End of life decisions in intensive care units - Ethical and legal aspects of patient autonomy and therapy restriction

Doctoral thesis

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1. Introduction

Being an anaesthetist and intensive care unit specialist I have often had to face legal and ethical issues that affect both physicians and patients. During healthcare interventions, making difficult decisions that may easily conflict with the interest of the physician or the patient is inevitable. A major cause is that the autonomy of patients within the operating theatre and the intensive care unit is impaired being transiently regarded as incapable for autonomy. At these important moments patients lack self autonomy and hence other people make decisions instead of them. At the end of life the necessity of previous will becomes increasingly significant as patient autonomy needs to be formalised. Naturally, problems are different during intensive care unit and anaesthesiology workflows. During anaesthesiology the processes of providing information, informed consent and extension of anaesthesia / surgical intervention may lead to ethically and legally demanding issues. In the intensive care unit statement the futility of medical care, and subsequent therapy restriction represent a significant burden for healthcare staff involved in the process.

Medical (bio-) ethics is also constantly facing new challenges as medical care options exponentially improve, however the financial capacity of healthcare systems are insufficient. The questions are the same everywhere in the world, although the answers vary depending on state of development of the society,

religion and the cultural habits of the society. Prior to providing my own recommendations for the these bioethical questions I would like to present the history of basic human rights including the right for autonomy, life and human dignity; this will be followed by an analysis and comparison of the national and international ethical and legal context.

My thesis will analyse autonomy of patients under two 'sensitive' conditions: first in informed consents in the context of anaesthesiology and then with respect to end of life decisions.

2. Aims

The aim of my studies was to assess patient rights during anaesthesiology-related and intensive care therapies, with the focus on the right for information, life and human dignity. Both studies were based on the same assumption stating that Hungarian physicians do not inform their patients adequately and that they make decisions in a paternalistic manner. Based on the hypothesis of our first study (related to anaesthesiology) the flow of information is readily measurable by the form and content of the informed consent form signed by patients prior to anaesthesiology and this also reflects on autonomy.

My second study mapped the practise of therapy restriction at national intensive care units. Based on our assumption, physicians establish a practise of their own for therapy restriction irrespective of

the opinion of the patient, relatives or other healthcare workers; this is also becoming routine in Hungary. As no such clinical study has yet been performed in Hungary, we have suggested that significant differences exist among the departments. The practical goal of my thesis is to introduce a new system that defines the forms of end of life decisions and connects patient status with the type of therapy restriction. My goal is to provide practical help for practising clinicians in the process of end of life decision making, which will also be acknowledged by society as well as ethicists and law specialists.

3. Methods

During our study we have been working with patient informed consent forms and we have compared and analysed the anaesthesiology informed consent forms of 36 hospitals and clinics in the Budapest based on 6 formal and 10 content-related aspects.

In our study dealing with end of life decisions, we have asked physicians working in intensive care units about their experience gained during their work. We have assembled a four-page questionnaire of 21 questions that has previously been validated by a pilot study. The questionnaires were sent out electronically through the internet to the registered members of the Hungarian Society of Anaesthesiology and Intensive Therapy; the anonymous responses were received either electronically or in printed format. The questions to be answered were either single or multiple choice, or used a six-grade (0-5) linear scale for evaluation. The Statistica software was utilised for statistical analysis [Statsoft. Inc (2008) data analysis software system; version 8.0 www.statsoft.com]. Statistical analysis was performed using non-parametric student-test and variance analysis. We have considered results as significant if $p<0.05$, or as tendency if $0.10>p\geq0.05$. For data representation we have used mean and SD values, while for discrete parameters frequencies were provided in percent format.

4. Results

It turned out during the analysis of anaesthesiology informed consent forms that there are several obstacles that block the appropriate flow of information during anaesthesiology examination performed before surgery. It can be stated based on the analysed formal parameters that the majority of the forms do not comply with international recommendations. Among hospitals, 61% utilise their proprietary informed consent form, and 19% comply with recommendations regarding the length (3-4 pages). Nevertheless most forms describe that informed consent has occurred in oral format (92%), provided the possibility to ask questions (86%) and the majority of forms are also signed by the physician who participated in the process of informed consent (94%).

It has been found during the analysis of the contents of the informed consent forms that the procedure is discussed in detail in only 39% of the cases, and alternative therapies are also rarely mentioned in the forms. Only 25% of the forms present the advantages and disadvantages of alternatives, 28% contain data on the risks of the planned intervention, while only 19% describe the chances of specific risks that may emerge. Among the forms 39% contain data on pre-surgical obligations while 19% discuss post-operative intensive care possibilities. The extension of the intervention is mentioned by 67% of the forms and 69% contain data on blood transfusion permits. Only 5% mention the possibility of

informed consent withdrawal and assigns a deputy decision making person.

The questionnaires concerning end of life decisions were filled out by 191 physicians working at intensive care units, their response rate was 26%. Among the respondents 48% were female and 52% were male. According to workplace, 23% of respondents work in hospitals, 27% in regional centres, 38% in city hospitals, 4% in specialised intensive care units and 8% in other places. Among respondents 27% have been working for less than 5 years, 21% between 6-10 years, 16% between 11-15 years and 36% for more than 16 years. Based on specialisation 62% of respondents had already finished their specialisation, among whom 9 have finished their specialisation abroad. Based on religion 26% of responders were actively religious, 40% were passively religious, while 16% considered themselves as atheist and 18% did not comment on this point.

Our questions were grouped around four themes: withholding of intensive therapy, withdrawal of already initiated therapy, the decision making process during therapy restriction and end of life decision subtype (DNR, therapy restriction, active shortening of the dying process) frequencies.

Concerning questions on withholding therapy we were interested as to what extent do autonomous patients, the relatives of non-autonomous patients, the number of free beds and the availability of required personnel and equipment influence patient

admission. The significance of the listed parameters were evaluated on a six-point (0-5) scale (0=not important, 5=very important). Based on our data we can conclude that Hungarian physicians only moderately take into account the will of patients and their relatives during admission to intensive care units (3.07+/-1.56). A similar degree of influence on patient admission is exerted by the number of free beds (3.03+/-1.40); while the availability of required personnel and equipment are considered less severe limiting factors (2.12+/-1.40 and 1.98+/-1.48) respectively.

Concerning the withdrawal of already initiated life sustaining treatment we were interested in which parameters influence it and to what extent the decision making process; in addition what is the exact method of therapy suspension.

In Hungarian practice the number of free beds (2.28+/-1.66), personnel and equipment requirements (1.85+/-1.45 and 1.39+/-1.44) weakly influence therapy withdrawal. The answers clearly indicate that in Hungary the treating physician decides over the life of the patient primarily based on long term life expectancy / quality of life (3.82+/-1.21). With minimal difference, the second most important parameter influencing therapy restriction was the current status of the patient (3.71+/-1.26). The patient's will is considered as moderately important (2.64+/-1.61) and physicians consider this less important than their own opinions (3.71+/-1.26). During the practise of therapy restriction the third most important parameter is the opinion of healthcare staff which is actually not regarded as very important by

treating physicians (2.36+/-1.41), while the least important is the opinion of relatives in considering therapy restriction (2.24+/-1.51).

The question we posed was what would the treating physician do if the patient's or the relatives' wish was to suspend therapy, but the physician still considers the patient's recovery as possible. Of note, only a small section of respondents (41.7%) would accept the patient's self autonomy if there are chances for medical recovery. The majority of physicians (54.5%) would rather ignore the patient's or the relatives' wish to suspend therapy in such cases. Our next question examined the case of futile medical intervention, what would the physician do if there was no chance for medical recovery of the patient. A minor fraction (7.6%) of intensive care unit doctors would not inform the relatives about the hopeless status of the situation (in such cases only a minority of patients have clear, vigilant mind) of these 2.2% would suspend while 5.4% would continue the inefficient therapy. For a significant proportion of physicians (83.8%) therapeutic inefficiency also appears through their communication. In such cases 63.8% of the respondents chose to continue the therapy if it was demanded by the patient or the relatives irrespective of their private opinions, while 20% of physicians would inform the patient or the relatives on the hopeless status of the situation and would discontinue the therapy irrespective of the opinion of the patient or the relatives.

After this we have searched for answers on how therapy restriction is actually performed by various intensive care units. Is

therapy withdrawal complete or partial once the decision has been made? Among respondents 11% replied that they do not perform therapy restriction while 30% discontinue all therapies at once. Among partial therapy withdrawals the suspension of vaso-active therapy is highest with 64% of respondents choosing this option; this is followed by the suspension of antibiotic treatment (47%). Restriction of multi-organ support therapies (nutrition, respiration, ventilation, and haemodialysis) scored equally among the respondents (18-22%).

Determining the frequencies of DNR, therapy restriction and active shortening of the dying process was focused on in the fourth topic. Based on our data it is clear that the DNR command (on 7.8%+/-8.49) and therapy restriction (8.3%+/-8.91) affect a relatively large proportion of patients. Average frequency of the active shortening of the dying process was the highest (9.4%+/-16.64). According to 80% of respondents neither the patients nor their relatives have initiated any form of therapy restriction. Among respondents 19.6% replied that there has been such a demand in their department during the past year and the request for therapy restriction emerged five times on average.

Our last point suggested the establishment of a professional protocol which was considered necessary by 93% of respondents.

5. Conclusions

My studies assessed the practical effectuation of patient's autonomy, through the aspects of informed consents in anaesthesiology and end of life decisions in intensive care units.

Since performing invasive medical intervention not approved by the patient is mayhem in legal terms, the approved informed consent is a basic condition of any medical intervention. During the analysis of anaesthesiology informed consent forms we have found that true to our assumption, providing information for the patients is not performed appropriately. Therefore there is inadequate cooperation in ethical and legal aspects; decisions are often made by the treating physician. Although the formal obligations of informed consent are more or less satisfactory, content-wise there are severe deficiencies, mostly in discussing alternative therapies, and the possibilities and chances of complications. Consent is only formal in such cases and does not comply with the ethical or legal aspects of medical regulations.

For the cases of end of life decisions we have also confirmed our assumptions stating that patients (relatives) receive insufficient information and that their decisions are not respected. Physicians make decisions in a paternalistic manner instead of together with the patients (relatives), their decisions are primarily based on life expectancy / quality of life and they largely neglect the opinions of patients, relatives and medical staff.

The strongest limiting parameter during patient admission (withholding of the life sustaining therapy) is the number of free beds, which corresponds with the results of major European studies. This limitation is regarded as more significant by younger physicians and in departments with few beds.

The number of free beds is also the most prominent limiting factor during therapy withdrawal, although here it is weaker than during patient admission. In therapy restriction the treating physician has the last word primarily deciding based on the patient’s life expectancy / quality of life rather than based on current patient status. This raises the possibility of discrimination favouring patients with fewer collateral diseases, of younger age and devoid of addictions. In contrast to European trends the decision is not made by the group involved in therapy, but the treating physician alone, largely neglecting the patient's or relatives' will.

In the execution of therapy restriction, the cessation of vaso-active and antibiotic treatments was most frequent, followed by the suspension of ventilation, haemodialysis and nutrition in equal frequency. According to this, Hungarian intensive care unit physicians do not comply with the generally accepted standard that patients should receive comfort therapy (substitution of fluids, nutrition, anaesthesia, sedation) following therapy restriction.

The proportion of end of life decisions in Hungarian studies is higher compared to data from European studies (Ethicus study, SAPS3 study), especially for the active shortening of the dying

process (9.4% vs. 2%). Through communication with the patient's relatives, restriction of the life sustaining therapy rarely appears, only every fifth Hungarian intensive care unit physician has received such a request.

How is it possible to harmonise the decision making process of end of life decisions with patient self autonomy, ethical and legal regulations? Currently this is the most important ethical-legal issue in intensive care therapy worldwide. Based on my research and perspective the first step towards this should be the improvement of patient autonomy. First of all the amelioration of information flow, informed consent forms and the dissemination of previous will (living will, advanced directives, substituted judgement) would make a significant step toward improvement.

The treatment of agonising patients with multi-organ failure requires medical competence and naturally this is accompanied with serious legal and ethical issues. The task of the physician in such cases is to align the medically required therapy to the status of the patient for each individual case.

I suggest the introduction of a novel classification from the aspect of decision choice options for intensive care physicians. The utilisation of this classification would enable the didactic separation and using requirements of different types of therapy restriction. The boundaries between different groups remaining flexible, simultaneously complying with contemporary scientific development and the financial capacity of the healthcare system. This is referred to

as end of life triage; with the use of this classification patients in agony (with organ failure) may be classified into three groups.

The first group contains patients whose organ failure can effectively be treated as we possess medical techniques required for the organ's functional supplementation or restoration (pacemaker implantation, haemodialysis procedures etc.) and hence proper quality of life is ensured for several years for the patients.

The second group is composed of patients in whom organ function restoration can not be fulfilled (patients with chronic disease reaching the final stage of the disease), for whom intensive (organ supplementing) therapy should not be initiated. For this group of patients (and their relatives) the aim is to reach the available maximal level of comfort, alleviation of suffering, and the treatment should be performed by a terminal stage palliative hospice institution rather then an intensive care unit.

The third group of patients with organ failure is composed of those in whom organ failure is not likely to be reverted due to their severe status (multi-organ failure), lack of causal therapy; and yet it can not be stated that there is no chance for restoring the patient's condition. For these patients curative intervention must be attempted with the available methods (supportive therapy) and the responses of the patients must continuously be observed. If the condition does not improve despite therapy and organ failure further aggravates making the medical intervention futile then there is need for therapy withdrawal and the initiation of comfort therapy.

Decisions made according to this end of life triage should not be executed by individuals but rather a committee involving physicians, assistants and physiotherapy specialists contributing to the therapy. Since during the process of agony the patient's conscious mind is not available, the relatives must be informed and their involvement in the decision making of therapy restriction can not be circumvented. Therapy withdrawal or withholding must not affect the patient's anaesthesia or sedation and also fluid and nutrient supplementation must be provided thus attempting to alleviate the torment of the patient and the relatives. From my perspective along with improvements in medical techniques and advancing intensive care unit studies (death forecasting score system, quality of life tests) the proportion of patients destined for death will decrease while the ratio of survivors will increase in the future.

6. List of personal publications

6.1 Publications related to doctoral thesis

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3. **Zubek L**, Élő G**:** Életvégi döntések magyarországi gyakorlata az intenzív osztályokon. *Aneszteziológia és Intenzív Terápia* 2009;39(S1):EA8.
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6. **Zubek L**., Pénzes I.: Az orvosnak is vannak emberi jogai? (Az emberi jogok vonatkozásai az egészségügyi dolgozókra) *Aneszteziológia és Intenzív Terápia* 30. Évf. A MAITT 30. Nemzeti Kongresszusa Előadás-Kivonatok 56. 2000

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