

〈Review〉

Ethical Framework for End of Life Decisions in Intensive Care in the UK

John KINSELLA¹⁾ and Malcolm G. BOOTH²⁾

¹⁾ Professor of Intensive Care Medicine, University Department of Anaesthesia, Glasgow Royal Infirmary

²⁾ Consultant in Anaesthesia and Intensive Care Medicine, University Department of Anaesthesia, Glasgow Royal Infirmary

Abstract

In the UK there has been a move away from a paternalistic model of medicine. A clearer ethical framework has now evolved and it is accepted that four main ethical principles, such as autonomy, non-maleficence, beneficence and justice in medical practice. There is no distinction ethically between withholding and withdrawing a mode of therapy. When a therapy is not considered to offer any benefit there is no obligation to institute it. On the other hand, there is an obligation to maximise comfort and minimise pain or distress of patients even when the side effects may actually appear to precipitate the patient's death (Principle of Double Effect). The General Medical Council, the British Medical Association Ethics Committee, as well as the various Royal Colleges provide guidance on healthcare related ethical issues, but do not provide advice on individual cases. Although, ethics committees in UK hospitals are mainly Research Ethics Committees, but gradually appearing those support on clinical ethics throughout the UK. For the patients who lack the ability to give consent, the various treatment options are discussed with the family and treatment is permitted by legislation in Scotland (Adults with Incapacity Act 2000). We describe specific aspects of end of life decisions in intensive care.

Abstract was edited by Editorial Board.

Keywords: ethical framework, ethical principles, consent, intensive care, end of life

(Accepted for publication 6th, December 2007)

In the UK there has been a move away from a paternalistic model of medicine. A clearer ethical framework has now evolved. It is accepted that four main ethical principles currently guide medical practice. These are autonomy, non-maleficence, beneficence and justice (1). *Autonomy* is the principle of self-determination. This is equates to the right to consent or refuse treatment. A doctor also has autonomy and cannot be compelled to provide treatment not clinically indicated. Nor can a doctor be obliged to provide treatment to which he has a moral or religious objection.

Non-maleficence signifies avoiding doing harm. It is originally known as "primum non nocere" or "first do no harm". This principle accepts that many beneficial therapies also have unwanted harmful side effects. Non-maleficence means that the potential harm of any therapy should be less than its potential benefit. *Beneficence* is the intention to do good. This is principle is secondary to non-maleficence in

that the primary aim must be to minimise harm. *Justice* refers to the equitable distribution of healthcare resources. There is no consensus on how this should be achieved. Different methods have been proposed such as needs based, utilitarian (maximising benefit), egalitarian (equal share to each person). Unfortunately each of these methods of equitable distribution can discriminate against particular groups of patients. For example, the elderly or those with chronic disease may be at a disadvantage in an egalitarian system (2).

Although all decisions should attempt to balance all 4 principles, autonomy is the leading principle. This is reflected in the importance placed on the patient's consent. The decision to provide a treatment lies with the clinician. The autonomous patient is then able to consent to or refuse. It is therefore important to ensure that the patient is informed of the risks and benefits of treatments. Any

10 Alexandra Parade, G32 2ER, Scotland UK.

jk19v@clinmed.gla.ac.uk

harm that occurs because of a refusal is the responsibility of the patient. The obligation to obtain a patient's consent in advance of any therapy changes when the patient lacks mental capacity. This may occur during emergency treatment or where the disease process or treatment renders the patient incapacitated.

Consent, best interests and necessity

It is common for critically ill patients to lack the ability to give or withhold consent. This may be due to the disease process or its treatment. Under these circumstances it is common practice to discuss the various treatment options with the family of the patient. In some jurisdictions the relatives may actually have the authority to consent on behalf of an adult patient (see later). In the United Kingdom relatives may give assent, which means that they agree to the proposed treatment but it is not a legal requirement. The discussions with relatives are of most value because they may help to give an indication about the patient's own attitudes and values concerning treatment.

When the views of the patients are known then they should be used to guide decision making. It is common that the patient's precise wishes are unknown and therefore decisions must then be made on the basis "best interests". A person's "best interests" are difficult to define. The concept is based on the responsibility of parents to act in the best interests of their children. It was assumed that parents do, generally, act in their children's best interests and that the state should not interfere unless the parents actions were to have serious adverse consequences for the child. It was because no best interests to the patient could be demonstrated that the practice of electively ventilating severely head injured patients until they became brain stem dead, so increasing the availability of organs for transplantation, was not allowed to continue. This was deemed illegal because there was no benefit to the patient from the ICU admission (3).

In an emergency situation doctors are allowed to commence treatment on the basis of necessity. This allows the initial treatment to save a life or limb but does not give the authority to undertake non life saving treatment. This is based on the reasonable assumption that most people would wish to have life saving treatment.

Ethical principles around withholding and withdrawing

With the advances in critical care and medicine it has come accepted that maintaining life is not the sole aim.

'the prolongation of life ...does not mean a mere

suspension of the act of dying, but contemplates at the very least, a remission of the symptoms enabling return towards a normal, functioning, integrated existence' (4).

Medical futility has been used to justify stopping or withholding medical therapies that can never achieve their intended aim. This is an extremely difficult concept to prove. No agreement has been reached as to whether a specific chance of survival equates to futility. For example, to some people this may mean a 1% chance of survival and to others a 0.1% chance. As a result emphasis is moving towards assessing the likelihood of person surviving to intensive care, or hospital discharge, whilst taking into account the risks or burdens of the treatment.

Ethically there is no distinction between withholding and withdrawing a mode of therapy. When a therapy is not considered to offer any benefit there is no obligation to institute it. Equally if a therapy fails to produce the intended beneficial effect then it should be stopped. Continuing every treatment, just because it had been started, would expose patients to the potential side effects of multiple treatments without expectation of benefit (5). This introduces the concept of ordinary and extraordinary means. Ordinary means are taken as those therapies that have a reasonable expectation of benefit with little or minimal burden. Extraordinary means are those involving excessive pain or distress. Differentiating ordinary from extraordinary treatment is problematic, as the terms have also been used incorrectly to refer to simple versus complicated treatments. More useful terms are proportionate and disproportionate as they reflect the relationship between the treatment and its effect upon the patient. Under differing circumstances the same intervention may be either proportionate or disproportionate. Whilst there is a duty to offer proportionate treatment there is no such obligation to consider the use of interventions thought disproportionate.

Acts and Omissions

It is permissible to withhold or withdraw treatment even if this allows the disease process to progress to a natural death for the patient. There is an important distinction between letting something happen (permitting an illness to progress naturally) and making something happen (acting intentionally). Any decision to withhold or stop therapy should be based upon the expectation that the patient cannot benefit from that treatment. When withdrawing treatment the clinician's intention must be to relieve the person of the burdens associated with that treatment.

Although it may be foreseeable that the person may die as a result it should not be the intention.

The case of Karen Quinlan in the USA demonstrates the issues involved. As a result of severe brain injuries Karen was left on a ventilator in a permanent vegetative state. It became obvious that she could not recover so her parents requested that ventilation be withdrawn. It was foreseeable that following this she may not have been able to breathe adequately for herself and so would die. When ventilation was discontinued, to everyone's surprise, she was able to breathe spontaneously and continued to do so for nine more years. This illustrates the burden of the intervention needs to be balanced against the likely benefits including survival or quality of life. Therefore, as demonstrated in this example, withdrawal of support does not necessarily mean that the patient will die as a result.

Principle of Double Effect

In the intensive care unit there is an obligation to maximise comfort and minimise pain or distress. This may even be the most important aspect of care. This duty continues even after a decision to withdraw treatment. Drugs such as opioids and benzodiazepines are often administered with this aim. These drugs have an intended beneficial effect (such as reduced distress) and also harmful side effects (such as respiratory depression). The side effects may actually appear to precipitate the patient's death hence the apparent double effect of such drugs. It is the intention behind their use that is of paramount importance. Providing the intended effect is to relieve pain or distress, and the dose titrated with this in mind, then their use cannot be successfully criticised. Equally there is an obligation to provide a sufficient amount of the drug to achieve its beneficial effect – only half treating a patient's distress is cruel. Should, however, the sole intention of administering the drug be to bring about the death of the patient then the doctor might be charged with murder.

Ethics committees and medical education

The General Medical Council, the British Medical Association Ethics Committee, as well as the various Royal Colleges provide guidance on healthcare related ethical issues. Generally they publish guidance on a variety of areas but do not provide advice on individual cases (6) (7). Individual difficult ethical decisions often receive extensive media coverage (8) (9). Ethics committees in UK hospitals are mainly Research Ethics Committees and have no role in clinical ethics. In contrast, Clinical Ethics Committees, as found in many hospitals in the United States, are gradually

appearing throughout the UK (10). There has been no rigorous assessment of the effectiveness of Clinical Ethics Committees in resolving ethical problems.

Religion

Christianity is the major religion of the UK and Europe. Both the Protestant and Roman Catholic churches accept that treatment may be withheld or withdrawn when indicated. Individuals may, however, have differing opinions based on their personal religious beliefs.

Legal

The legal situation in the UK and throughout Europe regarding withdrawal or withholding of treatment is fairly uniform. The case of Tony Bland in England illustrates this well and is probably one of the most notable in recent years. Tony Bland suffered severe brain injuries due to hypoxia. After 3 years it was clear that he was in a permanent vegetative state and would not recover. His family approached the court asking that the artificial hydration and nutrition which was keeping him alive be stopped. His case eventually reached the House of Lords, the highest court in the UK. The decision by the Law Lords was based upon whether Bland's interests were best served by continuing or stopping treatment. It was accepted although treatment was originally started in Tony Bland's best interests all hope of recovery had now receded. As a result his best interests in being kept alive had also disappeared (11)

Basis of decision

The decision making process at the start of Intensive Care is relatively simple. At this stage treatment is aimed at improving the patient's physiological condition and underlying acute pathology. This presents no significant ethical difficulties as it is presumed to be in the patient's best interests to attempt to treat. It is also relatively simple in legal terms as the patient may have been able to consent to this treatment. Even if the patient, because of his condition, is unable to consent treatment is permitted by legislation in Scotland (12). There are instances when patients referred for admission to intensive care are not admitted because the likelihood of benefit is small or nonexistent. This decision is based on the underlying pathology, the acute condition, and is discussed with the referring medical team, the patient and the patient's relatives as well. This is based on the ethical principle that in order to provide treatment there should be at least a presumption of potential benefit (beneficence). In this situation that is absent and there is only the possibility of

harm (maleficence).

The ethical dilemma develops when a patient does not respond to the therapies provided. Although all patients should be admitted with the expectation that they may improve, a significant proportion do not. Discussions occur between the medical staff and with the patient's relatives. Although it is possible to provide approximate chances of survival at the onset of intensive care these estimates apply to groups and not to individuals. Over time it becomes clearer whether the patient is likely to survive or not.

Those deemed to be nonsurvivors fall into three distinct groups. The clearest group are those who continue to deteriorate despite increasing levels of support. These patients will die soon even if full intensive care support is continued, or even escalated. The second, but more numerous, group is characterised by patients who require high levels of support but are neither deteriorating nor improving. A further distinct group of patients are those that ultimately require a low level of support, usually respiratory, but are unable to become independent of intensive care. Each group poses different ethical questions.

Patients that are deteriorating despite escalating support do not present an ethical dilemma. If it is impossible to reverse the acute pathological process and they are dying despite full therapy the decision making process is simple. If it is agreed that the patient is dying then there are only two options available. The first is to continue to treat with the expectation that the patient will die. The alternative is to withdraw or withhold active therapy whilst continuing all comfort care measures. Ethically there is no problem stopping because where the treatment cannot achieve its intended outcome then there is an obligation to stop it.

Decisions are more difficult in the situation where the patient requires high levels of support, is not deteriorating, but the underlying pathology has not resolved. In these circumstances it is mandatory that an assessment is made of the possible benefits to the patient of continuing these high levels of support. Providing there is judged to be no realistic expectation of recovery then the same ethical principles apply. Under certain circumstances a decision may be made to withhold or withdraw even though the patient is not actually dying at that time. This occurs because it may not be in that patient's best interests to continue. It may be that although recovery to extent of no longer requiring organ support could eventually be achieved, the chances of having an acceptable quality of

life following intensive care are remote. This can occur if the severity of underlying chronic co-morbidities was unknown or underestimated at the time of admission to ICU.

The third group present a considerably greater challenge. These patients appear stable on minimal support but are requiring a very prolonged period of intensive care. It is often very difficult to be certain that continuing therapy will be beneficial. In this situation it is most important to determine what the patient's wishes would have been. The underlying ethical principles here are autonomy and non-maleficence. These courses of action also are supported by a survey of critical care clinicians who ranked continuing organ failure or deterioration, a failure to improve and the patient's prognosis as the most important considerations in deciding to continue, withhold or withdraw treatment (13).

Occasionally the patient may be able to communicate their wish that no further active measures are desired. In that case the clinician must respect the autonomy of the patient and continue comfort care but cease all active interventions. There is no legal issue with this course of action as to continue treatment that the patient has refused would be assault. Unfortunately, communication with the patient is not usually feasible. Therefore a number of factors need to be considered such as the person's previously expressed wishes, post intensive care quality of life and the reversibility of the residual organ dysfunction. Although advance directives, which record a person's treatment wishes, are supported in law very few people have actually prepared one (14). As a substitute we often ask the relatives to give their opinion regarding the patient's wishes. There are limitations with this as it is known that the relatives may, despite their best intentions, not be accurate about the patient's wishes as they believe or even be aware of their role (15) (16). It therefore becomes the clinician's duty to determine the patient's "best interests". This has some similarities to the traditional paternalistic approach. The significant difference being that some effort to determine the patient's wishes must be made. The actual decision as to what is in the patient's "best interests" will be influenced by their previous action, the relatives, carers and information from their family physician.

Documentation

The General Medical Council, the regulatory body for doctors in the UK, recommends that prior to any decision being made regarding the futility of treatment that the issues are fully discussed and documented. This should

include the senior medical and nursing staff of the ICU as well as the referring medical team. It is important that the reason for considering therapy to be futile is established. Sometimes this is relatively simple if there is an evidence base that can be applied directly to this situation. An example would be persistent coma with the absence of papillary, corneal and motor responses at 24 or 72 hours following cardiac arrest. Unfortunately, such clear cut conditions are unusual. The diagnosis, other co-morbidities, prognosis and response to therapy all have to be considered before a final decision is made. This is not as precise as using a defined evidence base. It is, therefore, our practice to insist that there is unanimity amongst the consultant staff before a decision to withhold or withdraw therapy can be made. Should any member of consultant staff not agree then treatment is continued. Such an approach is consistent with the advice of the regulatory bodies in the UK (6,7). It must be recognised that at times a group may benefit from some impartial advice from colleagues from other units.

The General Medical Council and the British Medical Association recommend that following the steps outlined above the documentation of the decision to withdraw or withhold therapy should include:

- The relevant clinical findings.
- Details of the discussions with the patient.
- Details of the discussions with the health care team.
- Details of the discussions with others involved in the decision (for example relatives).
- All details of any treatment given, stopped or withheld.
- Review date, if appropriate.

Our Practice

Once a decision that the patient will not survive intensive care our first priority is to ensure the continued comfort of the patient and the family. This is consistent with the ethical principles of non-maleficence and beneficence.

The next decision is to whether there should be a limit on treatment or a withdrawal of treatment. Although in principle withdrawing of treatment would be the most consistent with the ethical principles this may not be the most practical approach. Sometimes the family needs time to come to terms with these decisions. There may also be practical issues such as the imminent arrival of other family members who wish to visit before treatment is stopped. Indeed there is evidence to suggest that even when a patient's death is sudden and unexpected that the family wish to be present. As most critically ill patients are on multiple organ support the mode and level of support affect how therapy is withdrawn. In our practice the majority of

patients receive ventilatory support and therefore curtailment of this is a usual feature of treatment withdrawal. Because of the sophisticated ventilators in use very few patients receive muscle relaxants to facilitate ventilatory support. We are therefore withdrawing high levels of support in patients that can breathe for themselves. This avoids the controversial practice of removing ventilatory support from a paralysed patient in whom the use of muscle relaxants which would make death inevitable. This could be interpreted as intentionally killing the patient. It is our practice to remove both the high levels of oxygen and positive end expiratory pressure. Distress from dyspnoea may be minimised by either maintaining some ventilatory support or by using drugs such as opioids. Should the patient not be distressed we may then remove the respiratory support and extubate. A high proportion of our patients also receive inotropic and vasopressor support. As withdrawal of these drugs is associated with hypotension but not distress we normally discontinue them. Renal support is also stopped. In addition other interventions such as antibiotics are discontinued.

The major controversies concerning withdrawal of support where treatment is considered futile occur when the patients are not receiving the levels of organ support that characterise a typical intensive care patient. In this situation the only supportive therapy that can be stopped is the artificial nutrition and hydration. This situation could arise in the ICU, a ward, or even in a nursing home. The current recommendations are that Court's permission to stop is sought prior to any decision is implemented. It is important to emphasise that this legal review is rarely needed. It is only required if there is a serious disagreement between the parties involved. In this rare situation the opinion of a senior judge is obtained. The judge then provides a ruling as to whether the proposed actions are unlawful, or not. It is then up to the clinicians involved as to whether they take or ignore this advice. If they take actions that were declared to be unlawful they then run the risk of being charged with a criminal offence. Unlike many other countries UK law is based on precedent. In other words the outcome of a judicial review is usually guided by the rulings of previous cases. This helps to resolve any conflict between the clinicians and the relatives, or where the family and clinicians are in agreement it protects the clinicians from any accusation of wrong-doing.

References

- 1) Beauchamp TL and Childress JF. Principles of Biomedical Ethics 5th ed. Oxford University Press,

- USA 2004.
- 2) Booth M. Ethical issues in critical care outcome. In Ridley S ed. *Outcomes in Critical Care*. Oxford, UK: Butterworth Heineman 2002:223-248 (or the section to actually read p240-243).
 - 3) Booth MG and Wallace PGM. Ventilating patients for organ donation. In Pace NA and McLean SAM eds. *Ethics and the law in intensive care*. Oxford, UK: Oxford University Press 1996:142-157.
 - 4) Dinnerstein Shirley (1978) Mass App380 N.E. 2d 134.
 - 5) Booth M. Ethical issues in resuscitation and intensive care medicine. *Anaesthesia and Intensive Care Medicine* 2006; 8: 36-39.
 - 6) British Medical Association. *Withholding and withdrawing life-prolonging medical treatment. Guidance for decision making*. 2nd edition. London: BMJ Publishing Group 2001.
 - 7) General Medical Council. *Withholding and withdrawing life prolonging treatments: good practice in decision-making*. London: General Medical Council, 2002.
 - 8) Miss B versus a NHS Trust 92002) EWHC 429 (Fam).
 - 9) http://en.wikipedia.org/wiki/Diane_Pretty
 - 10) Slowther AM & Hope T. (2000) *Clinical Ethics Committees*. *BMJ* 321, 649-650.
 - 11) Airedale NHS Trust v Bland [1993] 1 All ER 821.
 - 12) <http://www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm>
 - 13) McLean SAM and Booth M. *Withholding and withdrawing life-prolonging treatment*. 1998 *Medical Law International*; 3: 169-182.
 - 14) Wilson ES, Booth MG, Pace NA. *Advance statements: the intensivist's perspective*. *CPD Anaesthesia* 2003; 5: 132-136.
 - 15) Booth MG, Doherty P, Fairgrieve R, Kinsella J. *Relatives' knowledge of decision making in intensive care*. *J Medical Ethics* 2004; 30: 459-462.
 - 16) Shalowitz DI, Garrett-Mayer E, Wendler D. *The accuracy of surrogate decision makers*. *Archive of Internal Medicine* 2006; 166: 493-497.

〈総説〉

集中治療における終末期医療上の倫理的枠組み－英国の場合

英国では医療上での父権主義は過去のものとなり、明確な倫理的枠組みによる考え方が一般的となってきた。これは四つの原則、自主性 (autonomy)、無害性 (Non-maleficence)、有益性 (beneficence)、公正性 (justice) から成り立つ。総ての決定はこの四原則がバランス良く為されなくてはならないが、自主性こそが最優先原則であり、これは「患者の同意」の重要性を反映している。治療行為を実施するかどうかは臨床医側の決断であるが、自主性ある患者がその治療に同意するか拒否するか判断できるようにしておかなければならない。それ故、治療のリスクと利益について患者が情報・知識を有していることを確実にしておくことが肝要である。治療を拒否したことが原因となるあらゆる被害は患者の責任となる。患者に意思決定

能力が欠如している場合、つまり救急治療の際や、病気の経過や治療によって患者が意思決定能力を喪失した事態では治療に関して事前に患者の同意を得る義務は流動的になる。

「患者の同意」と「患者の最善の利益」、また治療の「必要性」、救急現場における治療の差し控えと中止に関する倫理的原則、ダブル・エフェクトの原則 (苦痛の緩和などの有益な作用が同時に有害な副作用 (呼吸抑制など) をもたらすことなど)、倫理委員会と医療従事者の啓蒙、司法や宗教との関連、集中医療開始時の判断の根拠と治療効果がみられない場合の倫理的ジレンマについて、生存見込みのない患者を3段階に分類した対応方法について述べる。