made by physicians to withhold or withdraw life-sustaining treatment. However, we argue that neither the concept of futility nor that of patient autonomy alone is apt for resolving situations in which physicians are confronted with patients' requests for active treatment. Instead, we integrate the relevant arguments that have been put forward in the academic discussion about 'futile' treatment into an ethical algorithm with five guiding questions: (1) Is there a chance that medical intervention will be effective in achieving the patient's treatment goal? (2) How does the *physician* evaluate the expected benefit and the potential harm of the treatment? (3) Does the patient understand his or her medical situation? (4) Does the *patient* prefer receiving treatment after evaluating the benefit-harm ratio and the costs? (5) Does the treatment require many resources? This algorithm shall facilitate approaching patients' requests for treatments deemed futile by the physician in a systematic way, and responding to these requests in an ethically appropriate manner. It thereby adds substantive considerations to the current procedural approaches of conflict resolution in order to improve decision making among physicians, patients and families.

## BACKGROUND

Empirical studies indicate that decisions to limit life-prolonging treatment precede up to two-thirds of all non-sudden hospital deaths in Western countries.<sup>1</sup> The most recent European studies show that physicians inform less than half their patients about their decisions to forgo certain treatments.<sup>2-3</sup> While physicians frequently share decisions to limit life-prolonging treatment with patients who prefer comfort care, they often do not inform patients who request life-prolonging treatment.<sup>3</sup> In a US study conducted in 1995, 80% of physicians reported unilaterally withholding or withdrawing life-sustaining treatment that they considered futile, sometimes without the knowledge or consent of the patient, and sometimes regardless of the patient's objec-

tions.<sup>4</sup> There is considerable controversy about the circumstances in which a physician may legitimately decide on behalf of a competent, critically ill patient without consent, or even without notifying the patient. 'Medical futility' is a common justification that is used when physicians decide against life-prolonging interventions without informing the patient. The concept of futility emerged in the 1980s as an attempt to objectively define what constitutes treatments that physicians are not obliged to provide. It soon became clear, however, that the meaning of 'futility' is ambiguous, since the term confounds morally distinct cases. Futility may refer to treatments that are not going to work at all, for example, defibrillating an asystolic patient (physiological futility). The term 'futility' is also used for effective treatments that the physician may consider inappropriate because they have an unfavourable benefit-harm ratio, for example, treating a patient with an aggressive chemotherapy with only marginal benefit and severe side effects (qualitative futility). In the first case, the physician is not obliged to offer the treatment or to seek patient consent for withdrawal, since ineffective treatments lie outside of standard medical care.<sup>5</sup> Yet, in the second case, simply calling a treatment futile obscures the underlying value disagreement about the legitimate ends of medical treatment and the fact that the patient and the physician may assess the benefit-to-harm ratio differently. Therefore, the concept of futility is not sufficiently robust to meet the ethical and clinical demands of being an aid to decision.<sup>6</sup> Critics of the concept of futility urged a move away from a substantive definition of futility.<sup>7</sup> Instead, they recommended a procedural approach that supports sound decision making, that is able to mediate between the two parties who hold diverging positions.<sup>8-11</sup> Procedures that attempt to resolve disputes over futility include policies that have been adopted by a number of hospitals in the US and that have been endorsed by the American Medical Association, as well as case discussions and mediation within hospital ethics committees.<sup>9</sup> While procedural approaches ideally ensure that every voice is heard, thereby arriving at a consensus about the right decision, they have been criticised for being prone to support the hospital's interests<sup>10</sup> and not being transparent on the grounds of their decisions—they may, for example, not adequately distinguish between futility and rationing.<sup>12</sup> Since ethics support services have some experience with mediating

conflicts, they have been called upon for resolving disagreements about futile treatment. However, in many situations when conflicts about futile treatment arise, there is insufficient ethical support either because it is not offered by the institution or not utilised by the providers. Even with a defined process for conflict resolution, inevitably, decisions must rely on some set of criteria for action. Therefore, the ethical framework we propose can either supplement procedural approaches for conflict resolution or help the individual clinician in responding to patients' requests for 'inappropriate' treatments. We hope that the utility of this conceptual framework will be that it combines the relevant ethical arguments in a structured way, thereby guiding the persons involved through the decision process. The evaluation of this algorithm in routine clinical care is planned as a second step.

### Five guiding questions to approach conflicts about limiting treatment

Decisions about medical treatments require both medical expertise and value judgements. Therefore, a dissent between patient and physician about what is the best course of action can result either from medical (factual) or normative (evaluative) aspects of the decision. One main goal of this article is to distinguish these two dimensions and to propose practical criteria that can guide decisions about patients' requests for life-prolonging treatments. These criteria are: the expected **effectiveness of the intervention** in question, the **benefit-harm ratio of the intervention**, and the **patient's understanding of his or her medical situation**. Under conditions of scarcity, **resources required for the treatment** may also play a role in the decision, especially if the treatment has a low likelihood of success or an unfavourable benefit-risk ratio. These criteria need careful evaluation and are therefore built into an ethical decision model with five guiding questions. The starting point is a situation in which a competent patient requests a treatment that might be perceived as inappropriate by the healthcare team (figure 1). We do not include proxy requests for incompetent patients because surrogate decision making requires other ethical considerations and decision processes. However, the family is often involved in the patient's decision-making process and is, therefore, considered throughout the decision pathway.

#### 1. Is there a chance that medical intervention will be effective in achieving the patient's treatment goal?

In general, medical decisions should be based on broad goals of care and the patient should—with the physician's support—play a key role in determining what those goals shall be. Therefore, the treatment under consideration has to be evaluated with regard to its ability to achieve the patient's treatment goal. Whether the treatment goal should be a cure, prolonging life or comfort care needs to be negotiated between the patient, family and the provider, and might change over the course of the disease. Offering treatment that is ineffective with respect to a certain treatment goal violates the rules of good clinical practice. However, in practice, predicting the outcome of an intervention can be difficult, because general success rates in defined study populations do not allow for prediction with certainty about the effectiveness in the specific medical situation of an individual patient. Furthermore, effectiveness as a criterion provides an incentive for setting a statistical threshold, as most treatments are effective only in a certain percentage of cases. Schneiderman *et al* suggested that physicians should not offer a treatment if empirical data shows that the treatment had a <1 in 100 chance of benefiting the patient.<sup>14</sup> Apart from the difficulties in breaking

down the statistics to individual patients and their individual risk profiles, this threshold might not be accepted by a substantial portion of patients who think that a 1% chance of success is still better than having no chance at all.<sup>15</sup>

Nevertheless, it is still an important first step to separate the rare cases (in which the treatment will be ineffective) from those cases in which success might be against the odds, but not entirely impossible. In the former case, an intervention can be ineffective either because a treatment does not work physiologically for the stated purpose, or has already proven to be ineffective in the individual patient.<sup>16</sup> An example is a patient's request for continuing a chemotherapy regimen during which tumour growth was excessive, even though continuing the chemotherapy would neither prolong the patient's life nor relieve tumour-related symptoms (physiological futility). If there is no chance that the requested intervention will achieve the patient's treatment goal, the physician should not offer the intervention. Instead, the physician should initiate a discussion with the patient and the family about alternative and more realistic treatment goals. This requires that the patient receives full and open information about his or her medical situation and the prognosis according to different treatment options. It is often observed that, over time, patients tend to adjust their unrealistic treatment goals.<sup>17</sup>

#### 2. How does the physician evaluate the benefit-harm ratio of the treatment?

If there is a chance that the requested treatment will achieve the patient's treatment goal, then the ethical obligations of beneficence and non-maleficence require that the physician initially evaluates the benefit-harm ratio independently of the patient's wishes. This evaluation demands not only medical expertise, but also value judgements about acceptable benefits and harms. Based on this evaluation, the physician can then enter into further discussions with the patient about treatment goals and the benefits and harms of different interventions from the patient's perspective.

While in theory the benefit-harm ratio is a continuous variable ranging from a clear net benefit to a clear net harm, it seems helpful for our purposes to distinguish three different prototypical situations that have important implications for further steps in evaluating the patient's request for a certain treatment (see figure 1, question 2):

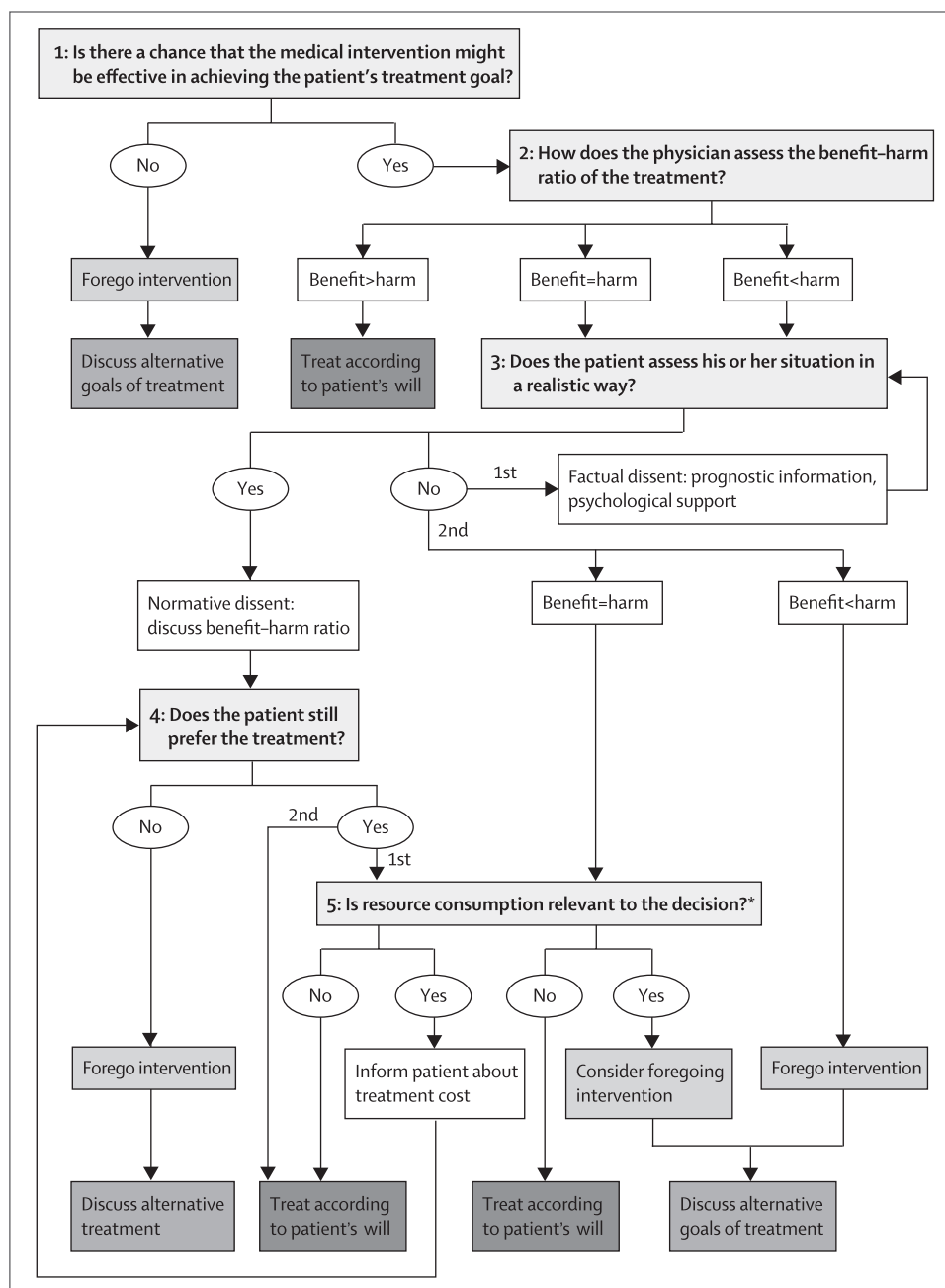
(A) **Benefit > harm**: If the benefits outweigh the potential harm, the physician should offer the treatment requested by the patient, even if the net benefit is small. In this case, the physician's beneficence-based obligations converge with the patient's preferences. An example could be a therapy with moderate side effects that might prolong the patient's life for another 2 weeks.

(B) **Benefit = harm**: There are cases in which benefits and harms seem to be in balance, either because the expected benefit is not very likely to be realised or because the harms counterbalance the benefits.

(C) **Harm > benefit**: The harms exceed the expected benefits of the intervention. This would be the case, for example, if a patient with progressive cancer disease under third-line chemotherapy wanted to switch to another chemotherapy regimen with considerable toxicity or risk of immunosuppression, in which the new regimen is very unlikely to change the course of the disease (qualitative futility).

In the last case (C) there is a conflict (and in the second case at least a tension) between the physician's obligation to respect patient autonomy on the one hand, and the physician's

**Figure 1** Systematic ethical decision model with five guiding questions for situations in which patients request a treatment that might be perceived as inappropriate by the healthcare team (see explanation of the guiding questions in the text). \*Implementing this last step of considerations requires a broader societal consensus about the physician's role in making resource-sensitive decisions at the bedside. Figure reprinted from Winkler *et al.*<sup>13</sup> Copyright (2011), with permission from Elsevier.



obligations of beneficence and non-maleficence on the other hand. How can the physician respond to this conflict? First, identifying the source of the dissent will help the physician to understand why the patient prefers active treatment.

### 3. Does the patient assess his or her medical situation in a realistic way?

The source of the dissent between physician and patient about what is the best course of treatment can either be located on a *factual* level (understanding of the medical situation) or on a *normative* level (balancing benefits and burdens). If the patient has a realistic understanding of the medical situation, the physician should enter into a deliberation with the patient about appropriate treatment goals and the benefits, risks and costs of the different treatment options (see question 4).

There are two main reasons why patients may not assess their medical situation in a realistic way: insufficient information or

denial. Patients are often not well informed about their situation and tend to see their prognosis in overly optimistic terms.<sup>18</sup> Reasons for this misunderstanding certainly can be that physicians overestimate survival, fail to explicitly explain the prognosis or palliative goal of the treatment, or do not involve patients in decisions on limiting treatment.<sup>5 19 20</sup> The physician should, therefore, explain the situation, provide prognostic information and psychological support to enable the patient to develop a more realistic understanding of his or her situation.

In some cases, however, the unrealistic assessment of the situation is a consequence of a denial reaction by the patient.<sup>3</sup> To date, the definitions of denial lack consensus as to whether denial is unconscious or conscious, whether it is a state or a trait, and whether it is a pathological mechanism of ineffective self-defence or an adaptive strategy to protect oneself against overwhelming events and feelings.<sup>21</sup> Still, all concepts imply that a coping strategy of denial leads to an inaccurate assessment

with respect to feasible treatment goals. Certainly, many patients become better at coping with their disease—oftentimes with the support of psychological or palliative care consults.<sup>22</sup>

However, the more the harms of an intervention outweigh its benefits, the higher are the demands on patients' informed understanding of their situation. We therefore suggest two different strategies depending on the physician's benefit-harm evaluation, if the patient is in persistent denial despite counselling and psychological support.

(A) If the patient runs the risk of having his or her denial cause more harm than good, the physician has good reasons to give the beneficence-based obligations priority over the patient's wishes, which will justify a unilateral decision not to offer the requested treatment. It is one of the physician's primary obligations to protect patients from burdensome and potentially harmful decisions that are not based on a realistic understanding of the situation—and which the patients might regret afterwards when they realise that it was based on false hopes. We are aware that the denial argument may be abused to ignore the patient's wishes because they deviate from the physician's recommendation. It is therefore important for a psychologist or psycho-oncologist, who is experienced in assessing coping behaviours and defence mechanisms, to evaluate the denial. This evaluation is often based on whether the patient can or cannot address his or her need for the denial of the informed understanding.<sup>23</sup> In addition, it can be helpful to involve the family in order to learn about the patient's hopes and values. With this information, the physician might succeed in developing goals with the patient in the near future that can realistically be achieved.

(B) If the patient is in denial, and harms and benefits are just about balanced—according to the physician's judgement—the beneficence-based obligations to withhold the requested treatment are not as strong. Therefore, the physician has more discretion whether he complies with the patient's wishes for active treatment or not. In this situation, it seems ethically legitimate to take the cost of care into consideration (elaborated in question 5).

#### 4. Does the patient prefer treatment after evaluating the benefit-harm ratio?

If the patient can assess his or her situation in a realistic way the physician should explain their own benefit-harm assessment (see question 2). The physician should empower the patient to not simply follow unexamined preferences, but instead to make a well-informed decision that is coherent with the patient's values and preferences. Whether the low odds of the benefits justify a trial of treatment, or whether an effect counts as a genuine benefit, involves value judgements. Studies show that a person's assessment of treatment options change as the person's health deteriorates: patients with advanced diseases are much more likely to opt for burdensome treatment with a minimal chance of benefit than healthy people would, including medical and nursing professionals.<sup>24–26</sup> Engaging in a joint deliberation about the worthiness of health-related values and outcomes (a deliberative model of the physician–patient relationship<sup>27</sup>) shall enhance patient autonomy: If the patient still prefers the requested intervention after this deliberation, the physician has good reasons to comply with the patient's wishes. However, if the intervention requires a lot of resources (either financial or personal), the physician should inform the patient about the resource consumption of different treatment options, so that resource consumption can become part of the patient's deliberation.

#### 5. Is resource consumption relevant to the decision?

All healthcare systems face the challenge of increasing demands for healthcare within limited financial budgets. Assuming that setting limits is inevitable, an explicit, rule-based rationing process is preferable to implicit, case-based rationing at the bedside.<sup>28</sup> Still, even the best consensus-based rationing guidelines will not be able to completely eliminate bedside rationing, since guidelines will never cover all medical areas and will have to be interpreted and applied to each individual case. Actually, some discretion appears to be desirable, for it allows the physician to do justice to the particularities of individual cases.<sup>29</sup>

It therefore seems ethically mandated to consider the required resources in medical decision making—to protect the resources of the individual, third-party payers or the community from ill-founded spending. While it is uncontroversial that physicians should always minimise costs while realising the goal of care, it is debated on what grounds patients and physicians should refrain from costly treatments that might result in only a minimal benefit for the patient.<sup>30–32</sup> Here, we delineate situations in which autonomy-based reasons prevail (A, below) from those in which cost considerations could play a decisive role in the decision (B, below).

(A) If a patient with a realistic understanding of the medical situation requests a treatment that—in the physician's judgement—has a questionable or nil net benefit, the physician should inform the patient that everybody in the healthcare system bears some responsibility for cost-sensitive decisions. The physician should point out to the patient that the requested treatment does provide only a small or no net benefit in this situation, and a lot of resources could be saved if the patient would not insist on the treatment. As a result, competent patients are invited to factor costs into their deliberations, however, they should ultimately be free to opt for the expensive treatment strategy. Hence, in this case, sound autonomy-based reasons take precedence over cost considerations at the bedside.

(B) If patients lack a realistic understanding of their medical situation, and the benefit-harm ratio of the treatment is neither clearly positive nor clearly negative, however, the required resources could play a decisive role. As long as the treatment is inexpensive, the physician may offer it, even if it provides a questionable benefit. However, if the treatment draws heavily on the resource pool (financial, material or staff), cost considerations may justify a unilateral decision to withhold the requested treatment since resource consumption is counter-balanced against neither a clear net benefit nor by sound autonomy-based reasons on behalf of the patient.

It is controversial whether clinicians should inform their patients when they withhold interventions based on cost considerations, and we also acknowledge that healthcare systems differ when speaking of the cost of care, especially with respect to different cultures. For example, physicians in Europe report that they did ration health services on the basis of some small expected benefit, low chances of success and low quality of life.<sup>33</sup> Problematically, it is often done in a covert and unpredictable manner. A more explicit process, like the one proposed here, contributes to the transparency of the underlying reasons of a decision against treatment, and to the patients' awareness about the costs of the requested care. In the long run, physicians should establish a 'culture' of responsibly discussing cost issues with their patients.<sup>34</sup> However, implementing this last step of considerations requires a broader societal consensus about the physician's role in making resource-sensitive decisions at the bedside.

**CONCLUSION**

This decision model contributes substantive criteria for a systematic deliberation in cases in which patients request treatments that are perceived as 'inappropriate' by the health-care team. The model is intended to honour the medical facts, the patient's autonomy and the clinical experience that 'inappropriate' treatments are often requested by patients in denial. It integrates the relevant arguments that have been put forward in the discussion about futile care.

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