

Impact case study (REF3b)

<p>Institution: University of York</p>
<p>Unit of Assessment: 20, Law</p>
<p>Title of case study: Organ Donation and Presumed Consent Legislation</p>
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>Until recently, there have been insufficient organs for transplantation in the UK. In 2008, the Prime Minister (Gordon Brown) signalled that, in order to remedy this shortfall, he favoured legislating for a system whereby everyone would be legally presumed to have consented to the ‘donation’ of their organs on death (unless one opted out). Brown commissioned the Organ Donation Taskforce to explore the potential impact of presumed consent legislation on organ ‘donation’ rates. The Taskforce, in turn, commissioned the <i>Centre for Reviews and Dissemination</i> at the University of York to conduct a systematic review of the international evidence. The <i>Centre for Reviews and Dissemination</i> has developed particular research expertise in the conduct of systematic reviews – an established scientific methodology for the conduct of meta-analyses of datasets. The Centre’s research findings, in the published view of the Taskforce, provided the “most compelling” argument <i>against</i> a legislative change. The Taskforce ultimately argued that a system of ‘presumed consent’ may actually have a negative effect on donation rates and may erode public trust in the NHS and Government. The alternative policy option it proposed would not only be more effective, it argued, but would avoid any negative side-effects of a ‘presumed consent’ system. Gordon Brown reluctantly accepted this recommendation and abandoned his legislative proposal so that the alternative policy option could be given time to prove its effectiveness. In 2013, this alternative voluntary system succeeded in meeting its target of increased donations. In this way, a 50% national increase in life-saving organ donations was achieved, while a costly and challenging legislative system with its potential erosion of public trust was avoided. The University of York’s research has thus helped to set the agenda for future organ donation policy in the UK.</p>
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>The <i>Centre for Reviews and Dissemination</i> at the University of York was commissioned by the <i>National Institute for Health Research</i> on behalf of the Department of Health Policy Research Programme to inform the work of the UK Organ Donation Taskforce. The commissioned research comprised a systematic review of evidence relating to a specific legal issue: the notion of presumed consent to organ transplantation after death. The research project focused on two key empirical questions about this legal phenomenon: (1) in countries which have legislated to render such consent presumed, what impact has the legislation had on organ ‘donation’ rates? <i>and</i> (2) what are the attitudes of the public, professionals and other stakeholders to presumed consent legislation? The systematic review examined a total of 26 studies and public opinion surveys from across the world in response to these core research questions.</p> <p>On the question of the impact of presumed consent (‘opt out’) legislation, the project team found five in-country studies that had compared donation rates before and after the introduction of legislation. These reported an increase in donation rates after the introduction of presumed consent legislation. However, they had conducted little investigation of any other changes taking place concurrently with the change in legislation and so were unable to locate legislative impact against the backdrop of other potentially significant contextual factors. This weakness was emphasised by the between-country studies examined. They demonstrated that additional factors were associated with an increase in donation rates. In the four best quality between-country comparisons, although presumed consent legislation was associated with increased organ donation, other factors were also found to be important: (a) the common/civil law nature of the legal system, (b) public access to information, (c) mortality from road traffic accidents and cerebrovascular causes, (d) transplant capacity, (e) gross domestic product per capita, (f) health expenditure per capita, (g) religion and (h) education. Ultimately, the review concluded that presumed consent legislation in isolation was unlikely to explain the variation in organ donation rates between different countries:</p> <p style="padding-left: 40px;">A combination of legislation, availability of donors, transplantation system organisation and</p>

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infrastructure, wealth and investment in healthcare, as well as underlying public attitudes to and awareness of organ donation and transplantation may all play a role (Rithalia *et al*, 2009, p. 39)

On the question of underlying attitudes to presumed consent legislation, thirteen surveys of public and professional attitudes to presumed consent were identified. Eight of these explored the attitudes of the UK public. The UK public opinion surveys showed support for presumed consent law but with variation in the levels of support. The project team concluded that the variation in results may have reflected differences in survey methods. Although recent UK surveys indicated support for a presumed consent system, the team ultimately concluded that it was inappropriate on the basis of existing evidence to draw any overall conclusions about public views in the UK.

Of the authors, Rithalia, McDaid, Suekarran, and Norman were employed as Research Fellows by the University of York at the time of the research. Myers held the position of Information Specialist, and Sowden held the position of Deputy Director of the *Centre for Reviews and Dissemination*.

3. References to the research (indicative maximum of six references)

References to the research are as follows:

- Awarded Grant: National Institute for Health Research (Health Technology Assessment programme) (<http://www.hta.ac.uk/1735>)
- Key Publication: Rithalia A, McDaid C, Suekarran S, Norman G, Myers L, Sowden A. 'A systematic review of presumed consent systems for cadaveric organ donation' *Health Technol Assess*. 2009; 13(26): pp. 1-118. (www.hta.ac.uk/fullmono/mon1326.pdf)

Although straddling the boundary between legal and health science research, this underpinning research is nonetheless still a study of law and legal phenomena drawing on the empirical methods of the social sciences. As such, it falls squarely within the description of legal research as set out in paras 12-13 of Part 2C of the Panel Criteria and Working Methods. Systematic reviews are an established scientific methodology. Indeed, the *Centre for Reviews and Dissemination* at York has itself produced the guidance on the conduct of systematic reviews that is recommended by a number of research agencies. It has been used widely, both nationally and internationally.

This research remains, to date, the most comprehensive review of the international evidence on the impact of 'opt-out' legislation on rates of organ 'donation'. It was methodologically rigorous and produced according to internationally accepted methods. Moreover, the review has been subject to external peer review for quality. It has been published in full in the journal *Health Technology Assessment*. Reports are only published in the HTA journal series if they are of a sufficiently high research quality as assessed by peer review. The journal is indexed on MEDLINE, CINAHL, EMBASE, the Cochrane Library and the ISI Science Citation Index and assessed for inclusion in the Database of Abstracts of Reviews of Effects. It has an impact factor of 4.255.

Given the scale and ambition of this systematic review, and the rigour with which it was conducted, this underpinning research is of *at least 2** quality.

4. Details of the impact (indicative maximum 750 words)

The UK has long suffered an under-supply of donated organs capable of transplantation. In 2008, the waiting list for transplants numbered over 8,000 people. It was estimated that, at a minimum, an additional 50% of donations would be required to meet existing needs. The human costs of unmet need are extremely high. In 2007/08, for example, approximately 1,000 people on the waiting list died from lack of available transplant organs [*Source 2: page 6, para 2.2*].

In light of this need, the UK Organ Donation Taskforce was established in 2006 to identify barriers to organ donation and to make appropriate policy recommendations to remedy the deficit. In January 2008 it issued a report that made 14 recommendations for policy change [*Source 1*]. However, the preparatory work for this report had not explored policy options that would have required legislative change [*Source 2: page 6, para 2.4*]. Consequent to this report, the Prime Minister, Gordon Brown, signalled his preference for new legislation introducing an 'opt out' system of presumed consent and called for a "serious debate" on this option [*Source 3*]. He commissioned the Organ Donation Taskforce to undertake further work: (1) to examine what measures would be

required to introduce a 'presumed consent' system; (2) to explore the potential impact of presumed consent legislation on organ donation rates in the UK; and (3) to consider public attitudes to presumed consent [Source 2: page 6, para 2.4]. To inform its work in relation to tasks (2) and (3), the Taskforce commissioned the University of York's *Centre for Reviews and Dissemination* to undertake a systematic review of relevant evidence [Source 2: page 7, para 3.2]. The University of York's findings were presented to the Taskforce in the Spring of 2008.

The Taskforce published its final report in November 2008 [Source 2]. Its overall recommendation was *not* to legislate for a system of presumed consent, but rather to attempt alternative policy options. It believed that organ donations should be increased *without* legislation. Not only would such legislation be costly and challenging, it argued, it may also erode public trust in the NHS and government and have a counter-productive effect on organ availability. The Taskforce, in light of the evidence it had received, put forward alternative non-legislative policy options and recommended that the government should wait for a period of 5 years to see if these alternative policy options would prove successful [Source 2: page 37, para 15.7].

The research of the University of York was a key feature of the evidence considered in the Taskforce's deliberations and it is clear that the University of York's research had a significant and material impact on the Taskforce's ultimate recommendation. Two of the 15 chapters in its report (chapters 11 and 12) discussed the University of York's findings at some length. The University of York's research findings were also published in full as an annexe to the report (Annexe I). In particular, its conclusion that presumed consent legislation in isolation was unlikely to explain variations in organ donation rates was stressed in the Taskforce's overall summary of its reasoning:

Taskforce members had a wide range of views at the outset. However, after examining the evidence, the Taskforce reached a clear consensus in recommending that an opt out system should not be introduced in the UK at the present time. The Taskforce concluded that such a system has the potential to undermine the concept of donation as a gift, to erode trust in the NHS professionals and the Government, and negatively impact on organ donation numbers. It would distract attention away from essential improvements to systems and infrastructure and from the urgent need to improve public awareness and understanding of organ donation. Furthermore, it would be challenging and costly to implement. ***Most compelling of all, we found no convincing evidence that it would deliver significant increases in the number of donated organs.*** (emphasis added) [Source 2: page 34, para 15.2]

On the publication of the Taskforce's report in November 2008, Gordon Brown accepted its recommendation and abandoned his preferred option of legislating for a presumed consent system. He conceded that a voluntary system should be given a period of 5 years to prove its effectiveness [Sources 4]. Speaking at No. 10 Downing Street, he noted,

"... they are not recommending the introduction of a presumed consent system, as I have done ... The proposal is that we double the number of volunteers to 50%. If we can't get there quickly we will return to the proposal." [Source 5]

The target of increasing the numbers of organ donations within 5 years without legislation was, in fact, achieved. NHS Blood and Transplant reported in April 2013 that:

More than 3,100 lives were transformed by deceased donors in the last 12 months as the NHS hit the 50% increase in deceased organ donation, the challenge set by the Organ Donation Taskforce in 2008... The number of deceased organ donors across the UK in 2012/13 hit 1212, representing a 50% increase since 2007/08 when the four UK governments accepted the recommendations of the 2008 Organ Donation Taskforce. There had been almost no increase in the number of deceased donors over the previous decade. [Source 6]

The University of York's research, accordingly, contributed substantially to the Taskforce's recommendations which, in turn, had the following highly significant impacts:

- A change in national policy direction on the part of the Prime Minister
- The prevention of a radical and costly alteration to the UK's voluntary system of transplant

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organ provision

- The avoidance of the potential corrosion of public trust in the NHS and Government
- A successful 50% increase in organ donations, thereby setting the UK agenda for future organ donation policy
- Corresponding life-saving benefits enjoyed by the recipients of the additional donated organs.

5. Sources to corroborate the impact (indicative maximum of 10 references)

1. *Organ Donation Taskforce, Organs For Transplant* (http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf)
2. *Organ Donation Taskforce, The potential impact of an opt out system for organ donation in the UK. An independent report from the Organ Donation Taskforce.* London: Dept of Health, 2008. (http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf)
3. Brown, G, Rt Hon 'Organ Donations Help us Make a Difference', *The Sunday Telegraph*, 13th January 2008 (<http://www.telegraph.co.uk/news/uknews/1575442/Organ-donations-help-us-make-a-difference.html>)
4. Von Radowitz, J 'Brown Shelves Change in Organ Donor Law' *The Independent*, 17th November, 2008 (<http://www.independent.co.uk/life-style/health-and-families/health-news/brown-shelves-change-in-organ-donor-law-1022010.html>)
5. Video of Gordon Brown announcing policy change: <http://www.guardian.co.uk/society/video/2008/nov/17/organ-donation-brown>
6. *NHS achieves ground breaking 50% increase in deceased organ donors:* NHS Blood and Transplant (<http://www.nhsbt.nhs.uk/news/2013/newsrelease110413.html>)