

# Impact of presumed consent for organ donation on donation rates: a systematic review

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## ABSTRACT

**Objectives** To examine the impact of a system of presumed consent for organ donation on donation rates and to review data on attitudes towards presumed consent.

**Design** Systematic review.

**Data sources** Studies retrieved by online searches to January 2008 of Medline, Medline In-Process, Embase, CINAHL, PsycINFO, HMIC, PAIS International, and OpenSIGLE.

**Studies reviewed** Five studies comparing donation rates before and after the introduction of legislation for presumed consent (before and after studies); eight studies comparing donation rates in countries with and without presumed consent systems (between country comparisons); 13 surveys of public and professional attitudes to presumed consent.

**Results** The five before and after studies represented three countries: all reported an increase in donation rates after the introduction of presumed consent, but there was little investigation of any other changes taking place concurrently with the change in legislation. In the four best quality between country comparisons, presumed consent law or practice was associated with increased organ donation—increases of 25-30%, 21-26%, 2.7 more donors per million population, and 6.14 more donors per million population in the four studies. Other factors found to be important in at least one study were mortality from road traffic accidents and cerebrovascular causes, transplant capacity, gross domestic product per capita, health expenditure per capita, religion (Catholicism), education, public access to information, and a common law legal system. Eight surveys of attitudes to presumed consent were of the UK public. These surveys varied 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, in 2007, reported that 64% of respondents supported a change to presumed consent.

**Conclusion** Presumed consent alone is unlikely to explain the variation in organ donation rates between countries. Legislation, availability of donors, organisation and infrastructure of the transplantation service, wealth and investment in health care, and public attitudes to and awareness of organ donation may all play a part, but their

relative importance is unclear. Recent UK surveys show support for presumed consent, though with variation in results that may reflect differences in survey methods.

## INTRODUCTION

There is currently an insufficient supply of donor organs to meet the demand for organ transplantations in the United Kingdom and worldwide. The UK active transplant waiting list is increasing by about 8% a year, and the ageing population and increasing incidence of type 2 diabetes are likely to exacerbate the shortage of available organs.<sup>1,2</sup> There were 13.2 dead organ donors per million population in the UK in 2007, substantially lower than in several other European countries and especially Spain, which had a rate of 34.3 per million population for the same year.<sup>3</sup>

In 2006 the UK Organ Donation Taskforce was established with the task of identifying barriers to donation and making recommendations for increasing organ donation and procurement within the current legal framework. An explicit or informed consent system operates in the UK and requires that individuals authorise organ removal after death by carrying a donor card or joining a national registry. An overhaul of UK transplant services is planned following the taskforce's recommendations.<sup>1</sup> These included establishing a UK-wide organisation to identify and allocate organs, doubling the number of transplant coordinators, having an organ donation "champion" in each hospital trust, and improving the processes for identifying potential donors and the monitoring of donation activity in all hospitals.

Several countries, including Spain, Austria, and Belgium, have opted for a change in legislation and introduced presumed consent, whereby organs can be used for transplantation after death unless individuals have objected during their lifetime (an opt out system). Countries vary in how organ donation legislation functions in practice, and the terms "hard" and "soft" have been used to characterise how much emphasis is placed on relatives' views in these countries. For example, in Spain the presumed consent law is "soft" in that doctors take active measures to ascertain that the next of kin do not object to organ recovery. In Austria the presumed consent law is relatively "hard" in that

**Box 1: Inclusion and exclusion criteria for studies in systematic review**

**Population and setting**—Any jurisdiction in which a system for deceased organ donation had been introduced

**Intervention**—Presumed consent system for organ donation at death. A presumed consent system was one in which a dead person is considered to be an organ donor unless the person made known his or her opposition to this before death. Countries were considered as presumed consent jurisdictions where such a law is in place, even if the system de facto requires consent of relatives

**Comparator**—A system not based on presumed consent (such as requiring individuals to register as organ donors) within another jurisdiction or in the same jurisdiction before the introduction of presumed consent

**Outcomes**—Organ donation rates were the primary outcome of interest

**Study design**—Studies comparing donation rates in a single country before and after the introduction of a presumed consent law and cross sectional studies comparing donation rates in countries with and without presumed consent systems

organ recovery proceeds unless it is known that the deceased objected before death, and the views of relatives are not actively sought.<sup>4</sup>

In the UK debate has been developing around different systems of consent, with support from the chief medical officer for a presumed consent system. The UK Organ Donation Taskforce was asked to investigate the impact of an opt out system, and its recommendations were published in November 2008. ([www.dh.gov.uk/en/Healthcare/Secondarycare/Transplantation/Organdonation/index.htm](http://www.dh.gov.uk/en/Healthcare/Secondarycare/Transplantation/Organdonation/index.htm))

To inform the work of the taskforce, a systematic review was commissioned of the best available evidence of the effect of presumed consent legislation on organ donation rates. A secondary objective was to assess the literature on public attitudes to presumed consent.

**METHODS****Search strategy**

We searched seven electronic databases from inception to January 2008 without language restrictions. Internet searches were carried out using the specialist engine Intute ([www.intute.ac.uk/healthandlifesciences/](http://www.intute.ac.uk/healthandlifesciences/)) and the meta-search engine Copernic ([www.copernic.com](http://www.copernic.com)). In addition, we browsed relevant organisation websites for additional information and checked the reference lists of included studies. Further details of the search strategy are in the full report.<sup>5</sup>

**Study selection and inclusion criteria**

We sought empirical studies that examined the impact of having a system of presumed consent on organ

donation rates (see box 1). Eligible studies were those which compared organ donation rates before and after the introduction of presumed consent or where organ donation rates were compared in countries with and without systems of presumed consent.

We assessed public and professional attitudes to organ donation and presumed consent. Only studies using survey methods and that focused explicitly on organ donation and presumed consent were included. Surveys from outside the UK were eligible for inclusion as they were a potentially useful source of contextual information for the evaluation studies from other countries.

Two reviewers independently screened all titles and abstracts. The full papers of relevant citations were obtained and independently screened by the two reviewers. Disagreements were resolved by discussion and consensus, and if necessary a third reviewer was consulted.

**Data extraction and quality assessment**

To investigate the impact of presumed consent on organ donation rates we extracted data about study design and method of analysis, country or countries investigated, time period, contextual factors and whether these were included in the analysis, donation rates, and any other outcomes, such as negative effects. We assessed study quality using criteria from a previous systematic review, and derived from the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies (see box 2).<sup>6</sup>

To assess attitudes to presumed consent, we extracted data about the survey methods, the participants, survey questions, and the key findings. We assessed the methodological quality of the surveys using a list of questions for the appraisal of surveys taken from *The Pocket Guide to Critical Appraisal*.<sup>7</sup> Data were extracted and the quality criteria applied by one reviewer and checked by a second reviewer. A statistician also assessed the appropriateness of any regression analyses used in the between country comparison studies.

**Data synthesis**

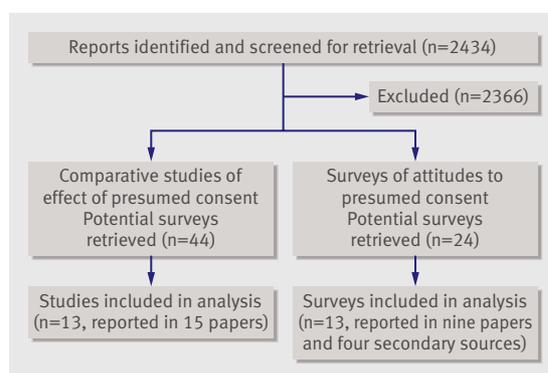
Given the diversity of the studies investigating the impact of presumed consent, we undertook a narrative synthesis. Studies were grouped based on study design, and the results were interpreted in the context of their methodological strengths and weaknesses and any contextual factors that might affect outcomes. The data from surveys were synthesised, taking into account issues of importance identified during the quality assessment.

**RESULTS**

Twenty six studies met our inclusion criteria (see figure). Of these, five assessed organ donation rates before and after the introduction of presumed consent legislation in a single country,<sup>w1-w5</sup> eight compared organ donation rates in countries with presumed consent systems with rates in countries with explicit

**Box 2: Quality assessment criteria used in systematic review**

- Were appropriate countries or cohorts and time periods chosen?
- Were potential confounders sought and, if found, adjusted for in the analysis?
- Were the sources of data for outcome (and explanatory factors) specified and did they appear credible?
- Was it reasonably likely that the observed effects were attributable to presumed consent effects alone?
- Was the statistical analysis appropriate, with no major flaws?



**Selection of studies for inclusion in systematic review of effects of presumed consent on organ donation rates**

or informed consent or similar systems,<sup>w6-w13</sup> and 13 surveys addressed attitudes towards presumed consent.<sup>w14-w26</sup> Of the 13 surveys identified, full details were obtained for nine.

#### Impact of presumed consent on organ donation rates in before and after studies

Before and after studies have the benefit of exploring the experience of individual countries but, because it is an uncontrolled study design, it is not possible to rule out the influence of other known or unknown factors influencing donation rates. All five studies, which represented the experience of three countries, found an increase in organ donation rates following the introduction of presumed consent legislation (table 1). In Austria the 4.6 donors per million population per year before legislation increased to 10.1 per million in the four years after the introduction of presumed consent and to 27.2 per million in the five years after introduction of infrastructure changes including full time transplant coordinators.<sup>w1</sup> In Belgium kidney donation increased from 18.9 to 41.3 per million population per year over a three year period,<sup>w3</sup> and in Singapore kidney procurement increased from 4.7 to

31.3 per million population, also over a three year period.<sup>w4</sup>

However, there was limited exploration of other changes such as increased publicity and organisational and infrastructure changes that might have taken place at the same time as the change in legislation. As such factors are likely to influence donation rates, it is unclear to what extent the increases found were directly attributable to the change in legislation.

#### Impact of presumed consent on organ donation rates in between country comparisons

The eight studies that compared organ donation rates in countries with presumed consent systems with those in countries with explicit or informed consent or other similar systems were based on secondary analyses of published data (table 2). Therefore, any relation found between presumed consent and organ donation rate is associative and cannot show whether the effect was directly attributable to the intervention, and this is reflected in the quality assessment.

Six studies included factors likely to influence organ donation rates, such as mortality from road traffic crashes and health systems, in their analyses.<sup>w6-w11</sup> Four of the eight comparisons between countries had significant limitations, either from lack of any formal statistical analysis or important limitations in the analysis.<sup>w7 w10 w12 w13</sup> and we focus here on the findings of the more robust studies.<sup>w6 w8 w9 w11</sup>

These four studies explored between three and seven explanatory variables in addition to legislation for presumed consent (see table 3). The number of countries and their rationale for inclusion varied, but several countries were common across more than one study. Three of the studies classified countries as having explicit or presumed consent based on the country's legislation, whereas one study<sup>w8</sup> used a classification system based on how presumed consent operated in practice rather than in law. Therefore, in this study 10 countries were classified as having explicit consent de

**Table 1 | Characteristics of before and after studies of legislation for presumed consent for organ donation**

Study	Year when law was implemented	Study region	Time periods compared		Quality assessment*			
			Before	After	Selection	Comparability	Data collection	Attributable to intervention
<b>Austria</b>								
Gnant (1991) <sup>w1</sup>	1982	Single transplantation centre with 32 km <sup>2</sup> catchment area and 3.6 million population	1965-81	1982-5, 1986-90†	-	+	?	-
<b>Belgium</b>								
Roels (1991) <sup>w3</sup>	1986	Countrywide	1982-5	1987-9	++	-	-	-
Vanrenterghem (1988) <sup>w5</sup>	1986	Leuven Collaborative Group for Transplantation (19 nephrology units)	1987-September 1988	1978-86	?	-	?	-
<b>Singapore</b>								
Soh (1992) <sup>w4</sup>	1987 (kidneys only)‡	Countrywide	1970-90	1988-90	-	-	-	-
Low (2006) <sup>w2</sup>	2004 (to include liver, heart, and corneas)	Countrywide	July 2002-June 2004	July 2004-June 2005	+	-	++	-

\*Quality assessment: ++ = criterion met, + = criterion partially met, - = criterion not met, ? = unclear from information provided.

†Period 1982-5 was after legislation only, 1986-90 was after employment of full time transplantation coordinators.

‡Medical Act 1972 provided for the voluntary donation of organs: this legislation continued in 1988-90 alongside the Human Organ and Transplantation Act 1987

facto, and in the other studies they were classified as having presumed consent legislation. Switzerland has a national informed consent law, but many of its constituent jurisdictions (cantons) have their own presumed consent laws: it was recorded having explicit consent in two studies<sup>w8 w11</sup> and in one as having presumed consent.<sup>w9</sup>

The studies also varied in the sources of data used, the time period covered, and the type of analyses performed. Table 3 gives a summary of the analysis, the variables considered, and the factors that were found to be statistically significant predictors in at least one of the models used in each study. Three of the four studies showed a significant association between presumed consent and increased organ donation rates.<sup>w6 w8 w11</sup> The fourth study reported a positive but not significant association.<sup>w9</sup> The size of the increase in organ donation rates with presumed consent varied: 25-30% higher,<sup>w6</sup> 21-26% higher,<sup>w11</sup> 2.7 more donors per million population,<sup>w9</sup> and 6.14 more donors per million population.<sup>w8</sup>

#### *Impact of other factors on organ donation rates*

Although the four robust studies suggest that presumed consent law was associated with increased organ donation rates, other explanatory factors were associated with variation in donation rates between countries (see table 3). (Further details about these are available in the full report.<sup>5</sup>) Organ donation would be expected to depend to some extent on the availability of potential donors, and, in the three studies where it was considered, mortality from road traffic accidents showed a significant association with donation rate (and in one study this was the only factor that had a significant association with donation rates<sup>w9</sup>).

The extent and efficiency of a country's transplant coordination might also be expected to influence organ donation rates. In the one study that considered it, transplant capacity (defined as the number of transplant centres per million population) was positively associated with higher donation rates and within the

statistical model it was the factor with the greatest predictive strength, greater than presumed consent practice, religion, and education.<sup>w8</sup>

Three of the four studies investigated the influence of wealth or healthcare expenditure.<sup>w6 w9 w11</sup> Two entered gross domestic product per capita and health expenditure per capita into separate models as they were found to be highly collinear,<sup>w6 w11</sup> and one used public health expenditure as a percentage of gross domestic product rather than health expenditure per capita.<sup>w9</sup> Gross domestic product per capita and health expenditure per capita were the strongest predictors of donation rates in one model, stronger than presumed consent law.<sup>w11</sup> In another gross domestic product per capita was significantly associated with donation rates,<sup>w6</sup> and a positive association was found in another<sup>w9</sup> but it is unclear whether this reached statistical significance.

The percentage of the population in higher education was included in one study, in order to assess the influence of social demographics on donation rates, and there was a significant positive association.<sup>w8</sup>

The only religion investigated was Catholicism, which is probably a reflection of the countries included in the models. It has been suggested that Catholicism may be associated with favourable attitudes towards organ donation as the religion officially recognises organ transplantation as a "service of life." It was a significant positive predictor of donation rates in one study<sup>w8</sup> and of importance in some sections of the regression model in another,<sup>w11</sup> but not in a study that specifically included only Western Catholic and Protestant countries.<sup>w6</sup> The differences may be partly explained by different samples of included countries. For example, only one study included Latin American and South American countries.<sup>w11</sup>

Two studies investigated the legislative system (common law versus civil law) based on the view that donation rates under a common law legal system, with its emphasis on individual rights, might differ from that under civil law, which places more emphasis on the

**Table 2** | Details of between country comparison studies of legislation for presumed consent for organ donation

Study	Country or region included in the analysis	Quality assessment*				
		Selection	Comparability	Data collection	Attributable to intervention	Appropriate analysis
<b>Studies with robust analysis</b>						
Abadie (2006) <sup>w6</sup>	22 Western Christian countries	+	++	++	?	++
Gimbel (2003) <sup>w8</sup>	28 European countries	+	++	-	?	++
Healy (2005) <sup>w9</sup>	17 OECD countries	+	++	+	?	++
Neto (2007) <sup>w11</sup>	34 OECD and non-OECD countries	++	++	+	?	++
<b>Studies with significant limitations</b>						
Coppen (2005) <sup>w7</sup>	10 European countries	-	+	++	-	-
Johnson (2004) <sup>w10</sup>	17 countries	?	++	?	-	-
McCunn (2003) <sup>w13</sup>	Two adult trauma hospitals, one in US and one in Austria	-	-	++	-	-
Roels (1996) <sup>w12</sup>	Four member countries of Eurotransplant	+	-	++	-	-

\*Quality assessment: ++ = criterion met, + = criterion partially met, - = criterion not met, ? = unclear from information provided. OECD = Organisation for Economic Cooperation and Development.

**Table 3** | Details of analysis and results for between country comparison studies of legislation for presumed consent for organ donation that had a robust analysis

Type of analysis	Statistical significance of factors considered in regression analysis										
	PC law (or practice)	CVA mortality	RTA mortality	GDP	Healthcare expenditure	Transplant capacity	Religion (Catholicism)	Education	Legislative system	Blood donation rate	Internet access
<b>Abadie (2006)<sup>w6</sup></b>											
Fixed regression with panel (longitudinal) data*	P≤0.05	P≤0.05	P≤0.05	P≤0.05	NS	—	NS	—	P≤0.05	NS	—
<b>Neto (2007)<sup>w11</sup></b>											
Quantile regression for panel (longitudinal) data†	P≤0.05	P≤0.05‡	P≤0.05	P≤0.05	P≤0.05	—	P≤0.05**	—	P≤0.05	—	P≤0.05††
<b>Healy (2005)<sup>w9</sup></b>											
Linear mixed-effects regression using time series data‡	NS	NS	P≤0.05	NS	NS	—	—	—	—	—	—
<b>Gimbel (2003)<sup>w8</sup></b>											
Linear ordinary least squares regression using single data point per country§	P≤0.05	—	—	—	—	P≤0.05	P≤0.05	P≤0.05	—	—	—

PC = presumed consent, CVA = cerebrovascular, RTA = road traffic accident, GDP = gross domestic product, NS = not significant.

\*Different combinations of variables considered in a series of models.

†Analysis based on Koenker 2004.<sup>8</sup> Two models were used—one with GDP and one with health expenditure (these were highly collinear). A generalised least squares regression was also performed for comparison.

‡The initial model did not fit the data, and the analysis was repeated excluding outliers (Spain and Italy).

§This study classified countries based on whether there was presumed consent in practice rather than whether presumed consent legislation was in place.

‡Significant in model using health expenditure per capita but not GDP per capita.

\*\*Significant at 25th centile only on one model and 25th and 50th centiles but not the 75th.

††Significant for 25th and 75th centiles.

rights of the state.<sup>w6 w11</sup> Common law was significantly associated with increased donation rates in both studies.

Blood donation rate was investigated as an indicator of social preferences towards organ donation in one study, and it showed a positive though non-significant association with organ donation rates.<sup>w6</sup>

Internet access was used in one study as a proxy measure for access to information.<sup>w11</sup> The percentage of the population with internet access correlated significantly with organ donation rate in some areas of the quantile regression model, suggesting a possible link between greater access to information and increased donation.

#### Attitudes to presumed consent

As the UK surveys are of most relevance, only these are reported here.<sup>w15 w17 w19 w22-w26</sup> (Details of surveys conducted elsewhere can be found in the full report.<sup>5</sup>) We obtained data from eight UK surveys (table 4)—four from full reports<sup>w15 w17 w19 w22</sup> and four from secondary sources.<sup>w23-w26</sup> The surveys obtained through secondary sources could not be fully quality assessed because of insufficient information.

The surveys took place between the mid-1970s and 2007. Details of the survey methods in the full reports were fairly limited. Details of sampling methods were not available for four surveys,<sup>w23-w26</sup> and they varied in how they framed the questions on presumed consent. The four surveys that did provide information about their methods varied in how they phrased the questions on presumed consent, whether it was a “hard” or “soft” version, and in whether they explicitly asked about seeking the views of relatives of potential donors.<sup>w15 w17 w19 w22</sup> These factors

are likely to have influenced the results that were obtained.

Among the four full surveys, the two earliest (conducted in 1976<sup>w19</sup> and 1999<sup>w25</sup>) reported the lowest levels of support, with 34% and 28% in favour of presumed consent, respectively. With the exception of one survey conducted in Scotland, in which 37% agreed that doctors should be allowed to take organs automatically,<sup>w17</sup> surveys conducted from 2000 onwards reported at least 60% of respondents being in support of presumed consent.<sup>w15 w22</sup>

Two UK surveys investigated demographic differences in attitudes.<sup>w17 w22</sup> The most recent found similar levels of support across age, sex, social class, and geographic region.<sup>w22</sup> The other survey found that those who stated they were unwilling to donate all their organs tended to be men, aged over 65 years, and from the least privileged social group: substantially more of these respondents agreed with the soft version of presumed consent than the hard version.<sup>w17</sup> A survey of the Asian community in Glasgow found that 61% were in agreement with presumed consent, but the respondents were from a project intended to be a public forum to promote organ donation rather than be a representative survey.<sup>w15</sup>

With the exception of one survey from Belgium,<sup>w21</sup> where there is presumed consent legislation, most respondents in surveys from outside the UK seemed opposed to presumed consent (full details reported elsewhere<sup>5</sup>).

## DISCUSSION

### Principal findings

We conducted a systematic review investigating the impact of presumed consent legislation on organ

donation rates; to our knowledge this is the first review to address this question. We found four good quality studies comparing organ donation rates between countries with and without systems of presumed consent.<sup>w6 w8 w9 w11</sup> Each study examined the association between presumed consent and organ donation rates in mainly European countries between 1990 and 2002. All four found an association between presumed consent legislation and higher organ donation rates, and in three this was statistically significant.

Estimates of the size of the effect varied: two studies reported a 20-30% increase in organ donation,<sup>w6 w11</sup> one reported 2.7 more donors per million population,<sup>w9</sup> and one reported 6.1 more donors per million population.<sup>w8</sup> There was evidence that factors other than presumed consent contributed to the variation in organ donation rates. In at least one study, mortality from road traffic accidents, the number of transplant centres, gross domestic product per capita, and health expenditure per capita were found to be important. Five before and after studies also showed an increase in organ donation rates following the introduction of presumed consent.

We investigated public attitudes towards presumed consent through surveys carried out in the UK and elsewhere. The eight UK surveys suggest variation in

the level of support for presumed consent, with earlier surveys finding lower levels of support. The most recent survey reported that 64% of respondents supported a change to presumed consent. The findings across the three surveys that investigated variation in attitudes by demographic characteristics were equivocal, but the groups surveyed, the questions asked, and the analyses conducted were dissimilar.

#### Strengths and weakness of the study

We followed systematic review methods to identify relevant studies, appraise their quality, and synthesise the results in a transparent, unbiased, and reproducible manner. We searched a wide range of sources for both published and unpublished studies, but it was not feasible to contact relevant bodies in countries with presumed consent for information about any missed evaluations.

We found only five studies comparing organ donation rates before and after the introduction of presumed consent legislation in a single country. It seems unlikely that no other such evaluations have taken place given the number of countries that have adopted systems of presumed consent over the previous four decades. Notably we did not find any studies focusing on Spain, the country with the highest

**Table 4** | UK population surveys of attitudes to organ donation and presumed consent

Date of survey	Participants	Survey methods	Results: overall attitude
<b>Baines (2002)<sup>w15</sup></b>			
Unclear, before 2001	80 members of Asian community in Glasgow and west of Scotland (89% response rate)	Non-random sample (attendees of Ethnic Transplant Forum) given self completion questionnaires	Concept of presumed consent: 61% in favour
<b>Haddow (2006)<sup>w17</sup></b>			
February to March 2004	1009 people aged ≥16 years in Scotland	Random sample weighted to match Scottish population given self completion questionnaire	Doctors should be automatically allowed to take organs for transplantation: 53% opposed, 37% agreed Relatives' wishes should be considered before organs are automatically taken: 74% agreed, 16% opposed
<b>Moore (1976)<sup>w19</sup></b>			
Unclear, before 1976	500 people in the UK	Non-random sample (described as representative of age, sex, and social class) interviewed	Doctors should not have the power to remove kidneys without consulting next of kin: 74% agreed Change of the law to one of presumed consent: 65% opposed, 34% agreed
<b>YouGov (2007)<sup>w22</sup></b>			
9-11 October 2007	2034 adults in the UK	Random sample from base sample of 185000, sent an email invitation to take part in survey	Change to a presumed consent system as described: 64% agreed, 23% opposed, 14% did not know
<b>BBC (2005)<sup>w24*</sup></b>			
May 2005	2067 people aged >16 years in the UK	Described as representative sample (no further details)	Change in the law to an opt out system: 60% agreed
<b>Department of Health<sup>w25*</sup></b>			
May 1999	1757 people in the UK	Omnibus survey with face-to-face interviews (no further details)	Willingness to donate organs under the current system: 68% willing, 14% unwilling, 18% did not know In favour of donating organs under an opt out system: 50% agreed, 32% opposed, 18% did not know Preference for the current system 50%, preference for shift to presumed consent 28%, no preference 22%
<b>National Kidney Research Fund<sup>w26*</sup></b>			
July 2000	1976 people in the UK	Omnibus survey (no further details)	Concept of presumed consent: 57% in favour
<b>Watchdog Healthcheck<sup>w23*</sup></b>			
February 2001	Almost 52000 people in the UK	Telephone poll (no further details)	Change of donation system to presumed consent: 78% in favour

\*Additional survey data obtained from a secondary source<sup>w23</sup> (full reports not obtained)

**WHAT IS ALREADY KNOWN ABOUT THIS TOPIC**

The supply of donor organs is insufficient to meet the need for transplantation in the UK, and a change in legislation to one of presumed consent has been proposed

The introduction of presumed consent legislation in other countries is thought to have led to increased donation rates

**WHAT THIS STUDY ADDS**

The evidence suggests that presumed consent law is associated with increased organ donation rates

Other factors such as availability of potential donors, infrastructure for transplantation, investment in health care, and public attitudes may all have a role, but the relative importance of these factors is unclear

donation rates, or Brazil, a widely cited example of an unsuccessful law change to presumed consent. The small number of studies identified may be the result of our searches failing to identify all relevant publications, such evaluations not being performed, or the findings of evaluations not being publicly available. Others have noted the difficulties in obtaining documentation about the effects of national-level initiatives<sup>9</sup> and the fact that strategic policies tend not to receive the same evaluative attention as, for example, medical procedures.<sup>10</sup>

The available studies had methodological weaknesses. We evaluated three different types of research evidence—before and after studies, between country comparisons using secondary data, and surveys. Unlike evaluations of medical interventions, the “hierarchy” of evidence is not clear when evaluating a policy such as a change in legislation. The before and after studies and the cross country comparisons each have strengths and weaknesses. Before and after studies have a quasi-experimental design and provide evidence on the experience of individual countries, but their usefulness was limited by the small number of countries covered and the lack of information about, and in-depth analysis of, any structural and contextual changes during the same time period. Such changes might have contributed to the increases in donation rates.

The studies comparing different countries performed secondary analysis of data obtained from countries with and without presumed consent legislation in place. They can show only associations between legislation and organ donation rates, but they had the advantage of exploring the impact of other important factors such as mortality from road traffic accidents. Each study included explanatory factors based on what the authors considered important, and these varied between studies, as did their relative importance. Other factors likely to be important were not investigated. For example, Catholicism was the only religion considered, despite the likely importance of other religions such as Islam and Judaism, which have been reported to have a negative impact on organ donation rates.<sup>11</sup>

The countries represented in the studies were mainly Western European. Although this increases the likelihood that the findings are generalisable to the UK, it

resulted in considerable overlap between the samples used. This duplication means that the studies are naturally biased towards giving similar results.

Although presumed consent is not a binary variable, it has been treated as such in the between country comparisons. Countries vary in the nature of their legislation and how the legislation is interpreted. Of key importance is the extent of consultation about donation with relatives of the deceased. This was partly addressed in one study that compared countries on the basis of how legislation was implemented in practice, rather than the actual legislation in place.<sup>12</sup> Regardless of the legislative system, the procedures for contact with relatives of newly deceased people are likely to be important determinants in whether consent is given.

The surveys provided useful information about public attitudes to presumed consent, but important methodological detail was not available in four of the surveys and caution is needed in the interpretation of the findings. There was also little exploration of potential differences across sociodemographic groups. In addition, attitudes alone are unlikely to be a reliable predictor of behaviour. This is already reflected in the gap between high levels of support for organ donation in UK surveys and lower rates of registration on the organ donor register.

**Conclusions**

The available evidence suggests that presumed consent is associated with increased organ donation rates, even when other factors are accounted for. However, it cannot be inferred from this that the introduction of presumed consent legislation per se will lead to an increase in organ donation rates. The availability of potential donors, the underpinning infrastructure for transplantation, wealth and investment in health care, and underlying public attitudes may all have a role.

This review cannot be fully informative with respect to policy. It focuses on a particular aspect of the evidence and does not address all the relevant issues. To fully inform policy the findings of this systematic review need to be considered in the context of the current UK infrastructure for organ donation, the possible impact on donation rates of introducing the recommendations from the UK Organ Donation Taskforce,<sup>1</sup> the moral and ethical issues of presumed consent, and how the public may respond.

The evidence in this review was primarily in relation to country-level indicators such as gross domestic product and deaths from road traffic accidents. Further work is required to investigate factors at the personal level that may modify donor rates such as how families are approached to discuss donation of a relative's organs. A review of qualitative research addressing these issues would be useful, and further primary research may also be necessary.

Policy evaluation using a before and after design should collect information relating to context, to ensure that potentially important factors other than the intervention itself are given proper consideration.

There was variation in the quality of reporting of the included surveys. Reporting guidelines similar to those for other study designs—such as QUORUM, CONSORT, and STROBE—would be beneficial. The framing of questions on organ donation and presumed consent should also be carefully considered in future surveys.

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