REVIEW

Emergency medicine, organ donation and the Human Tissue Act

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The Human Tissue Act 2004, which governs all activity relating to the human body, organs or tissues, is grounded in the principle of fully informed consent in line with societal expectations. The associated intention to deal with the current deficit of transplantable organs has paradoxically been translated into the legitimisation of non-consensual organ preservation manoeuvres after death. The procurement strategy targeted under this new statute is ''uncontrolled'' non-heart-beating donation, and the clinical arenas would be accident and emergency departments and acute medical wards. Practitioners in these fields need to have an understanding of the process and the associated ethical, logistical and legal hurdles to defensible implementation. In the light of these hurdles, there is an obvious need for more widespread professional and public consultation before adoption of this programme.

The Human Tissue Act 2004,[1] which now governs all activities of the human body, organs or tissue, arose primarily in response to a series of scandals involving the retention of body parts.[2 3] The key theme of the legislation is understandably mandating fully informed consent for any undertaking in this field, with custodial sentences and financial penalties for non-compliance. The medical profession has understood and accepted societal expectations with regard to consent,[4] and the main concerns regarding the proposed Bill revolved around the inherent restrictions on research, resulting in concessionary changes to the final formatting.[5] An aspect that has received less scrutiny, but has a marked effect on the acute medical specialties, relates to the associated intention within the Act to deal with the current deficit of transplantable organs.

Section 43 of the Act will make it lawful for hospital authorities, without any requirement to seek or obtain consent from next of kin, to rapidly target any patient who has died and ''to take steps for the purpose of preserving the part for use for transplantation and to retain the body for that purpose''. The original explanatory notes for the Bill (http://www.publications.parliament.uk/pa/cm200304/cmbills/009/en/04009x--.htm) declared that such action, before consent to organ retrieval and transplantation was sought, was in any regard lawful at that time, without offering an objective point of reference for this assertion. This position was maintained on tenuous grounds by the minister of state before the standing committee, declaring such interventions ''lawful because there is no law against it …. Just as embalming is lawful, so is cold perfusion''[6] (the rapid perfusion of intra-abdominal organs with ice-cold preservation solution via an aortic catheter).

The justification for undertaking these interventions without the consent of the next of kin is set out in Section 27 of the Act, ''Provision with respect to consent'', subparagraph 8, ''a person's relationship shall be left out of account if—(c) having regard to the activity in relation to which consent is sought, it is not reasonably practicable to communicate with him within the time available if consent in relation to the activity is to be acted on''.

The Act therefore, in direct contradiction to the founding principle of fully informed consent, legitimises non-consensual invasive interventions for the potential benefit of a third party, without specifying the nature and extent of those interventions. Furthermore, although the interventions seem restricted to preservation of organs, it can be argued that Section 27 is paving the way for organ retrieval and transplantation. Requests for clarification on these issues during readings of the Bill[6] did not result in greater specificity, justification for the underlying principle, nor any amendment in the final legislation. It should be noted that as the Act progressed through parliament, there was extensive lobbying from bodies such as the British Medical Association, not for clarification but for the incorporation of ''presumed consent'' within the new legislation. Although unsuccessful on a formal footing, it can clearly be seen that aspects of this approach are accommodated in the new statute.

What then are the drivers behind the new legislation, what precisely is being targeted, and what are the implications for accident and emergency and the acute specialties?

DRIVERS BEHIND THE NEW LEGISLATION

An undoubted worldwide imbalance exists between demand for and availability of transplantable organs, with recognised morbidity and mortality for those people on a waiting list. The traditional donor source of the brain stem dead is receding owing to a combination of injury-prevention strategies (seatbelts, airbags, cycle helmets, etc) and more aggressive treatment of

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Abbreviation: NHBOD, non-heart-beating organ donation

both traumatic and vascular brain injury.[7] An increasingly high rate of refusal by relatives [8 9] further compromises donation from this diminishing pool. Given that alternative sources of transplantable tissue and organs, such as xenotransplantation and stem-cell technology, are not currently feasible, the only remaining options are living donation or a return to classic cadaveric retrieval. The cadaveric retrieval process slipped into oblivion with the adoption of the brain stem death concept, which allowed retrieval of vital organs at optimal viability, but the combination of need and evidence of satisfactory function of organs retrieved under these circumstances[10] has forced reconsideration and the subsequent promotion of non-heart-beating organ donation (NHBOD) in the UK[11 12] and worldwide. It can be observed that any arguments on questionable organ viability from asystolic donation become somewhat blunted in the face of retrieval of marginal organs from the brain stem dead in an attempt to meet the demand.[13]

TARGETED PROCUREMENT STRATEGY

NHBOD covers a wide range of donation scenarios, conveniently classified by Kootstra of Maastricht[14] into the controlled group, after a planned withdrawal of active support usually within an intensive care unit, or the uncontrolled categories relevant to accident and emergency: (1) dead on arrival and (2) unsuccessful resuscitation.

However, there are salient ethical, legal and logistical hurdles to defensible introduction of either controlled or uncontrolled NHBOD,[15 16] and it should be noted that in promoting this procurement strategy, neither UK Transplant nor the Department of Health acknowledged these problems or offered solutions, limiting advice to the statement:

> There are recognised differences in international practice and procedures relating to non-heart beating organ and tissue donation. We will therefore work with relevant professional bodies to develop clear national guidance to support these programmes.

Although it is possible to defensibly introduce a controlled donation programme on contemporary ethical principles, despite persistent barriers at law,[17] it is debatable whether the problems can be overcome at all in the emergency setting. The legitimisation of preservation manoeuvres under the new Act modifies rather than excludes the previous legal vulnerability of practitioners engaged in this activity, and does not redefine the process as ethically acceptable or clinically feasible.

KEY ISSUES FOR ACCIDENT AND EMERGENCY AND THE ACUTE MEDICAL SPECIALTIES

An accurate determination of the futility of initiating or maintaining resuscitation manoeuvres, the diagnosis of death and the subsequent consolidation of death to the point at which the patient is unequivocally beyond any capacity for suffering, sufficient to undergo invasive organ-preservation manoeuvres, are the principal clinical challenges. Equivocation over which organ-preservation techniques are permissible, and those which create difficulty with a diagnosis of death, will lead to challenges as to the lawfulness of these despite the new Act. The preservation techniques may also compromise a determination of the cause of death and thereby interfere with the statutory role of the coroner. In an emergency situation, without possession of all information, it is extremely difficult to countenance that a case would not automatically fall within the jurisdiction of a coroner, rendering any such intervention inherently unlawful without the explicit agreement of the coroner. This consideration creates obvious conflict with the unequivocal declaration of lawfulness under the Act, and even a senior clinician, if available, would have no inherent authority to establish primacy over the body. The interventions may also interfere with an evaluation of the role of medical care in the patient's death, within the accident and emergency department or elsewhere, thereby impeding the statutory human rights of the next of kin to a full investigation. Even if these aspects were all satisfactorily dealt with, there would still remain a fundamental ''conflict of interest'' capable of jeopardising public confidence, when invasive non-consensual interventions are undertaken for the benefit of a third party.

DEFINING FUTILITY

The first of the clinical obstacles, defining the futility of either initiating or continuing resuscitation manoeuvres, is extremely problematical in emergency situations. Little is known of the patient, the precipitating cause, underlying comorbidity or indeed the patient's wishes. Futility itself is rarely an all-or-none phenomenon, but a spectrum which accommodates uncertainty and which medical advances will influence, given, for example, the potential for aggressive postinsult care to increase the chances of successful resuscitation[18 19] or to successfully modify neurological outcomes after hypoxic or ischaemic brain injury.[20] Responsibility in these situations often falls to the most junior members of a clinical team who may not have the experience or expertise to exercise the high level of clinical judgement required. Although arguably these decisions are made on pragmatic grounds every day in every institution, these are not currently complicated by the benefit of such a decision to a third party. Given that the process has to be sufficiently transparent to withstand an accusation of conflict of interest, it would seem at least advisable to have the decision taken by more than one senior member of the team, thereby creating logistical problems for most out-of-hours cases.

DIAGNOSIS OF DEATH

Diagnosis of death is notoriously difficult,[21] and the lack of any statutory definition in the UK law creates an obvious and marked hurdle. The original medical arguments for brain stem death to be considered equivalent to classical cardiorespiratory death—namely, ''A person is not dead unless his brain is dead. Arrest of the heart and circulation indicate death only when they persist long enough for the brain to die''[22]—were clearly directed towards judicial and public acceptance of the concept and thereby the legitimisation of beating-heart organ retrieval. In successfully altering the concepts and definitions of death, albeit, in case law rather than statute,[23] there was little foresight for the problems that would arise when attempting to return to the classical cardiovascular criteria of death, particularly in the face of senior legal commentary that ''brain stem death is the only true death''.[24] Although a pragmatic approach to the diagnosis of death has been established[17] and the Academy of Medical Royal Colleges has embarked on a consultation exercise with similar proposals,[25] a more problematical issue still remains. The point at which death has been consolidated sufficiently for organ-preservation or retrieval manoeuvres not to trigger cardiac activity or generate neuronal stimulation and potential suffering is vexed, and cannot be considered to reside solely with medical opinion and authority. It should be noted that certain centres have embarked on organ retrieval 2 min after asystole,[26] the suggested limit at which autoresuscitation can take place, and it is difficult to countenance public or professional acceptance of this approach. Although clinicians in emergency medicine may be comfortable with their current

requirement to certify death, there has never been a need to diagnose death so urgently before to limit the warm ischaemia time, and the diagnosis of death has not previously resulted in immediate interventions on the body. This would represent a considerable change from current procedure, where the simple passage of time and observation of the patient is sufficient to consolidate the diagnosis of death.

These hurdles would appear to be ignored by the process previously described in accident and emergency departments, whereby resuscitative manoeuvres were continued after a declaration of death while organ perfusion was established,[27] a return of cognitive function being possible in these circumstances. If in these circumstances death cannot be assumed by the above criteria, then this activity could be construed as assault.

With regard to the legality of this described process, if the patient were indeed dead, the practice still could not be accommodated under the then active Human Tissue Act 1961, as it did not constitute removal of organs for therapeutic purposes and ''lack of objection'' of the next of kin had not been confirmed. The new Human Tissue Act has thereby declared a process that was hitherto unlawful, lawful, despite the assertions of previous legality.

It should be noted that without a robust definition of death, the lawfulness of the preservation techniques remains questionable even with the new legislation.

NATURE OF THE PRESERVATION TECHNIQUES COVERED UNDER THE ACT

Clarification as to which organ-preservation manoeuvres are lawful has not been forthcoming, and this is clearly not helpful to any party. The approach described earlier shows considerable similarities to the process of elective ventilation,[28] which was declared unlawful in 1994[29]—that is, before the publication of those undertakings in the accident and emergency department. We can assume pragmatically that any intervention before the consolidation of death, and any that restores flow or oxygen delivery to the brain or heart, will inherently invalidate the diagnosis of death and thereby render those interventions unlawful, but it would clearly be beneficial for a transparent definitive position on this issue.

ADDITIONAL AREAS OF CONCERN

Even if all these aspects are resolved satisfactorily, there still remains uncertainty about who has the authority to initiate the process and who will take responsibility for these interventions. Arbitrarily declaring a process lawful does not automatically bestow rights over the body and, regardless of the statutory power of the coroner, the courts also recognise that whoever is responsible for disposal of the body does have a possession right.[30] Interference with this right could clearly create liability, and if the interventions are construed as mutilation, this, although purposeful, may be actionable. A further possibility would be the deceased's relatives raising a claim for psychiatric injury, particularly if the interventions have been witnessed, a key factor in litigation success.[31] Even though the general public may accept that a corpse cannot be harmed, respect for the dignity of the human body, particularly immediately after a diagnosis of death, is foreseeable.[32] This invasive, non-consensual, organ-preservation process could easily be interpreted as a lack of respect for the human body, the patient and indeed any potential concerns of the family, thereby generating mistrust and opposition towards the process of organ donation. A predictably high incidence of non-viability after this recruitment strategy raises further questions on the justification for embarking on it in the first instance, and if the organs cannot be used or cause actual harm to the recipient, this alone may compromise public acceptance.

It is inevitable therefore that without resolution of the above issues, practitioners in accident and emergency and acute medicine will harbour misgivings on ethical, if not legal, grounds. There is no reference in the Act to an obligation to comply with a process that is now deemed lawful, or to the status of conscientious objection, which leaves a further hiatus. A separate team is proposed as responsible for these interventions and subsequent retrieval, but this would not deal with the above problems or absolve the primary clinicians making the referral from any responsibility. Arguably, if the patient attends in these circumstances carrying a donor card, then staff are under some ethical obligation to fulfil his or her wishes, but it can be counter-argued that the card or indeed entry on the donor register does not constitute an adequate standard of informed consent that is applied in other aspects of medical activity and indeed within the directions of the new Human Tissue Act itself. Even with such detailed consent, staff would still be vulnerable to accusations of conflict of interest.

CONCLUSIONS

Under the new Human Tissue Act, invasive organ-preservation techniques in the event of sudden death and in the absence of consent are now deemed lawful. The inherent clinical, ethical, legal and logistical problems surrounding this process have not been explained, explored or resolved. While accepting the case of need for transplantable organs, this approach is neither ethically defensible nor sustainable. These issues require the broadest professional and public consultation, not simplistic legislation. Accident and emergency medicine and the acute specialties should consider all the inherent problems before endorsing and implementing this latest organ-procurement strategy.

Competing interests: None.

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