UKDEC
UK Donation Ethics Committee

ACADEMY OF MEDICAL ROYAL COLLEGES

Nontherapeutic elective ventilation

A discussion paper
April 2016

Introduction

1 As long as there are people waiting for organ transplants, there will be a need to identify more potential organ donors. Many people express a willingness to donate organs, but most people who die are not able to become donors despite their wishes. Those involved in organ transplantation have sought to widen the range of circumstances in which donation is possible, both to fulfil the wishes of those who wanted to donate and to help those who need to receive organs.

2 One such approach for widening the circumstances in which donation is possible is often known as elective ventilation. This was described in the literature and adopted some years ago in one part of the UK but then abandoned on legal advice. Although it has not been practised in the UK since 1994, it has continued to be the subject of intermittent debate. This paper seeks to distil that debate and to suggest what next steps should be taken.

3 For current purposes, elective ventilation will be defined as the instigation of invasive ventilation for the sole purpose of facilitating organ donation and with no expectation of therapeutic benefit to the person ventilated. It is separate from the practice, solely to allow organ donation, of continuing ventilation in the patient who is already ventilated but dying. Given this definition, the term 'elective ventilation' will be replaced with 'non-therapeutic elective ventilation' (NTEV) for both accuracy and continuity with the existing literature.

Exeter Protocol

4 The 'Exeter protocol' was published in 1990[1] and the process it outlined became known as elective ventilation. It involved identifying, for the purpose of organ-preserving ventilation, unventilated patients who were dying from raised intracranial pressure due to intracranial haemorrhage (ICH). Family consent to organ donation would be sought once it was clear to the clinical team and the family that the patient was dying. Subject to consent, the protocol involved intubation and invasive ventilation at the moment of the patient's terminal breath, either on the ward or following transfer to the intensive care unit (ICU). It was argued that ventilation was being initiated at the moment when the patient died. Organ donation would follow after death had been confirmed by neurological criteria.

[1] Feest TG et al. Protocol for increasing organ donation after cerebrovascular deaths in a district general hospital. Lancet 1990;335:1133-5

Ensuing controversy

5 Publication of the protocol led to considerable debate. Some clinicians objected that it is impossible to know for certain that the patient has, in fact, taken their last breath and that without ventilation they would imminently be shown to have died. In 1994 the Department of Health (DH) advised that this practice was unlawful[2] as elective ventilation, being non-therapeutic, would not be 'for the patient's own benefit'. In the face of this advice, elective ventilation was inevitably abandoned. Its original proponents argued[3], and continue[4] to argue, that its practice could safely and lawfully have been developed across the UK.

Changes in practice

6 In the Exeter protocol, elective ventilation was described specifically in ICH. The medical care of patients with ICH now usually involves more intervention than in 1990, and this often includes ventilation. For this reason the number of patients with ICH potentially suitable for NTEV may be much smaller than was reported in 1990. Whereas that report offered estimates of the numbers of suitable patients with ICH, in this paper it is assumed that the number of patients in whom NTEV could be considered is unknown, as is the range of conditions in which it could be considered.

Changes in politics

7 As well as changes in medical practice, there have been changes in the political structures of health care in the UK. The devolution settlements in the late 1990s saw the establishment or reestablishment of legislative and executive bodies in Scotland, Wales and Northern Ireland. The complexity of the relationships between different branches of government and the extent of legislative competence over transplantation activities and consent are beyond the scope of this paper but there may be increasing divergence of policy and law in this area in future years.

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[2] Acute Services Policy Unit, Identification of Potential Donors of Organs for Transplantation, NHS Executive HSG (94), 41, 1994

[3] Riad H, Nicholls A. An ethical debate: elective ventilation of potential organ donors. *British Medical Journal* 1995;310:714

[4] personal communication from Mr Hany Riad

Changes in law

8 The law governing decisions about what is in the best interests, or to the benefit, of a person lacking capacity to decide has changed since the DH legal advice in 1994. It is now clear that a decision about whether something is to a person's overall benefit[5] should be judged not solely on the basis of clinical factors (such as what effect a treatment would have on their survival) but also on the basis of what is known of their wishes, feelings, beliefs and values. The application of this changed legal emphasis to NTEV has not been tested, because NTEV has not subsequently been practised in the UK. However, it is at least arguable that for a person with a strong wish to donate organs in the event of his or her death, an intervention to make that possible could be to their overall benefit and lawful, even if it is done with no expectation that it would improve his or her own outcome. Whatever the merits of that argument, the legal context has changed so dramatically since 1994 that the legal advice generated in that different era is no longer reliable.

Current position

9 NTEV is not practised in the UK and is still widely regarded as unlawful, notwithstanding the changed clinical and legal context. UKDEC has, however, published guidance on the ethics of using non-therapeutic interventions designed to 'optimise donor organ quality and improve transplant outcomes'[6]. Nothing in that guidance would preclude the application of its principles to NTEV.

Continuing barriers to use of NTEV

10 Outdated perceptions of the legal position, and the potential lack of suitable patients, are not the only barriers to NTEV. As discussed below, there are risks associated with NTEV that would need to be balanced against the benefits associated with fulfilling a person's wish to donate should NTEV be considered in the future.

[5] In this guidance we have used the term 'overall benefit' to ensure that the points discussed are applicable to the different legal frameworks throughout the UK. Other terms, such as 'best interests', are only used in the context of specific legislation.

[6] Interventions before death to optimise donor organ quality and improve transplant outcomes: guidance from the UK Donation Ethics Committee, June 2015.

Potential harm to the patient receiving NTEV

11 Endotracheal intubation and ventilation may cause physical or psychological distress. This distress may be thought unlikely in very ill patients with reduced awareness but in those circumstances the clinical assessment of distress and of specific symptoms is difficult and it may be hard to exclude their presence. There is at least some risk of causing additional distress to patients who are expected to be in the last hours of life, when it would normally be most strenuously avoided. However, account needs to be taken of the extent to which symptoms of pain, discomfort or distress might be alleviated, for example by appropriate analgesia or sedation.

12 There is a risk that a patient who unexpectedly survived following NTEV would have very severe neurological impairment. This risk is probably small but healthcare professionals remain concerned about the seriousness of the potential consequences for the patient.

Potential harm to other patients through pressure on ICU capacity

13 ICU capacity is a scarce resource. Decisions on admission to ICU are carefully judged according to the potential for the admission to improve the patient's prospects of recovery. Use of NTEV without provision of additional ICU beds would inevitably add to the pressure on ICU capacity.

Potential harm to families

14 Visibly intrusive non-therapeutic interventions may cause distress to some relatives of a potential donor. This harm might outweigh the benefit of providing NTEV to facilitate organ donation, However, such distress may be alleviated by their knowledge that the intervention increases the chances of fulfilling the patient's prior wish to donate.

Potential harm to staff

15 ICU staff may feel that providing care that is intrusive and potentially harmful is justified only if the benefit of improved survival outweighs those burdens. The evidence about the effect on staff of NTEV is limited because it has not been practised widely or recently. That limited evidence, and speculation by some ICU practitioners, suggests that NTEV might expose ICU staff to an increased risk of distress when staff perceive no prospect of clinical benefit to their patient. In addition to the important duty to consider the

direct effects on the staff themselves, the indirect effects of corrosion of the ethos of ICU care could lead to harm to future patients.[7]

Potential harm to the public reputation of organ donation

16 Poorly handled adoption of new transplantation activities risks harming the reputation on which the availability of organs rests. The interests of future potential recipients should be considered in evaluating the effect of any such risk from the adoption of NTEV, alongside the potential benefits to them.

Summary and next steps

17 The UK faces a continuing shortage of organ donors and many people who wished to donate die in circumstances that do not allow them to do so. NTEV has been reported as a technique that, for some patients, can make donation possible and can increase the number of organs available. It has not been used in the UK for over two decades because it was thought to be unlawful, but major changes in the law since then may suggest that NTEV is lawful in some cases. Clinical practice has also changed so that we no longer know when NTEV would be possible or suitable, or for how many patients. There is existing generic guidance on non-therapeutic interventions, and if the law allowed it then the principles of this guidance could be applied to NTEV to help determine its suitability.

18 The debate about the use of NTEV has become unproductive because of the perception that it is unlawful. That perception is driven by legal advice that is no longer reliable because the legal context has changed. The barriers to the use of NTEV are so large that it could not yet be readily recommended, but its potential use needs to be re-examined.

[7] Blackwell C (1993). 'Elective Ventilation for Transplant Purposes', *Intensive & Critical Care Nursing* 9:122-128.

Recommendations

We propose the re-examination of NTEV as follows:

Recommendation 1

There should be clarity and accuracy in naming the intervention. A single term should be agreed. 'Elective ventilation' lacks specificity. The term 'organ-preserving ventilation' has the advantage of accuracy and consistency with published work on some other treatments, but lacks continuity with the important body of literature on elective ventilation. NTEV is used in this paper as a compromise between accuracy and continuity with the literature and is proposed as the single term to be used.

Recommendation 2

NTEV should be considered under the law as it now stands, not as it stood in 1994. Advice on the law as it stood then is now out of date.

Recommendation 3

There should be re-examination of the clinical role of NTEV, by establishing an expert consensus about the patient groups in which it could be used, the size of its potential effect on organ donation, and the harms that could arise. No assumptions should be made about what role, if any, the consensus would suggest.

Recommendation 4

If there is an expert consensus that there may be a further role for NTEV, there should then be wider professional and public consultation to determine its acceptability, application and effect on the reputation of organ donation. Again, no assumptions should be made about the outcome of that consultation process.

Recommendation 5

If, following consideration of the law, the clinical potential, and the wider professional and public response, proposals were made for the use of NTEV, then ethical principles such as those in the UKDEC generic guidance on nontherapeutic interventions should be used to make case-by-case decisions on its use. Further detailed work and published guidance on the application of those generic principles to this specific question may be required but for the purpose of deciding on individual cases there is no reason to think that different principles should apply.