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LETTERS

PRESUMED CONSENT

Incentivising organ donation



MICHELLE DEL GUERCIO/ISPL

Bird and Harris argue that the time has come to move to presumed consent for organ donation.¹ The United Kingdom has one of the lowest organ donor rates in the developed world, roughly 14.5 donors per million population, or 12.9 in 2006 compared with 35.5 in Spain, 26.9 in the United States, and 23.2 in France.²

Surveys have shown that up to 90% of Britons would donate their organs, yet only 27% are on the register.^{3,4} Consequently the first time that most people are faced with the issue is on being asked to consent to their next of kin's donation of his or her organs. If the next of kin is registered, only 10% of relatives will obstruct or question the wish of the deceased to donate. The rate of denial rises to 40% if the next of kin is not on the organ donor register.

Here lies the importance of an incentive scheme. Haddow's recent survey in Scotland reinforces the public's lack of engagement with the issue: "Strikingly, over two thirds of those 'willing' [to donate] were uncertain whether they had registered or had left no indication. Other results show that just under half of those willing to donate had not told their family despite the majority (74%) saying they were aware their next of kin would have the final decision."⁵

People must engage fully with the issue in advance. Publicity and education are important but may not be enough to overcome the apathy with which many public health campaigns are greeted. It is not enough to approve of the idea of donation without acting on the thought.

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Realise potential of current systems before changing the law

Consent is only one of several factors influencing donation rates.¹ We note that the before and after studies considered by the Organ Donation Taskforce and referenced by Bird and Harris² assessed a broad range of measures, in addition to a change in law.

Since *Organs for Transplant*, the report proposing changes to organ donation in the United Kingdom, was accepted by government, donation from deceased patients has increased despite a reduction in the number of brain stem dead patients. In some parts of the UK the number of donors per million population is reaching rates seen in Europe: in Cambridge the current rate is 28.1 and in Plymouth 25.2 after the introduction of inhouse coordination and the engagement and cooperation of local intensivists.³

This emphasises the need to implement all of the recommendations of the Organ Donation Taskforce's first report, and raises further doubts about the need to move to presumed consent. It is the view of the taskforce that an immediate change in legislation may jeopardise the interventions needed to further increase the donor pool. Realising the potential of the current systems now in place to support donation is likely to have a faster impact, with the potential of increasing donation rates by at least 50% by 2013.

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Competing interests: None declared.

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View from France: coming full circle

Bird and Harris propose moving to presumed consent to increase organ donation in the United Kingdom.¹ France moved to presumed consent 34 years ago.² All people are considered to consent to organ donation after death unless they have recorded opposition while alive (Laws of Bioethics).³ Interestingly, despite this encouraging policy, refusal rates in France are still high—32.2% in 2009⁴—and comparable to those currently observed in the UK. Presumed consent failed to substantially increase the number of organs available in France.

Even more strikingly, the policy of presumed consent (or the opt-out system) for organ donation is very difficult to apply in practice. Indeed, physicians are legally responsible for asking the patient's family if the deceased had expressed opposition to organ donation. The boundaries between expressed opposition by the deceased and relatives' refusal are extremely difficult for families and physicians to define. Therefore, relatives' refusal often overrides the decision, and presumed consent does not change this attitude.

Furthermore, recent public debate organised by the French government before a planned revision of the Laws of Bioethics has brought clear evidence that citizens misunderstand and distrust the current presumed consent system with its little known opt-out register.⁵ To guarantee informed choice for organ donation, citizens have strongly expressed their support for the system to evolve to a more transparent and balanced opt-out and... opt-in register.

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Competing interests: None declared.

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What about mandated choice?

Bird and Harris argue for a move to presumed consent for organ donation.¹ As Harris has previously noted, “presumed consent is a fiction. Without the actual consent of the individual, there is no consent.”² This bypassing of respect for autonomy, one of the cornerstones of modern medical practice, could alienate a large proportion of the public.

The resulting lack of support is thought to have resulted in the fall in donation rates in Sweden with the introduction of presumed consent in 1996, from an average of 13.4 donors per million of population in the five years before 1996 to an average of 12.7 over the next five years.³ The potential for negative publicity to affect donation rates was also seen in France after the so called Amiens affair, in which corneas were removed without consent from 19 year old Christophe Tesniere, the rate of corneal donation falling by 37% over the following two years.⁴

Bird and Harris do not discuss alternatives to presumed consent such as required request or mandated choice, in which people are asked to express their preference about organ donation when completing an application form for one of several state related services. Mandated choice has recently been advocated by the Royal College of Physicians⁵ and discussed in the House of Commons as a Ten Minute Rule Bill. Unlike presumed consent, mandated choice is both open and honest—crucial in retaining the full confidence of the public. In the United States the introduction of the New Jersey Hero Act in July 2008 means that from 2013, a decision on donation will be a condition of obtaining or renewing a driving licence in that state. This timing coincides with the Organ Donation Taskforce’s target of a 50% increase in donations—if its efforts do not produce these results then the results in New Jersey should be analysed and mandated choice reconsidered.

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Competing interests: None declared.

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Authors’ reply

The Organ Donation Taskforce has managed to find numerous reasons for doing nothing about heart-beating brain-stem dead donors, thus preserving a system that on any figures or methods of estimation costs many hundreds of lives. Our critics, however well intentioned, do not address this massive and needless loss of quality and length of life.

Buggins doubts the need to move to presumed consent,¹ but the need is made acute by the lives needlessly lost. Opting-out would save lives at a moral cost which is trivial compared with the benefits and which society has demonstrated it is more than willing to pay by its acceptance of coronial postmortem examination. We point out: “In the UK, there are fewer than 3000 confirmed brain stem deaths a year in which presumed consent for organ donation, as a public good, would apply if the deceased had not opted-out in life. For comparison, over 120 000 coronial or fiscal postmortem examinations are done in the UK each year.”² Thus the UK already accepts a vast interference without consent with bodies after death.

There is nothing dishonest or covert in opting out: the citizen retains control and so there can be no basis for threat to patients’ trust in the medical profession.³ If opt-out has been exercised, organs will not be used.

The Organ Donation Taskforce argued that a 50% increase in heart-beating brain-stem dead donors by 2013 was possible through structural changes to NHS. We challenge this. There is simply no precedent for such a major shift in relatives’ refusal rate. And evidence from the UK shows that even major sustained publicity about transplantation was capable of inducing only a quarter reduction in relatives’ refusal rate.

The UK’s 40% relatives’ refusal rate, higher than in France,⁴ is a massive problem. Mandated choice obliges citizens to register or forfeit, for example, their right to drive.⁵ Well informed citizens who mistrust Big Brother databases but favour organ donation are in a bind.

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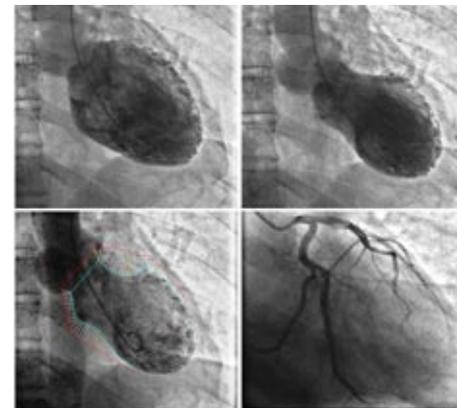
Competing interests: None declared.

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TAKOTSUBO CARDIOMYOPATHY

An underdiagnosed complication of anaesthesia?



Coronary angiography and left ventricular ventriculography show non-obstructive coronary arteries and apical ballooning

Takotsubo cardiomyopathy (TC) can be a serious but reversible cause of acute myocardial dysfunction after anaesthesia.¹ A 43 year old man recently underwent laparoscopic cholecystectomy at our day case unit. He was systemically well with no comorbidities but was extremely anxious about the procedure.

Anaesthetic induction and surgery were uneventful but shortly after he developed acute respiratory failure requiring reintubation and transfer to intensive care. Clinical and radiological findings confirmed acute pulmonary oedema and electrocardiography showed a sinus tachycardia.

Echocardiography showed dyskinesia of apical and mid-ventricular segments, with normokinesis of basal segments and a reduced ejection fraction. This “apical ballooning” of the left ventricle (figure) raised the suspicion of TC. Within 12 hours deep T wave inversion developed on all chest leads on electrocardiography and troponin T was mildly raised disproportionate to the degree of left ventricle impairment.

Coronary angiography confirmed non-obstructive coronary arteries and a left ventriculogram confirmed the echocardiographic findings, with apical ballooning and an ejection fraction of 36%. He was weaned from mechanical ventilation and extubated after angiography. He was started on β blockers and discharged with outpatient follow-up. Left

ventricular function was normal two months later.

TC has been reported after general anaesthesia,² but with more day case procedures will we see it more often? Patients turn up on the morning of surgery, anxious. No premedication is possible because of consent, and the patient needs to be discharged that day. This sounds like a recipe for TC.

Anaesthetists are all aware of the cases of “negative pressure pulmonary oedema” on emergence from general anaesthesia. We propose that this might be accounted for by TC. Emergence is stressful—patients may be in pain, and the pulmonary oedema that ensues is generally reversible over the next few hours—again, a recipe for TC.

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Competing interests: None declared.

Patient consent obtained.

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Cite this as: *BMJ* 2010;340:c3141

HOSPITAL MORTALITY RATES

Beware surgeon specific rates

Despite evidence that hospital specific mortality rates are vulnerable to differences in clinical coding and admission practices across the NHS,¹ and criticism of their use as a surrogate measure of hospital performance,² hospitals are attempting to use these data to calculate surgeon specific mortality. This should be done with great caution because of the limitations of these data for determining surgical mortality.

Surgeons are vulnerable to being misjudged through mortality data (unadjusted to reflect clinical decision making) collected by hospitals and sent to organisations such as Dr Foster. This is not to say that as surgeons our patient mortality should not be audited. Several excellent audits of surgical mortality exist.

The Western Australia audit of surgical mortality (WAASM),³ Tasmanian audit of surgical mortality (TASM),⁴ and Scottish audit of surgical mortality (SASM)⁵ are state or national audits of deaths under surgical care, which evaluate areas of concern (identified in 15-35% of cases) and when these contribute to death (2-7.3% of cases).

Critical appraisal through national audits suggests that most deaths under surgical care result from underlying terminal disease or are within an acceptable range of postoperative

risk. Surgeons should not be discouraged from operating on patients with ruptured aneurysms or perforated bowels merely to reduce postoperative mortality statistics. Surgeons should themselves be more involved in providing the public an account of their performance rather than relying on inaccurate surrogates such as hospital specific mortality rates.

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Competing interests: None declared.

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ACUPUNCTURE INFECTIONS

Editorial exaggerates the risk



TIM MALYON & PAUL BIDDLE/SPL

Acupuncture is increasingly popular, and Woo and colleagues correctly emphasise the need to increase awareness of its side effects and for training and regulation.¹

But the risk of infection is overstated because the editorial is based largely on anecdotal evidence: a 33 year old review, four case reports, a retrospective case series, and one epidemiological study from South Korea. It omits several large prospective observational studies that provide the most reliable assessments of risk. Two surveys of over 66 000 consultations found just one case of cellulitis,^{2,3} and another survey of over 200 000 treatments found 31 events.⁴ Both studies were designed to detect delayed adverse events such as infections; Woo and colleagues are right that there is a “tip,” but there is certainly no “iceberg” beneath.

The authors recommend routine use of skin disinfection, but this runs against the opinion of experts.^{5,6} Routine disinfection of skin is unnecessary before acupuncture in healthy patients, just as it is before injection, as long as the skin looks healthy and clean. Skin disinfection before venepuncture and immunisation has been largely discontinued without adverse effects, and an acupuncture needle tip carries very few bacteria. Routine disinfection before acupuncture would increase the pain of needling without reducing risk of infection. Use of sterile disposable needles and thorough cleaning of the practitioner's hands between patients should be routine. Only where risk is increased, such as in immunocompromised patients, should a practitioner take further precautions.

The editorial exaggerates the risk to patients of acupuncture by fully trained practitioners, and at least in developed countries, patients can be reassured that acupuncture is a remarkably safe procedure, especially compared with some drugs.

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Competing interests: Both authors are employed by the British Medical Acupuncture Society and are editors of *Acupuncture in Medicine*.

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Cite this as: *BMJ* 2010;340:c3148

EMBRACING LEADERSHIP ROLES

Management skills need to be recognised

The Royal College of Physicians (RCP) *Future physician* report,^{1,2} a continuation of its seminal work on medical professionalism,³ emphasises again the crucial part doctors play in leadership. As chairman of the working parties that produced these reports,^{1,3} I strongly endorse their messages and believe in their fundamental importance for the preservation and development of excellent health care. But this belief is tempered with concern.

To date, too few doctors are installed in leadership and management positions

beyond those of clinical director. The RCP and King's Fund review of a series of medical professionalism road shows provided insight into doctors' views on this matter.⁴ Part of the problem may stem from a lack of recognition that the skills of leadership and management need to be valued in the same way as other specialist training. All the royal colleges and faculties need to ensure that their members understand the contribution of clinicians to leadership and management and they need to equip doctors with the right skills to lead and manage. As the road show report emphasises,⁴ doctors must value leadership within the profession and ask what symbols of recognition can be accorded to colleagues who go in this direction to ensure that the experience and expertise of doctors is fully integrated into the running of a well managed service.

The foreword of *Future Physician* ends with the hope that the report will encourage doctors to be at the forefront of change and of shaping the future of health care.¹ It also states that if doctors do not accept the challenges ahead, they do not deserve to lead.

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Competing interests: None declared.

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REMOVING TRANS FAT FROM FOODS

Rendering food injurious to health

In many jurisdictions it is unlawful to render food injurious to health. For example, the UK Food Safety Act section 7 states:

"Rendering food injurious to health: (1) Any person who renders any food injurious to health by means of any of the following operations, namely—(a) adding any article or substance to the food; (b) using any article or substance as an ingredient in the preparation of the food; . . . (2) In determining . . . whether any food is injurious to health, regard shall be had—(a) not only to the probable effect of that food on the health of a person consuming it; but (b) also to the probable cumulative effect of food of substantially the same composition on the health of a person consuming it in ordinary quantities."

Note the emphasis in section 7(2)(b) on probable cumulative effects when consumed in ordinary quantities.

If it is the case that people on poor diets

consume considerable amounts of industrial trans fatty acids, even where the average is quite low, it seems that using industrial trans fatty acids as food ingredients,¹ in any foods that some consumers would eat regularly and frequently, may be unlawful in the United Kingdom.

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Competing interests: None declared.

- 1 Mozaffarian D, Stampfer MJ. Removing industrial trans fat from foods. *BMJ* 2010;340:c1826. (15 April.)

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INDEPENDENT NUTRITIONAL DATA?

British Nutrition Foundation replies

Chamberlain attacks the governance and reputation of the British Nutrition Foundation in his feature article.¹

To ensure integrity and independence, the British Nutrition Foundation has developed a rigorous structure of governance that is also followed by many other organisations. It entails a board of trustees, a council, and scientific committees that are purposely weighted towards independent academics of the highest repute (lists are available to the public on our website, www.nutrition.org.uk). We operate a competing interests register, have a policy for declaring interests at meetings, and have an ethical policy for members. Our council, under the leadership of our honorary president, not our board of trustees, directs our science strategy. Our sources of income are made publicly available on our website and in our annual reports. We make it absolutely clear to the companies that support us financially (all of which are listed on our website) that they can have no influence over policy decisions and the scientific outcomes of our work. Our reputation for integrity and independence is also why the British Nutrition Foundation continues to flourish among those who commission or use our work in promoting greater understanding of the role of diet and nutrition in the health of the population, from governments to educators, from industry to the media.

Yet the picture Chamberlain attempts to paint is the antithesis of this. He also misquotes one of the sources he cites and as a consequence misdescribes the chairman of our board of trustees, Paul Hebblethwaite. Mr Hebblethwaite has previously been chairman of the communications committee of the Biscuit, Cake, Chocolate and Confectionery's trade association but never chairman of the Biscuit, Cake, Chocolate and Confectionery Alliance.

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Competing interests: None declared.

- 1 Chamberlain P. Independence of nutritional information? *BMJ* 2010;340:c1438. (22 March.)
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LETHAL INJECTIONS

Case for a doctor's involvement in judicial executions

Weaver provides some good arguments against the involvement of doctors in judicial executions.¹ However, I do not find them persuasive. (For the record, I am firmly opposed to capital punishment.)

For instance, he writes, "There is no patient; harm is done on purpose; and there is no consent. So, no healthcare professionals belongs here." He is right to make the lack of consent a central argument, but what if the subject does give consent, or even implores the doctor to make the death as painless as possible? Might it not be argued that there is case for the doctor to use his or her skills to make the death (which will happen whether or not the doctor takes part) as painless as possible? After all, as no doubt Weaver would accept, one of the duties of a doctor is to help alleviate pain and minimise suffering.

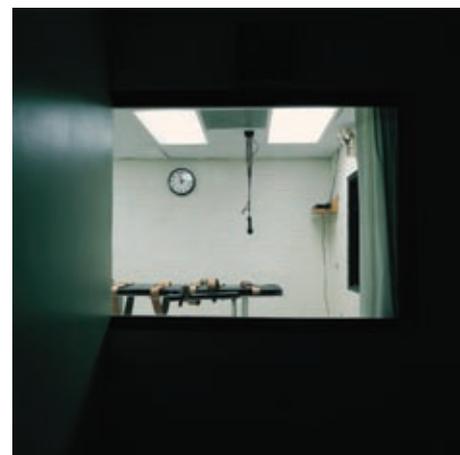
I accept that consent might not be valid because it is not being given voluntarily. But this might not always be the case. The subject might well fill all the criteria for valid informed consent. Indeed, it is arguable that it is rational for the subject to make such a request. In any case, consent is often given by patients when they are in extreme situations.

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Competing interests: None declared.

- 1 Weaver M. Lethal injections: no healthcare professionals should be involved. *BMJ* 2010;340:c2643. (19 May.)

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Lucinda Devlin: *Lethal Injection Chamber from Family Witness Room. Parchman State Penitentiary, Parchman, Mississippi, 1998*