A systematic review of presumed consent systems for deceased organ donation

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Executive summary

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Executive summary

Introduction

In the UK there is currently an insufficient supply of donor organs to meet the demand for organ transplantations. At present the UK has an informed consent legislative system in which individuals opt in if they are willing for their organs to be used after death. The process involves carrying a signed donor card, joining the NHS organ donor register or filling in the relevant sections of a passport or driving licence. However, only approximately 25% of the UK population are on the NHS register. The number of organ donors in the UK in 2007/8 was 13.4 per million population (pmp). It has been proposed that a change in legislation to that of presumed consent, in which everyone is considered a donor unless they have explicitly opted out, would increase donor rates.

Objectives

The primary objective of the review was to examine the impact of presumed consent legislation on organ donation rates by identifying, appraising and synthesising empirical studies that have examined the impact of having a presumed consent or opt-out system. The secondary objective was to identify, appraise and synthesise data on attitudes of the public, professionals and any other stakeholders to presumed consent.

Methods

A systematic review was conducted. Eight electronic databases (MEDLINE, MEDLINE In-Process, EMBASE, CINAHL, PsycINFO, HMIC, PAIS International and OpenSIGLE) were searched from inception to January 2008 to locate published and unpublished studies on organ donation and presumed consent. Supplementary internet searches were also performed.

To be included studies had to compare donation rates in a single country before and after the introduction of a presumed consent law (before-and-after studies) or compare donation rates in countries with and without presumed consent systems (between-country comparisons). The methodological quality of these studies was assessed and a narrative synthesis of results was undertaken. In addition, surveys of attitudes towards presumed consent legislation were included. The methodological quality of the surveys was assessed and considered within a summary of the results of the surveys.

Results

Over 2000 potentially relevant citations were identified, of which 68 were retrieved as full papers (44 for the primary objective and 24 for the secondary objective). After screening, a total of 13 studies (reported in 15 publications) met the inclusion criteria for the primary objective and 13 studies met the inclusion criteria for the secondary objective.

Of the 13 studies addressing the primary objective, eight were between-country comparisons and five were before-and-after studies. Four of the eight between-country comparisons were of sufficient methodological quality to provide reliable results. These studies all used regression models to compare data from different countries. In all four studies presumed consent law or practice was associated with increased rates of organ donation, ranging from an increase of 2.7 donors pmp in one study to 6.14 donors pmp in another. In the third study there was an increase in the rate of organ donation of between 25% and 30% in presumed consent countries and in the fourth study the increase was between 21% and 26%. The studies all assessed the impact of factors other than presumed consent on organ donation rates. Factors found to be important in at least one study were mortality from road traffic accidents and cerebrovascular accident, the transplant capacity of a country, gross domestic product (GDP) per capita and health expenditure per capita, religion (Catholicism), education, public access to information and a common law legal system.

The five before-and-after studies represented three countries, all of which reported an increase

in donation rates following the introduction of a presumed consent system. For example, in Austria the donation rates rose from 4.6 donors pmp to 27.2 pmp over a 5-year period; in Belgium kidney donation rose from 10.9 pmp to 41.3 pmp during a 3-year period; and in Singapore kidney procurement rose from an average of 4.7 per year to 31.3 per year in the 3 years after the change in legislation. Importantly, however, there was very limited investigation of any other changes taking place concurrently with the changes in legislation across this set of studies.

Of the 13 studies addressing the secondary objective, eight were surveys of the UK public and four were from other countries, along with one international survey of health professionals. There was variation among the UK surveys in the level of support for presumed consent, with surveys conducted before 2000 reporting the lowest levels of support (28–57%). The most recent survey by YouGov in 2007 reported that 64% of respondents supported a change to presumed consent. Among the surveys from other countries, only in Belgium, a presumed consent country, was there overall approval of presumed consent.

Conclusions

1. Presumed consent alone is unlikely to explain the variation in organ donation rates between different countries. A combination of legislation, availability of donors, transplantation system organisation and infrastructure, wealth and investment in health care, as well as underlying public attitudes to and awareness of organ donation and transplantation, may all play a role, although the relative importance of each is unclear. The between-country comparison studies overall point to presumed consent law being associated with increased organ donation rates (even when other factors are accounted for) although it cannot be inferred from this that the introduction of presumed consent legislation per se leads to an increase in donation rates. The before-and-after studies suggest an increase in donation rates following the introduction of presumed consent legislation; however, it is not possible to rule out the influence of other factors on donation rates.
2. It is important to note that the survey evidence is incomplete and the variation in attitudes between surveys may reflect differences in methods and the phrasing of questions. Some surveys suggest a lack of public support for presumed consent, both in the UK and in other countries; however, more recent UK surveys provide evidence of support for presumed consent.

Implications for policy

The evidence identified and included in this review relates only to the specific questions posed. It does not address all of the issues relevant to the work of the UK Organ Donation Taskforce and, therefore, cannot be fully informative with respect to policy. In addition, it is important to be aware of the methodological limitations of the evidence that we have identified and appraised. The available evidence suggests that presumed consent legislation is associated with an increase in organ donation rates, although the size of the association varied between studies. Other factors also appear to be associated with organ donation rates, such as transplant capacity and GDP and health expenditure per capita. It is therefore important to consider such factors when attempting to predict the impact of changing to a presumed consent system. It is also important to take into account the likely public response to presumed consent should legislation be changed. The limited and incomplete evidence available from surveys suggests variable levels of support. In addition, consideration needs to be given to potential variation in attitudes between different sociodemographic subgroups.

Implications for research

When a change in legislation occurs it is important to evaluate and monitor the impact on donor rates and other factors, such as registration to opt out. Further reviews could investigate the factors likely to modify donor rates, such as procedures for family involvement. The way in which families of any potential donor are approached is likely to be an important factor and a review of qualitative research examining the experience of relatives in this context would be useful. The information obtained could be used to determine a priori the factors to be investigated in any evaluation of a change in legislation. At the same time contextual information should be gathered such as transplant capacity and any concurrently running media campaigns.

As public views about presumed consent are crucial, any future surveys should carefully consider the

framing of questions and be designed to minimise the strong possibility of providing what is viewed as a socially acceptable answer. To identify groups with whom it would be particularly important to engage with about presumed consent, any future surveys need to be large enough to investigate variations in attitudes across different sociodemographic groups.

Publication

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First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, from the public and consumer groups and from professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA programme then commissions the research by competitive tender.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA programme as project number 08/33/01. The protocol was agreed in April 2008. The assessment report began editorial review in August 2008 and was accepted for publication in December 2008. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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