

Parenteral nutrition: ethical and legal considerations

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Parenteral nutrition is an expensive therapeutic modality that is used to treat patients with intestinal failure. The benefit it offers in terms of life prolongation needs to be weighed against its risks and burdens. Through the use of descriptive clinical vignettes, this article illustrates the ethical and legal principles that underpin decisions to administer and, more importantly, to withhold or withdraw parenteral nutrition.

situations in which feeding can be withheld or withdrawn. The situational contexts will be illustrated by clinical vignettes, some of which have been adapted from our own experience. Although our focus is on parenteral nutrition, the ethical reasoning and legal principles are similarly applicable to enteral feeding and to other invasive forms of life prolonging treatment such as renal replacement treatment.⁴

BENEFITS AND BURDENS

When intestinal failure occurs, the gastrointestinal tract is unable to absorb sufficient fluids, electrolytes, and/or nutrients to meet metabolic requirements. Enteral feeding is therefore not an option. Instead, nutrients are supplied directly into a large vein. This form of nutritional delivery—parenteral nutrition—may be used for both short and long term treatment of intestinal failure.

Intestinal failure may be due to inability to achieve or retain enteral intake, but more commonly refers to a loss of functioning intestinal mucosa. Bowel resection (with resultant short bowel), impaired intestinal motility, impaired intestinal mucosal function, or a combination of the three can result in intestinal failure. The failure may be temporary, as in the case of postoperative ileus, or long term, for example after massive small bowel resection. Intestinal transplantation is reserved for extreme cases where patients are developing complications while receiving long term parenteral nutrition.

The causes of intestinal failure include both benign and malignant disease, and the pattern of provision of parenteral support, especially long term and home parenteral nutrition, varies in different Western countries. In the UK home parenteral nutrition is used largely for treatment of patients with complex Crohn's disease who have had multiple resections, followed by patients with the sequelae of small bowel infarction.¹ The use of parenteral nutrition in the treatment of patients with malignant disease is comparatively uncommon, and has not increased significantly over the past decade.² By contrast, the use of parenteral nutrition in the treatment of patients with cancer is more common in both North America (where it seems to be increasing) and in other countries in Europe such as Italy.³

Untreated intestinal failure is fatal and, in common with other forms of life prolonging treatment, withholding or withdrawing parenteral nutrition raises both ethical and legal issues. We will approach these issues by considering

The primary benefit of parenteral nutrition is life prolongation but, on the other side of the balance, there are considerable risks and burdens. Although short term support can be given via peripheral veins, long term parenteral nutrition requires central venous access with its concomitant risks. Central line insertion can cause pneumothorax, and complications can arise from long term indwelling catheters. There is a significant risk of central venous catheter infection, which can lead to bacteraemia and candidaemia, and subsequent systemic sepsis. The risk of infection may be compounded by the intestinal mucosal atrophy that accompanies intravenous feeding, with theoretically increased bacterial passage across the gut. It is estimated that with optimal care the incidence of central venous catheter sepsis is about 1 per 1000 catheter days.⁵

Occlusion of the central venous catheter or venous thrombosis may occur that can lead to severe difficulties achieving venous access. The incidence of central venous catheter occlusion is about 1 per 5000 catheter days.⁶ Loss of venous access, usually attributable to extensive and multiple central venous thromboses is an indication for consideration of intestinal transplantation.⁷ Long term parenteral nutrition may also be associated with hepatic dysfunction; hepatic fibrosis can occur and this, in some cases, may progress to cirrhosis.⁸ It has been estimated that up to 15% of patients who receive parenteral nutrition for more than one year will develop end stage liver disease.⁹

Unlike enteral nutrition, parenteral nutrition is complex, intensive, and expensive. The feeds are technically difficult to manufacture because the sterile solution of nutrients, minerals, and trace elements needs to be tailor made to suit the individual patient; also required is an aseptic delivery system. The upshot is that parenteral feeding is much more expensive than enteral feeding. In the UK, home parenteral nutrition for patients with benign disease has been shown to cost £36 000 per year (after an initial £45 000 cost) with a calculated cost of £69 000 per quality of life year (QALY).¹⁰

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In the UK, the financial burden is borne by the NHS, but the emotional and physical burden of extracorporeal feeding is borne by the patient. An ethical approach to parenteral feeding needs to balance the benefits (life) and burdens (physical and psychological costs to the patient) and economic costs to the health service.

In some respects the burdens of parenteral nutrition are of assistance when it comes to deciding under what circumstances such treatment should be given. If oral feeding and supplementation is “ordinary”—in that it is comparatively easy to administer, comparatively inexpensive, and comparatively free of risk—parenteral nutrition is “extraordinary”. The tendency is therefore to offer it to patients who are competent, can understand the risks involved, and can consent to treatment.

We will start with the presumptions that life should be prolonged when possible, and that prolongation of life by artificial nutrition is a good thing. We will then argue that both of these are rebuttable presumptions, by providing clinical vignettes demonstrating when it may be better to withhold rather than to administer parenteral nutrition.

PROLONGATION OF LIFE

“English law places a very high value on life”,¹¹ and from an ethical perspective the cornerstone of any debate about life prolonging treatment is the “value of life”. This subject, however, will always be contentious because the value of life means different things to different people.

The idea that life is intrinsically valuable derives from traditional Judaeo-Christian theological beliefs in the sanctity of life. The extreme form of belief, a vitalistic view, holds that life is an absolute good that should always be preserved no matter what the cost. The more moderate sanctity of life view acknowledges that life needs not be preserved at all cost, but nevertheless holds that life is a basic good with intrinsic value. Both views accept that:

Patients must never have their lives intentionally shortened (whether by act or omission), or have their life-prolonging medical treatment withheld/withdrawn on the grounds that, because of their disability, their lives are worth less or are worthless.¹²

Others assess the value of life by the instrumental good that it provides, such as self awareness and the ability to experience and interact with the surrounding environment. James Rachels believes that the value of being alive derives from the importance of having a life in the biographical sense, rather than being alive in a simply biological sense.¹³ Such notions are rightly labelled as quality of life concerns, and when tension arises in the medical-ethical arena it is often because of the opposing tugs of sanctity and quality of life principles.

Quality of life assessment is a value judgement best made by the person whose life it is. Alison Davis, an adult with spina bifida, rejects quality of life arguments based on her own worthwhile quality of life,¹⁴ and claims that most disabled people value their lives.¹⁵ There are times, however, when clinical decisions need to be made for patients who are not competent to decide for themselves, and account should be taken of the type of life they are likely to experience after treatment—an objective quality of life assessment—as well as their previously expressed views when such views are available.

It will be clear from this brief account that when assessing the value of life, the views of the patient are paramount, and prime place is given to the principle of autonomy. In the

words of Lord Goff: “the principle of the sanctity of human life must yield to the principle of self-determination”.¹⁶

AUTONOMY

The most uncontroversial example of when parenteral nutrition cannot be started, or when it should be withdrawn, is when a competent patient refuses treatment.

Vignette 1

A mentally competent 61 year old patient underwent massive small bowel resection after mesenteric infarction. Postoperatively, she developed a fistula that caused chronic pain. Parenteral feeding was started and although cholestatic jaundice, secondary to ultra short bowel, limited the amount of nutrition feasible, she completed home training and was discharged. She was admitted the following year with superior vena cava thrombosis, and her treatment was complicated by repeated gastrointestinal bleeds. At this point she stated that she had undergone enough and requested that all treatment, including parenteral nutrition, should be stopped. She was fully aware that this would result in her death.

Respect for a patient’s autonomy, in moral terms, derives from the respect we owe patients as persons. A person’s freedom of self determination was expressed by John Stewart Mill in these words: “In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign”.¹⁷

English law enforces the competent patient’s right to self determination: “A mentally competent patient has an absolute right to refuse to consent to medical treatment for any reason, rational or irrational, or for no reason at all, even when that decision may lead to his or her own death”.¹⁸ Treating a competent patient without consent is unlawful and can result in a charge of battery or assault,¹⁹ therefore an accurate assessment of competence is necessary. This test for competence is functional and requires the patient to understand the nature of the treatment and the reasons for its proposal; the benefits, risks, and alternatives as well as the consequences of non-treatment. The patient must also be able to retain the information, weigh it, and thereby decide.²⁰

DECISION MAKING FOR PATIENTS WHO LACK CAPACITY: “BEST INTERESTS”

When a patient is unable to make treatment decisions, and in the absence of a valid advance directive, someone has to decide on their behalf. At present in England and Wales, but not in Scotland, the doctor is charged with deciding in the patient’s best interests. This will change in 2007 when the Mental Capacity Act 2005 comes into effect. At that time, people will have the right to appoint a donee with lasting power of attorney for personal welfare.²¹

There are two ways of making decisions for adults who are unable to decide and who have not previously appointed an attorney for healthcare decisions or provided advance directives. In England the test used is that of best interests, whereas in North America the preferred test is that of substituted judgement. Both of these tests are fallible. “Best interests” is a value judgement, and substituted judgement may be affected by the projected values or wishes of the surrogate decision maker.²²

In English law the test of best interests is objective, namely what a reasonable person similarly afflicted would choose; but in as much as it relates to a particular patient, it is

subjective.²³ This is evident in s 4(6) of The Mental Capacity Act, which requires that the person making the best interests determination should consider: “the person’s past and present wishes and feelings; the beliefs and values that would be likely to influence his decision if he had capacity; and the other factors that he would be likely to consider if he were able to do so”²⁴

In the USA, the preferred test is that of substituted judgement. This test inquires what the patient would have wanted for herself, had she been capable of choosing. This test approximates the principle of autonomy, and would be ethically ideal provided the patient had made clear advance statements regarding her preferences.

Vignette 2

A 70 year old woman, who lived alone, required massive small bowel resection. She was trained for home parenteral nutrition and this was successfully administered for eight years. She was then admitted with a dense hemiplegia and severe cognitive impairment after an intracranial haemorrhage. She had no relatives and had made no known advance statements.

In vignette 2, a decision was made to withdraw parenteral nutrition from the patient who was seriously impaired by a stroke. This patient had little remaining awareness and no prospect for rehabilitation or recovery. It is arguably impossible to ignore quality of life considerations when making “best interests” assessments. If the patient’s quality of life is unquestionably poor this affects the cost/benefit equation. The risks and costs of treatment were here perceived to outweigh the benefits. As the patient’s own preferences were unknown a purely objective standard of best interests was applied.

Vignette 3

A 71 year old woman with a history of dementia was admitted after a mesenteric infarction. After massive small bowel resection she remained dependent on parenteral nutrition. On the ward, she was confused, disorientated, and unable to comprehend any instructions relating to intravenous feeding. She lived with her husband who was keen to take her home.

Before continuing, it must be emphasised that cognitive impairment is a more or less rather than an all or none concept. It covers a spectrum of disability that ranges from persistent vegetative state (PVS), through minimally aware states, to severe, moderate, and mild impairment. Therefore cognitive impairment as such is not a reason to withhold parenteral nutrition as shown by the next vignette.

In England (at present) relatives’ views, although instructive, are not determinative of treatment; but whether this should be so is arguable. In vignette 3, the patient’s husband was trained to deliver home parenteral nutrition and the patient was discharged. Her cognitive function improved at home, and one year later she was able to complete training and so self administer her parenteral nutrition. Judgements and assumptions made in haste can be incorrect. Clearly in this vignette the patient had a degree of reversible confusion because of her acute illness. This may not always be the case but it is important to take due consideration of close relatives

who can be best placed to influence decisions made on a patient’s behalf.

DURATION OF TREATMENT

Parenteral nutrition is considered useful in the critical care setting particularly when the factors necessitating feeding are reversible. This is illustrated by vignette 4.

Vignette 4

A previously well 51 year old man was admitted with large bowel obstruction. At laparotomy he was found to have an obstructing sigmoid tumour with widespread intraperitoneal and hepatic metastases. After a palliative Hartmann’s procedure the patient developed a prolonged ileus and was, as a result, intolerant of enteral feeding. Parenteral nutrition was started and continued for two weeks, during which time his ileus resolved and he was able to restart oral nutrition.

The risks and burdens with short term parenteral feeding are far less than those associated with long term treatment. The cost/benefit equation is consequently more favourable. This vignette should be compared with the next, where intractable vomiting determined the need for long term parenteral feeding.

Vignette 5

A 50 year old woman with a background history of familial adenomatous polyposis was admitted with gastric outlet obstruction caused by gastric carcinoma. She underwent gastrectomy and chemotherapy. Parenteral nutrition was started because she could not tolerate enteral feeding.

The patient then developed liver metastases, and after discussions, requested that her feeding be withdrawn. She believed that the burdens of continuing treatment outweighed the benefit of life prolongation.

FUTILITY

In the case of *Airedale NHS Trust v Bland*,²⁵ the court authorised withdrawal of enteral nutrition because continuing life prolonging treatment was no longer in the patient’s best interests. Anthony Bland, who suffered anoxic brain damage during the Hillsborough disaster, had been in a persistent vegetative state for three years. The court decided that as there was no hope of improvement, life prolonging treatment was, in medical terms, futile.²⁶

The Human Rights Act 1998 came into force in 2000, and thereby incorporated the European Convention on Human Rights and freedoms into English Law. Article 2 includes the phrase “everyone’s right to life shall be protected by law”. This involves the State in a negative obligation—not to act in a manner that threatens the life of any citizen.²⁷ The weaker positive obligation to act, that is taking steps to preserve life, must not impose a disproportionate burden on the authorities; hence there is no obligation to provide treatment that is futile.²⁸

The meaning of futility is open to interpretation and Schneiderman *et al* distinguish between quantitative futility—when treatment does not work, and qualitative futility—when treatment does not benefit the patient as a

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whole.²⁹ Feeding a patient in PVS is qualitatively futile as nutrition cannot restore awareness, and without awareness the patient can have no experiential life. Many studies have shown that nutritional support provides no clinical benefit to those close to the end of life,³⁰ and such feeding can therefore be described as quantitatively futile.

Qualitative futility, although understandably applicable to those who are permanently unconscious, is less easy to apply to patients who are severely neurologically impaired but nevertheless aware. This is illustrated by a recent English case,³¹ which although dealing with enteral nutrition could arguably be equally applicable to parenteral nutrition.

Vignette 6

A 59 year old woman with longstanding multiple sclerosis who had lacked competence for 20 years was admitted to hospital because her PEG tube had fallen out. She lived in a nursing home and required total care. She was conscious, could obey simple commands, and say single words. She recognised no one. Her doctors wished to replace the feeding tube but the family felt that the patient had no quality of life, experienced pain, and suffering, and did not want to be kept alive.

The court decided that in the absence of a clear and relevant advance directive, the decision whether to replace the tube depended on whether continuing feeding was in the patient's best interests. The judge ordered replacement of the tube because life prolonging treatment could not be declared to be of no benefit, and he believed that death through starvation would be even less dignified than the death that would ultimately occur.³²

RESOURCE CONSTRAINTS

It is appropriate to withhold treatment that will not work, and artificial nutrition, either enteral or parenteral, is not life prolonging in patients with cancer related cachexia. Parenteral nutrition, however, can increase long term survival in selected patients with local symptoms such as intestinal obstruction or malabsorption that are attributable to metastatic disease³³ but in the UK it is rarely provided for this group of patients.

It is acknowledged that the NHS is under-funded, and although doctors tend not to make overt resource related

Key points 1

- Long term parenteral nutrition is required in the treatment of severe intestinal failure.
- Intestinal failure may result from massive bowel resection, impaired gut motility, and/or impaired mucosal function
- The commonest indication for starting long term parenteral feeding in the UK is short bowel syndrome secondary to Crohn's disease or mesenteric infarction.

Key points 2

Ethical considerations regarding provision of parenteral feeding include the following:

- Consent of the patient
- Benefits of treatment
- Burdens of treatment
- Feasibility of treatment
- Resource constraints

decisions, decision making may be influenced (consciously or unconsciously) by patient related factors that may be disguising a resource based reason for withholding treatment. Alternatively, some clinicians may withhold parenteral nutrition believing, paternalistically, that the increased duration of life afforded by such treatment is outweighed by the quality of life issues attached to advanced malignancy.

In many countries, abdominal malignancy is a common reason for providing parenteral nutrition. In North America cancer patients are the single largest group receiving home nutritional support.³ This could reflect both freer access to the resources necessary for community care and the centrality of patient autonomy and choice in the USA. Perhaps, as the UK broadens the scope for delivery of parenteral nutrition, more patients with advanced malignancy will become candidates for treatment. Treatment decisions should then be informed by multidisciplinary input and offered to patients who are likely to benefit and who, after comprehensive discussions of the burdens and benefits, choose to accept parenteral nutrition with its potential survival advantage.³³

The English courts have been sympathetic with resource based decisions. In the case of a child requiring costly treatment for leukaemia, the judge said: "Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients".³⁴ The court, also, would not compel a doctor "to make available scarce resources (both human and material) to a particular child, without knowing whether or not there are other patients to whom those resources might more advantageously be devoted".³⁵

The BMA guidance on withholding and withdrawing life prolonging treatment expresses the matter thus: "Where resources are limited, it is inevitable that some patients will not receive all of the treatment they request even though such treatment could potentially benefit them".³⁶

PATIENT UNDERSTANDING AND PARTICIPATION IN PARENTERAL NUTRITION

Unlike long term enteral tube feeding, which is comparatively safe, commonplace, and usually administered in a

nursing home environment, long term parenteral nutrition is ordinarily administered in the community and requires a degree of patient understanding and participation. Occasionally there are patient related factors that increase the risks of parenteral nutrition and shift the balance in favour of non-treatment.

Vignette 7

A 32 year old patient with Crohn’s disease had short bowel syndrome from previous surgery and was unable to be maintained with enteral nutrition. She was also HIV positive, used intravenous heroin, and suffered from a severe behavioural disorder. Despite psychiatric intervention and repeated attempts at training, the patient would not engage in home parenteral nutrition nor would she contemplate nursing home care.

In this case it was decided that parenteral nutrition was simply not feasible. The patient did not wish to be trained to look after her parenteral nutrition and could not safely look after it in the community. In addition, the presence of an indwelling venous catheter in a patient who was known to misuse intravenous heroin presents a considerable risk to the patient. This patient’s outcome might therefore be the same with or without parenteral nutrition and it was felt to be safer to withhold this option.

CONCLUSION

We have broadly illustrated the ethical and legal principles that influence decisions to withhold parenteral nutrition. The competent patient’s wishes are pivotal and consent is obligatory. When the patient is incapable of decision making, other factors need to be considered such as the presence of advance directives, the benefit of treatment, the quality of life, and the resource implications.

Although our vignettes may seem to be fairly clear cut, it is important to emphasise that in many cases decisions to withhold or withdraw treatment are made against a background of moral uncertainty, as well as uncertainty regarding the prognosis of the illness and the continuing acceptability of treatment for the patient. Hence we advise a flexible approach to the patient group requiring parenteral nutrition.

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