



INTRODUCTION PART TO THE ESPEN GUIDELINES ON ENTERAL NUTRITION

Ethical and Legal Aspects of Enteral Nutrition

U. Körner^{a,*}, A. Bondolfi^b, E. Bühler^c, J. MacFie^d, M.M. Meguid^e,
B. Messing^f, F. Oehmichen^g, L. Valentini^h, S.P. Allisonⁱ

^aCharité—Universitätsmedizin Berlin, Berlin, Germany

^bCentre lémanique d'éthique, Batiment de Provence, Lausanne, Switzerland

^cGeriatrischer Schwerpunkt, Städtische Kliniken Esslingen, Esslingen, Germany

^dDepartment of Surgery, Scarborough Hospital, Scarborough, UK

^eDepartment of Surgery, Upstate Medical University, Syracuse, USA

^fService d'hépatogastroentérologie et d'assistance nutritive, Hôpital Lariboisière, Paris, France

^gAbt. Intensivrehabilitation, Bavaria Klinik Kreischa, Kreischa, Germany

^hDepartment Gastroenterology, Charité—Universitätsmedizin Berlin, Berlin, Germany

ⁱClinical Nutrition Unit, University Hospital, Queens Medical Centre, Nottingham, UK

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Summary European ethical and legal positions with regard to EN vary slightly from country to country but are based on a common tradition derived from Graeco Roman ideas, religious thought and events of the 20th century. The Hippocratic tradition is based on 'beneficence' (do good) and 'non-maleficence' (do no harm). Religious thinking is based upon the presumption of providing food and drink by whatever means unless burden outweighs benefit. The concept of 'autonomy' (the patients right to decide) arose following in the decades after the Second World War and is enshrined in Human Rights law. The competent patient has the right to participate in decision making and to refuse treatment although the doctor is not obliged to give treatment which he or she considers futile or against the patient's interests. The incompetent patient is protected by law. The fourth principle is that of 'justice' i.e. equal access to healthcare for all.

The law regards withholding and withdrawing treatment as the same. It also defines the provision of food and drink by mouth as basic care and feeding by artificial means as a medical treatment. It requires doctors to act in the best interests of the patient.

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*Corresponding author.

E-mail address: uwe.koerner@charite.de (U. Körner).

Introduction

These guidelines address some of the ethical and legal issues which are increasingly part of the clinical decision-making process involved in providing nutrition support. The European ethical tradition is based on the Graeco–Roman ideas, refined by religious considerations and further developed during the 20th century.

Q: What is the basis for the European ethical tradition in Medicine?

A: The Hippocratic ethical code is based on 'beneficence' i.e. do good, and 'non-maleficence' i.e. do no harm. This tradition was, however, paternalistic, and it was not until the 20th century that the notions of 'autonomy' i.e. the patient's right to decide, and 'justice' i.e. equal rights for all, were introduced. Religious ideas have also contributed.

Comment: The Hippocratic tradition, refined by Roman physicians, was based on the 'do good but do no harm' principles. It also embodied the notion of confidentiality but eschewed autonomy, and was motivated by 'philanthropia' i.e. do good in order to preserve the physician's reputation. Hippocrates wrote 'Give necessary orders with cheerfulness and sincerity, turning his (the patient's) attention away from what is being done to him ... revealing nothing of the patient's future or present condition' In the 1st century AD, Scribonius Largus, physician to the Emperor Claudius, took a step nearer our modern attitude by encouraging physicians to base decisions on Humanitas, that is love of mankind, and on Misericordia, or mercy. Enteral feeding has a 500 yr history in Europe and its principles were defined by John Hunter in 1793, when he wrote concerning a patient with paralysis of the swallowing muscles. 'It becomes our duty to adopt some artificial mode of conveying food into the stomach, by which the patient may be kept alive while the disease continues'. The concept of 'starve a fever and feed a cold', prevalent since Galen in the 4th century AD, was abandoned in the 19th century, when several authors emphasised the importance of feeding in medical care.

As a new principle the respect for patient's autonomy arose in the seventies of the 20th century. The competent patient now has the right to participate in all the decision-making concerning his treatment, and the law provides safeguards for the patient who is 'incompetent' i.e. incapable of understanding or making decision. The paternalistic approach of Hippocrates was therefore super-

seded by that of autonomy. On the other hand, despite a number of recent legal cases, the doctor is still not obliged to submit to pressure by the patient, relatives or others, to give treatment which he or she believes to be futile or against the patients' interests i.e. the burden or adverse effects outweigh benefit. European religious traditions, both Christian and Jewish, are sometimes erroneously supposed to favour preservation of life at all costs. In fact, Roman Catholic teaching is clear that there should be a presumption in favour of providing nutrition and hydration *provided that it is of sufficient benefit to outweigh the burdens to the patient*. This involves judgements concerning the quality of life which has assumed increasing importance in assessing the efficacy of treatment. One may contrast the use of tube feeding in situations where it may not prolong life, but where it improves it's quality, with treatments which may prolong life at the expense of prolonged suffering. In most countries the physician may not end life, but on the other hand is not required officiously to prolong the process of dying. Orthodox Jewish thinkers regard the dying person in a special light and argue against impediments to dying in the final year of life.

The growth of National Health Services in Europe has seen the increasing recognition of 'justice' (equal access to healthcare for all) as an important ethical concept. On the other hand the growth in demand for healthcare and new technical developments face all societies with the problem of satisfying infinite demand with finite resources.

Society and its political representatives have yet to face up to the problem of enormously expensive and sometimes futile treatment of the few, which may so consume resources in staff, facilities and money as to deny proper treatment of those more likely to benefit and survive. The doctor is therefore faced with balancing 'justice' against 'beneficence' and 'autonomy', and trying to deploy the limited resources available to achieve the maximum benefit. Through legal and other conflicts (see below), there may be difficulties in the way of withdrawing expensive but ineffective treatment in order to use the resources of the nutrition care team to better effect. In cases of conflict, the advice and support of local ethical committees may be helpful.

Q: Is there a difference between ethical principles and legal framework?

A: Yes, although the laws of European countries (which may differ in some details between

countries) are based on the common ethical tradition described above.

Comment: Ethical codes of caring professions include not only minimal acceptable standards of behaviour, but also ideals, and have been described as 'the collective conscience of our profession'. The law, on the other hand, defends individual rights and liberties and sets minimum standards below which professional conduct can be regarded as lacking in care, negligent or downright criminal. It also protects those who are unable or incompetent to make decisions on themselves. In addition, it provides some safeguards and protection for doctors and other professions. It has embodied the principle, for example, that no doctor can be obliged to provide treatment which he/she believes to be against the patients' interests or futile. This delicate balance between patients' legal rights and professional judgement has, however, been threatened by recent unfortunate legal judgements in the UK and USA, whose consequences have yet to be defined. Unprincipled political interference, stimulated by extreme pressure groups, is also a threat that the professions will need to resist. Fortunately, Europe in general has continued to maintain a liberal and humane approach to these problems.

In the judgement of risk versus benefit in the medico-legal context, it is clearly vital that the professional who wishes to avoid or to provide a defence against litigation should be fully conversant with the latest medical evidence and be appropriately trained and experienced.

Q: What are the implications of the law for the organisation and conduct of nutritional support?

A: As with other treatments, the best results are obtained by teams trained and organised to carry it out. This is of particular relevance to artificial means of nutritional support.

Comment: There is sufficient evidence, in the case of parenteral nutrition, that specialised nutrition teams obtain the best results, with the fewest complications. There is some evidence also, in the case of enteral tube feeding, that experienced and properly organised groups, working to agreed protocols, have fewer complications and better outcomes than those who provide occasional or ad hoc treatment. There is, therefore, a risk of litigation if artificial nutrition, conducted by the inexperienced, results in serious complications, beyond the normal risks inevitably associated with any form of intervention.

Q: How does the law regard enteral nutrition? Is it basic care or a medical treatment?

A: The law differentiates between oral intake and enteral tube feeding. While tube feeding is clearly considered therapy, oral nutritional supplements can be basic care as well as therapy. Oral nutritional supplements are therapy under certain conditions e.g. if pharmacologic effects should be achieved by specific composition (BCAA, etc.) The provision of adequate fluid and nutrients by mouth including oral nutritional supplements in most instances as well as help with drinking and eating where necessary is regarded by the law as basic care.

Comment: Although paediatricians have argued, with good reason, that tube feeding of the neonate is part of basic care, in the older child and adult it is generally accepted that nutrition by artificial means is a medical treatment, involving professional judgement and intervention, governed by the laws related to medical practice. On the other hand, oral intake is governed by the laws related to duty of care and to Human Rights, whereby any person, organisation or institution that undertakes to provide care is obliged to provide and ensure an adequate oral intake of food and fluid where possible and as acceptable to the patient. A competent patient is entitled to refuse food and drink and, indeed, many dying patients do. It is unkind and improper to try to force unwilling patients to eat or swallow.

Q: When is a patient competent to exercise autonomy and who decides for the incompetent patient?

A: The laws differ in detail and emphasis on this point between countries, although the principles remain similar. For the definition of competence, see below. If by reason of psychiatric or brain disease the patient is not able to understand the issue or express a view, the doctor has a number of options.

1. Has the patient written a 'living will' expressing his/her wishes concerning treatment under these circumstances? Such written testaments should be respected and will increasingly be regarded as legally binding.
2. Alternatively, has the patient ever expressed his/her wishes verbally to family or friends? Such expressions should be considered and respected.
3. In some countries the family has legal rights to make decisions.

4. The patient may previously have appointed a member of the family, a friend, or lawyer to be their legal guardian at a time when he/she was incompetent to make decisions. Such persons have legal autonomy.
5. In a few cases, (see below), reference to the courts may be necessary. The court may appoint 'guardian ad litem' (particularly in children) or empower the doctor to take a decision 'in the best interests of the patient'.
6. Although it is not legally binding to do so, the doctor should always consider and respect the views of all the members of the team who should be participants in any decision making whether the patient is competent or not.

Q: How is legal competence defined?

A: Competence under civil law is not to be equated with patient's ability to give his/her consent. Only the following conditions exclude individuals from legal competence under civil law:

1. Children under 14 resp. 18yr: In children under 14yr (in some countries under 16yr), the parents have the authority to make decisions unless the courts specifically remove or take over that authority. Adolescents between 14 and 18yr should be informed according to their psychosocial maturity and their consent should be recognised and/or carried out.
2. Severe psychiatric illness. Whenever a psychiatrist and other required people have certified the patient, in a legally approved manner, as incapable of making rational decisions. This includes those with anorexia nervosa and severe depression, but not those imprisoned for other reasons. Indeed it is conceivable that doctors could be sued for failing to give artificial nutrition in such cases where malnutrition is life threatening.
3. Primary brain or other disease, which renders the patient temporarily or permanently incapable of understanding or of expressing, wishes by any means.

Comment: Even patients without legal competence under civil law should be informed about the planned measures according to his/her mental capacity.

In general, a patient has the ability to consent when he/she is able to understand the benefits, risks and consequences of the respective intervention as well as the consequences of the omission of the measure, and is able to make a self-determined

decision. The patient may be temporarily or permanently unable to consent to complex measures, but may well be able to consent to simple ones. Intellectually, the decision concerning tube feeding may be a simple one, yet emotionally it is a complex issue. The attending physician must assess the patient's ability to consent separately for each therapeutic decision and must document the conversation carefully. For instance, underaged adolescents will obtain their ability to decide about a nutritional therapy quite early, because normally this is a rather simple and low-risk therapeutic measure.

In relation to (3) above, the British Medical Association and the Law Society have published clear guidelines on the assessment of mental capacity:

A person should be able to:

- Understand in simple language what the medical treatment (or research intervention) is, its purpose and why it is proposed.
- Understand its principle benefits, risks and alternatives.
- Understand in broad terms what will be the consequences of not receiving the proposed treatment.
- Retain the information for long enough to make an effective decision.
- Make a free choice without pressure.

The process of communicating verbally, by written word, or by signs, may sometimes be difficult. However, the doctor should not be tempted to underestimate the patient's capacity to make a decision and should make every attempt to assist this process, including, in the case of a fluctuating mental state, returning at a time when the patient is in a less confused phase.

Q: What should be done in case of doubt whether enteral tube feeding will be beneficial or when the prognosis of the underlying condition is uncertain?

A: If in doubt give a trial of treatment. This should be for a defined period agreed among all members of the team and with the patient's family and/or representative. Goals and criteria for continuing or discontinuing the feed should be agreed in advance.

Comment: Acute stroke affecting swallowing is a typical example of this type of problem, in which prognosis may be uncertain for the first 2–3 weeks, during which nutritional support should be given to

prevent malnutrition developing and thereby impairing recovery in those whose neurological condition improves. The decision to start treatment is also governed, of course, by the current or previously expressed wishes of the patient or by the views of a legal guardian. In contrast, patients with terminal brain disease e.g. tumour, Alzheimer's etc may suffer more risk from tube feeding than benefit, so that the ethical balance may be against treatment.

Q: How does the law regard withdrawing or withholding tube feeding?

A: Withdrawal is regarded in the same way as withholding treatment in the first place i.e. is it in the best interests of the patient, and do the risks outweigh the benefits? Also, it is concerned that autonomy has been preserved and that the patient or legal guardian have been consulted and given approval.

Comment: There are certain situations e.g. persistent vegetative state or when there is conflict between professional judgement and the wishes of legal guardian or family, when the courts need to be involved before any action is taken.

The current attitude of the law is summarized by a legal judgement as follows:

Medical science and technology has advanced for a fundamental purpose: the purpose of benefiting the life and health of those who turn to medicine to be healed. It surely was never intended that it be used to prolong biological life in patients bereft of the prospect of returning to an even limited exercise of human life

One religious and ethical authority has argued that preventing doctors withdrawing treatment where it is providing no benefit is unethical since it would discourage trials of treatment where benefit is initially in doubt. This view supports the concept of planned and limited trials of treatment undertaken after full discussion with all concerned, with agreed goals and grounds for withdrawal should the treatment prove ineffective or burdensome to the patient.

Special situations

Persistent vegetative state

Q: In cases of severe brain damage where the prospect of recovery is extremely unlikely, how

does the law regard withdrawal of food and fluid administration by tube?

A: The law was clarified by the Cuzan case in the US and by the Tony Bland case in the UK. The courts will not entertain an application to withdraw treatment within 12 months of the onset of the condition, by which time it becomes possible to determine whether the patient has lost all features of personhood although brain stem function persists i.e. a persistent vegetative state. The court may then give permission for doctors to stop treatment, 'if it is in the best interests of the patient'.

Comment: The courts usually require that the patient has been examined serially over a period of time by an expert in the field of brain damage with special experience of such cases.

Dementia

Q: What is the role of enteral feeding in dementia?

A: In early or mild dementia, memory loss affects people's awareness or memory of meal times, so that meals may be missed. The supervision of meals and the provision of finger buffet snacks from which the demented person can help themselves between meals have proved adequate to ensure proper nutrition. As the condition worsens, oral supplements may be justified. With intercurrent reversible illness, the patient should be considered in the same way as those without dementia. In the late stages of disease, Alzheimer's or cerebrovascular dementia, the balance of evidence is that artificial tube feeding has more risks than benefits, and should not be undertaken. Attention to comfort and dignity take precedence over nutritional or fluid therapy.

Comment: In recent studies of terminal dementia, it was shown that tube feeding does not prolong life and causes more complications than benefits. It reminds us that loss of appetite and thirst are terminal features in this fatal condition, as in other terminal illnesses at a late stage.

Malignant disease

Q: Does enteral feeding have a significant role in terminal cancer?

A: The role of enteral feeding in oncology generally is summarised in chapter Oncology, in terminal cancer, oral supplements may be useful,

and tube feeding may be beneficial on obstructive lesions of the gastrointestinal tract. Treatment should be dominated by the need to provide comfort and symptom relief rather than by any form of aggressive nutritional support.

The dying patient

Q: How does our ethical tradition guide us?

A: Even religions e.g. Roman Catholicism, Judaism, which may be supposed to be in favour of life, regard the process of dying in a special light and only urge a presumption in favour of providing nutrition and hydration provided that this is of sufficient benefit to outweigh the burdens involved to the patient. It is one of the physician skills to know when curative or aggressive treatment should be abandoned in favour of the provision of care, comfort, symptom relief and the preservation of dignity. It involves a recognition of the dying process, which may be rapid or prolonged over many months.

Q: What are the threats to medical ethics?

A: There are political, business, insurance, reimbursement and management issues, which may directly or subtly erode professional ethical practice. For the proper conduct of medical care, it is important that the professions resist any erosion of a firm and clear ethical stance, which is the mark of a profession.

Comment: Doctors themselves should ensure their own ethical behaviour as well as resisting external pressures to weaken ethical rules. On the other hand, ethics must be made relevant to modern conditions and the doctor has, increasingly, a responsibility to balance fair distribution of resources (justice) against individual benefit (beneficence) and even autonomy where this becomes unreasonable in its demands on resources.

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