Is providing elective ventilation in the best interests of potential donors?

ABSTRACT: In this paper, we examine the lawfulness of a proposal to provide elective ventilation to incompetent patients who are potential organ donors. Under the current legal framework, this depends on whether the best interests test could be satisfied. It might be argued that, because the *Mental Capacity Act 2005* (UK) (and the common law) make it clear that the best interests test is not confined to the patient's clinical interests, but extends to include the individual's own values, wishes and beliefs, the proposal will be in the patient's best interests. We reject this claim. We argue that, as things currently stand, the proposal could not lawfully be justified as a blanket proposition by reference to the best interests test. Accordingly, a modification of the law would be necessary to render the proposal lawful. We conclude with a suggestion about how that could be achieved.

INTRODUCTION

In a recent guideline published by the National Institute for Health and Clinical Excellence (NICE),[1] endorsed by the British Medical Association's Medical Ethics Committee,[2] proposals have been put forward to clinically stabilise all patients who have suffered a catastrophic brain injury that will otherwise quickly become lethal, but that falls short of leaving them brain dead. These patients are potential organ donors, but they lack capacity to make decisions as a consequence of their injury. As things currently stand, admission to an intensive care unit (ICU) for these patients would not normally be considered appropriate.[3 i] However, these new proposals for clinically stabilising these patients would allow them to be admitted to an ICU to enable inquiries to be made to determine whether the patient has expressed any wish or desire to be a donor. By stabilising such patients, the number of lost opportunities for donation would be minimised.

Elective ventilation, also perhaps more accurately known as 'non-therapeutic ventilation',[4] refers to the practice of initiating ventilation once it has been decided that further treatment is not in the patient's best clinical interests. The ultimate purpose of introducing the ventilation at this stage is to preserve the patient's organs for possible transplantation. In other words, the intention is to enable the patient to benefit *others* by donating their organs, if there is evidence that this is what the patient would have wanted. However, the ventilation would generally have to be provided before there is any such evidence. The more immediate purpose of providing the ventilation is therefore to create enough time to find out what those wishes actually were either through direct knowledge of those wishes or via discussion with relevant parties about what the patient would have wanted, given their values and beliefs. The practice was briefly in operation in Exeter from 1988 to 1994, leading to a 50% increase in the number of organs available for transplantation,[2] but it was stopped after advice from the Department of Health that the practice is unlawful.[5] If the practice were reintroduced today, would it be lawful?

LEGAL ISSUES

1. The broad conception of best interests under the *Mental Capacity Act 2005* (UK)

The basis on which the Department of Health advised that the practice was unlawful is that the initiation of ventilation *after* it has already been decided that no further medical treatment is in the

[i] See reference 3. The authors note admitting them to the ICU would prolong dying and may result in harm.

patient's best interests cannot, logically, be in the patient's best interests.[5] Rather, it is administered in the interests of a potential recipient.

The basis for this legal opinion no longer applies today. As John Coggon and colleagues have pointed out, the best interests test has a wide meaning at both common law and under the *Mental Capacity Act 2005* (UK) (MCA), s 4, and so cannot be confined to clinical interests. Instead, the views and values of the patient, if known, must, as far as is reasonably ascertainable, be taken into account.[6] This will include the patient's own wishes and feelings as expressed when he or she had capacity.[7] On this basis, Coggon and colleagues mount an argument that this could include an expressed desire to donate:

> The law is clear: treating a patient in accordance with his or her best interests means more than doing what is medically indicated. It requires us to explore the patient's values and to choose the course of action that accords best with them. Where a patient would wish to donate, measures such as those described here are not unlawful if they are necessary for organ donation to proceed. They serve, rather than deny, the best interests of the patient.[6]

There are precedents that support this claim. In the context of living donation, the law will allow a child in some circumstances to donate an organ even though, clearly, losing an organ is not in the child's best clinical interests. This is on the basis that it may nonetheless be in the child's best interests, overall.[8] [ii] In the case of In the Matter of G (TJ) [2010] EWHC 3005 (COP) (hereafter G), it has also been found, in the context of a testamentary gift, that the term 'best interests' does not mean 'self-interest' but 'could include altruistic sentiments and concern for others'.[9] There is therefore express judicial authority for the proposition that acting in the interests of others can amount to acting in one's own best interests.[10] Perhaps equally significantly, Morgan J in G stated that '[i]t is not necessary to establish that P [the testator] would have been aware of the fact that P's wishes were carried into effect':

> Respect for P's wishes, actual or putative, can be a relevant factor even where P has no awareness of, and no reaction to, the fact that such wishes are being respected.[11]

It is also worth noting that, in In Re M [2009] EWHC 2525 (Fam), Munby J stated that our best interests continue after death and can include an interest in organ donation for research purposes:

> Best interests do not cease at the moment of death. We have an interest in how our bodies are disposed of after death, whether by burial, cremation or donation for medical research.[12]

Although donation for medical research would not require any pre-mortem interventions (and so Munby J's statement cannot be taken to authorise some pre-mortem procedures designed to facilitate donation as being in the patient's best interests), there is arguably no reason in principle why procedures necessary to facilitate the carrying out of a patient's wish to donate could not be in the best interests of a patient. But this point is subject also to an important caveat stressed by the cases: whether in a given case a procedure is in the best interests of a patient will turn on the particular facts – we cannot erect a presumption that a particular course of conduct is always in the patient's best interests. As Munby J stated in In Re M:

[ii] See reference 8, which cites a US case involving solid organs. The UK and Australian cases, by contrast, involve the donation of bone marrow.

> It all depends, it must depend, upon the individual circumstances of the particular case.[13] [iii]

Indeed, the courts have repeatedly warned against putting a 'gloss' on the legislation by applying presumptions which are not set out in the MCA. Lewison J makes this point in Re P [2009] EWHC 163 (Ch) (expressly endorsed by Morgan J in G), in response to a submission about the known wishes of the testator in that case:

> ….although P's wishes must be given weight, if, as I think, Parliament has endorsed the 'balance sheet' approach, they are only one part of the balance. I agree that those wishes are to be given great weight, but I would prefer not to speak in terms of presumptions.[14]

These dicta in respect of the correct approach under the MCA align with the approach taken at common law, as stated by the English Court of Appeal in *Burke (on the application of) v General Medical Council & Ors* [2006] QB 273. In that case, Lord Phillips MR, Waller LJ and Wall LJ stated:

> The test of whether it is in the best interests of the patient to provide or continue ANH [artificial nutrition and hydration] *must depend on the particular circumstances*.... We do not think it possible to attempt to define what is in the best interests of a patient by a single test, *applicable in all circumstances* [62]-[63] (emphasis added).[15]

In its recent document, 'Legal Issues Relevant to Non-heartbeating Organ Donation', which applies in the UK, the Department of Health has expressly taken the view that '*if a person's wishes were to be a donor*, then certain actions which facilitate donation may be considered in their best interests if they do not cause the person harm or distress or place them at a material risk of experiencing harm or distress' (emphasis added).[16] It goes on to add that, '[a]s with any decision concerning medical treatment, the details of individual cases may vary'.[17] What the case law and the legal opinion by the Department of Health have in common, however, is a statement that the procedures which may be considered to be in the best interests of the patient will be adjudged to be so on the basis of the patient's known wish to be a donor, or on the basis of evidence of what they would have wanted from what is known about their values. As the Department of Health document notes:

> *Once it has been established that a person wanted to donate*, either through direct knowledge of their wishes or as a result of discussions about what the patient would have wanted, successful donation may be seen to be in the person's wider best interests…(emphasis added)[18]

The question, in the case of the current proposals, is whether elective ventilation could be determined to be in the best interests of a patient when those wishes are not yet known and, if so, how this is to be determined. Further, we need to know how to determine this question on a case by case basis, without falling into the trap of erecting a presumption that it is always in the patient's best interests to be placed on ventilation pending discovery of their wishes.

2. Does the best interests test apply broadly enough to include elective ventilation?

It should be noted that the NICE proposals concerning elective ventilation do not automatically fall within the circumstances discussed by the judicial dicta cited above and the Department of Health's recent legal opinion. Only once it is established that a person wanted to donate would such facilitative measures be in the person's best interests, according to the latest Department of Health

[iii] See reference 13, cited with approval by Morgan J in In the Matter of G (TJ) [2010] EWHC 3005 (COP), para 50.

advice of 2009.[19] [iv] But in the changes being proposed, patients are to be clinically stabilised – that is, non-therapeutically ventilated – before those wishes are known. We are one step removed from knowing the patient's wishes or what they would have wanted if they had expressed any view. The whole purpose of these procedures is to provide enough time to find out what those wishes actually are. In spite of this, the NICE guideline suggests that these measures could nonetheless be in the best interests of candidate patients and therefore lawful. In a section entitled 'Assessing best interests', guideline 1.1.7 provides that if 'a delay [to determine a patient's donation wishes] is in the patient's overall best interests, life-sustaining treatments should not be withdrawn *or limited* until the patient's wishes around organ donation have been explored...'.[1] The words 'or limited' imply that the proposed practice in these circumstances extends to *initiating* treatments which suggests that admitting these patients into an ICU for elective ventilation could be in their best interests.

It is not clear how it could be determined whether 'a delay to determine a patient's donation wishes is in the patient's overall best interests'. As noted, we already know that, currently, with many of these patients it would not be appropriate clinically to commence invasive measures. We also know that, at this stage, doctors will often not be in a position to know anything about the patient's past wishes, beliefs and values. How could a medical team determine, then, that a delay to ascertain a patient's donation wishes is in the patient's overall best interests?

One suggestion is that it is in a person's best interests, overall, to have their wishes, or probable wishes, carried out. It would therefore follow that it is in a person's best interests that we make efforts, 'so far as is reasonably ascertainable',[v] to find out what they may have wanted, and so this justifies the provision of these measures. Otherwise, the patient may be deprived of the opportunity to fulfil a wish to donate. This suggestion is *prima facie* plausible. It would certainly be justified in cases where it is discovered that a patient had a strong desire to donate, and possibly also in cases where, even though a strong desire was not expressed, there is evidence that a person would have wanted to donate. But would the same conclusion be possible if it is subsequently discovered that a person did *not* want to donate? What if there was evidence that a patient had said to their family that they never wanted to be on a ventilator? Given how little practitioners would have to go on, once they have determined that further treatment is not in the patient's best *clinical* interests, it does not seem justifiable to determine that treatment is nonetheless in the patient's best interests overall. If a person didn't ever want to be on a ventilator in their condition, and had expressly disavowed any desire to donate, then it is surely not in their interests to be put on a ventilator *at any stage*, and not merely when we discover this fact having first provided the unwanted measures. This means that it might be in one person's best interests, but against another's best interests, to provide these measures. But we will not know in advance – at the point we must make the best interests judgement – which patient will be which.

Could we nonetheless avoid this problem by taking the view that it remains in a patient's best interests in all cases to at least *find out* what their wishes were, this outweighing any subsequent discovery of an aversion to ventilation and donation? The difficulty with this suggestion is that it

[iv] See reference 19: 'if, *having considered and weighed up all of the factors* relevant to the person's situation and *consulted their family*…as required by the MCA, it is decided that a particular action or actions that will facilitate NHBD [non-heartbeating donation] are in that person's best interests, then they may be carried out' (emphasis added). See also, to the same effect, para 6.11 and para 6.17 which carry the same qualification.

[v] These words appear in section 4(6) of the MCA and should not be ignored. Clearly, they qualify the word 'must' in that section.

seems no longer to be an application of the best interests test as required by law. Recall that Munby J stated of the best interests test: "it all depends, it must depend, upon the individual circumstances of the particular case".[13] Recall also the warnings not to elevate a factor to the status of a presumption that is not stated in the MCA, Parliament having been taken by the case law to have endorsed the balance sheet approach.[14] But the proposal would effectively be attempting to attribute a priori weight or importance to the discovery of a person's wishes and feelings, rather than it being a factor to be balanced against others on a case by case basis. It would erect, instead, a presumption that it is always in a person's best interests to at least take steps (which may include invasive procedures) to discover their wishes and values. Similarly, this reasoning would contradict the recent legal opinion of the Department of Health, paragraph 1.5 of which states that a 'person's best interests depend on their individual circumstances – it is therefore not possible to say categorically whether a specific action or decision will always be in every patient's best interests'.[20]

In summary, then, our point is that, although there will be some cases where it is possible to determine that it is in the best interests of a patient to commence elective ventilation, these are likely to be cases where the wishes of the patient are already known – and even when such wishes are known, they will not be decisive for, as the cases make clear, those wishes are only one factor amongst others to be balanced in the circumstances of the case.[vi] But in many cases, the wishes will not be known and elective ventilation would be provided on the basis that it is in the best interests of the patient to find out what their wishes were. This seems to us to amount to the adoption of a presumption that it is in a patient's best interests to do so, which is inconsistent with how the case law on the best interests test has developed. For these reasons, we do not think that the proposals could be considered lawful under the law as it currently stands.

3. Best interests and conflict of interest

A second problem with the proposal concerns its compatibility with the often repeated requirement that a decision to withhold or withdraw life-prolonging measures must be made independently of any considerations of donation. This is a long standing requirement to avoid conflicts of interest. Paragraph 2.1 of the Department of Health's 2009 legal opinion states:

> It is clear that any decision about the futility of further treatment and whether or not such treatment should be withdrawn must be made purely in the interests of the person and independently of any consideration of possible organ donation.[21]

Similarly, the UK Donation Ethics Committee has stated, of the decision to withhold or withdraw life sustaining treatment:

> This decision point needs to be completely independent of consideration of organ donation.[22]

These statements do not distinguish between cases where the patient's wishes are known or not known. The effect of the statements is that, in all cases, a decision to withhold or withdraw life-

[vi] To take the wishes as decisive could be tantamount to confusing the best interests test with the substituted judgement test, a danger the courts have repeatedly warned against. See, for example, Lewison J in Re P [2009] EWHC 163 (Ch), at para 41, expressly endorsed by Morgan J in G. This point applies, of course, *a fortiori* when those wishes are not even known. There can, when balancing the factors, be what is known as 'the factor of magnetic importance' which can be given significant weight, but we do not consider that the desire to ascertain a patient's wishes because those wishes are presently unknown could constitute such a factor, still less that it could do so in every case so as to amount once again to a presumption, contrary to the judicial dicta discussed above.

sustaining measures from a patient must be made in the best interests of the patient, but must be 'completely independent' of consideration of organ donation. But once it is recognised that the wider best interests test under the MCA is the basis for the decision to withhold or withdraw, it seems to us to be impossible to meet this requirement. For the views of the patient, including a wish to donate or evidence of such a wish, would already form part of the test that must supposedly ground a decision made without any reference to organ donation. This problem applies still more if under the current proposals all such patients who are at least potential donors but whose wishes are *not* known will be admitted to ICUs and ventilated, pending discovery of their wishes about donation. For once a point is reached at which treatment would not be considered appropriate, a decision must be made, on the basis of the best interests test, about whether the treatment must be withheld or withdrawn, and if that decision is to be made 'independently of considerations of possible organ donation', then a decision cannot be made at that point to provide or continue non-therapeutic treatment without that decision being made on the basis of possible organ donation. Again, then, there are difficulties in using the best interests test as a possible legal justification for the proposals.

It might be thought that one way round this problem could be to insist that the decision to withhold or withdraw be made exclusively in the patient's *clinical* interests, with the wider application of the test which includes patient's views applying later. But it is inconsistent with the law to make a decision to withhold or withdraw treatment exclusively on the basis of the patient's clinical interests alone. Section 4 of the MCA requires the wider best interests test to be applied in making such a decision. This means that, if the best interests test is to be the foundation of a decision to withhold/withdraw or to provide the treatment, the decision cannot be made independently of a consideration of organ donation.

HOW LEGISLATION MIGHT BE MODIFIED TO SOLVE THE PROBLEM

Although we think that the best interests test would not, as a blanket proposition, permit elective ventilation simply to find out if the patient wanted to be a donor, the legislation could be modified to cater for these circumstances.

The optimal way to achieve this is to enact a provision in the MCA stating that, where a patient has expressed a desire to donate, pre-mortem measures facilitating donation can be undertaken. This will remove any uncertainty about whether the law in the UK can extend to such pre-mortem measures where a wish to donate is known. A separate provision could then be added permitting the use of elective ventilation so as to provide sufficient time to find out what the donor's wishes are. Parliament should make clear its view that the measures can be initiated even if they are not in the patient's best *clinical* interests. While this is, of course, possible as a matter of law, whether this should occur ethically is the subject of ongoing debate.

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