a persistent vegetative state remains unknown. Clearly, if any patient undergoing interventional ventilation survived in a vegetative state this would not be in the best interest of patient, his or her family, or society. This question needs a definitive answer before any point of law is addressed, if only to allow people to give more informed consent.

Secondly, admitting an incompetent patient to an intensive care unit and applying invasive support and monitoring solely to benefit others is a new concept that represents a substantial deviation from the way we practise and the way the public expects us to practise—that is, in the best interest of the individual. It is therefore not surprising that many people feel uncomfortable about interventional ventilation. It can be acceptable only if individuals have given prior informed consent not only to organ donation but specifically to interventional ventilation. They must understand that in these circumstances invasive treatment is not simply prolonged after brain stem death to allow organ donation. It is specifically started for no indication other than to allow the fulfilment of the criteria for brain stem death and organ donation. This may be a subtle difference, but it may matter to the people making a choice.

Thirdly, it is questionable whether many of the patients with stroke who would be considered suitable for the protocol would or should be routinely resuscitated and admitted to an intensive care unit simply because the resources are available. Offering futile treatment is undesirable and should be resisted, whether beds in an intensive care unit are available or not.

Finally, many people still consider that dying in a general ward is more peaceful and dignified than being admitted to an intensive care unit, intubated, and mechanically ventilated and then undergoing surgery to harvest organs. This argument, while emotive, is in our experience widely held by health care professionals and should not be simply dismissed. The fact that interventional ventilation was agreed with the patient's relatives does not refute this argument, for reasons discussed by Julia Neuberger.

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1 Riad H, Nicholls A, Neuberger J, Williams SM, Sells RA, Jones MA, *et al.* Elective ventilation of potential organ donors. *BMJ* 1995;310:714-8. (18 March.)

Written protocols do not solve difficulties

EDITOR,—Much is made by the protagonists of interventional ventilation[1] of its approval by, among others, the BMA. The association's guidance included the recommendation that, in each unit, a comprehensive protocol should exist from which no deviation should be permitted.[2] It is therefore worrying that, in the study in Exeter on which the strategy is based, circumstances "made some deviation from the protocol necessary" in four of the nine patients admitted to intensive care.[3] If this was the case in the ideal circumstances of the centre that pioneered the approach, considerable "bending of the rules" might well occur in less well organised hospitals.

Robert Francis proposes incorporating appropriately worded consent to interventional ventilation in the wording of the organ donor card as a means of overcoming existing legal barriers.[1] He argues that, if competent patients can decline lifesaving treatment, why should they not be able to consent to such a non-therapeutic procedure? This approach is flawed since doctors unhappy with the practice could not be compelled to ventilate patients for whom such treatment would be of no benefit.[4]

Finally, even if, as Hany Riad and Anthony Nicholls hope, some legal formula can be found to allow them to resume interventional ventilation, it is difficult to see how the system could operate when, with current provision of beds, the rate of refusal for medically appropriate referrals to intensive care currently runs at 18%.[5]

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Protocol balanced ethical principles

EDITOR,—I was the chairman of the working party that drew up the Exeter protocol for organ retrieval. The original protocol did not use the term "elective ventilation" because of the confusion this would cause. Last October the Department of Health issued guidance that the protocol was unlawful.[1] In view of the protocol's success in increasing the number of kidneys available for donation it is not surprising that Hany Riad and Anthony Nicholls have defended it vigorously and are pressing for a change in the law.[2] When the original protocol was drafted we recognised that for any medical intervention to be lawful it had to be for the patient's benefit. However, the case of F *v* West Berkshire Health Authority had not occurred,[3] and we believed that the consent of the next of kin under the specific circumstances with which we were concerned was adequate.

Careful consideration was given to the four basic principles of medical ethics. Firstly, we were aware that starting mechanical ventilation in a patient with an intracranial haemorrhage on the point of death so that organs could be procured for transplantation was not for that patient's benefit. But then no intervention of any sort was in that patient's interest as the only possible outcome was death.

Secondly, we recognised that such patients are incompetent. They are unable to exercise autonomy. For this reason we brought the matter into the open by frank and honest discussion with the next of kin.

The next questions were, "Would the patient be harmed? Would death be rendered undignified for the patient and even more distressing for the relatives?" Our experience of caring for dying patients, including those with brain stem death, led us to conclude that this would not be the case. Furthermore, to prevent the harm of the persistent vegetative state, mechanical ventilation was not started before the moment of terminal respiratory arrest.

Fourthly, we considered the claims of justice: the needs of those awaiting transplantation and the cost benefits of getting patients off dialysis. We were clear that these claims supported our protocol.

As so often happens in medicine, we were trying to balance several ethical principles in the light of the clinical evidence at the time. For patients dying of intracranial haemorrhage death is inevitable. Nothing can be done to alter that; neither is it usual for their wishes to be known. The ethical basis for the Exeter protocol is openness with the next of kin, ensuring that the patient is not harmed, the welfare of those who need a transplant, and the compassionate and effective use of resources.

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Increase in incidence of tuberculosis

EDITOR,—As Janet Darbyshire points out, the recent increase in notifications of tuberculosis may partly be due to a fall in undernotification.[1] However, the incidence of this condition probably has increased, particularly in areas of social deprivation.[2] At St George's Hospital, which serves a large area of south London, notifications have risen from 44 in 1988 to 118 in 1994.

In the United States, particularly in New York, where the incidence of both tuberculosis and infection with resistant organisms has risen, poor compliance has been a major contributory factor.[3] The introduction of supervised chemotherapy has led to a considerable improvement.[4] Supervision of treatment in Britain is often lackadaisical, and we could learn from the American experience. In a review of the situation in New York Bellin suggested that, in addition to the disease being notified, the satisfactory completion of treatment should be reported to a national authority.[5] Doctors with a high proportion of patients who fail to complete treatment could be targeted and areas with low rates of completion investigated, and further resources could be made available if necessary.

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Bottle feeding and the sudden infant death syndrome

EDITOR,—R E Gilbert and colleagues report that bottle feeding is not a significant independent risk factor for the sudden infant death syndrome.[1] We believe that they may have made a type 2 error (stating that there is no difference when in fact there is one). They report that the risk of the syndrome in breast fed infants was almost half that seen in bottle fed infants after adjustment for a small number of potential confounders. As the reduction in risk did not reach significance, however, they conclude that bottle feeding was not an independent risk factor.

The New Zealand cot death study, a large nationwide case-control study (485 cases and 1800 controls), found after adjustment for a wide range of potential confounders, that infants exclusively breast fed had a significantly reduced risk of the sudden infant death syndrome compared with infants who were bottle fed.[2] The reduced risk was of a similar magnitude to that reported in Gilbert and colleagues' study. Residual confounding due to social or cultural factors is unlikely to explain the results from the New Zealand study. We controlled for a wide range of potential con-