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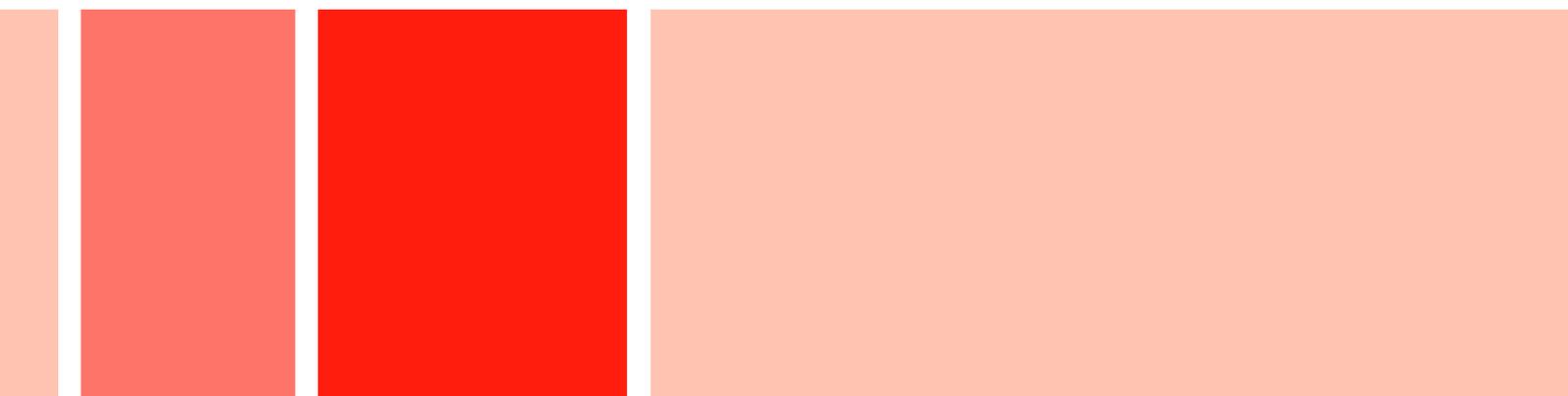
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Opt-out systems of organ donation: International evidence review



Opt-out systems of organ donation:

International evidence review

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Glossary

Comparative studies	Studies that compares donation rates in countries with and without presumed consent systems.
Informed or explicit consent system	The individual authorises the removal of their organs after death, for example, by carrying a donor card.
Opt-in system	An informed or explicit consent system.
Opt-out system	A presumed consent system.
Organ donation	The process of removal and transplantation of viable organs from donor to recipient.
PMP	Per million population.
Presumed consent	Legislation that allows the organs to be used for transplantation after death if there is an opportunity to do so, unless the individual has objected during their life.
Strong/Hard organ donation law	The views of the deceased's relatives are not actively sought and organ recovery takes place unless it is known that the deceased objected to organ removal prior to death.
Weak/Soft organ donation law	The views of the deceased's relatives are taken into consideration regardless of whether or not it is known that the deceased objected to organ removal prior to death.
UK Organ Donation Taskforce	The UK-wide Organ Donation Taskforce was established in 2006 to identify barriers to organ donation and recommend actions needed to increase organ donation and procurement within the current legal framework.
95% Confidence Interval	The confidence interval provides a range for the size of the estimate. 95% of the time, confidence intervals should contain the true value of the variable of interest.

Executive summary

- This review was carried out with the aim of updating an existing systematic review conducted by the University of York in 2008 (Rithalia et al., 2008) which examined the impact of 'opt-out' (or 'presumed consent') legislation on organ donation rates.
- The current report reviews literature published since 2008 assessing the impact of 'opt-out' legislation on organ donation rates, in addition to recent public opinion surveys and experimental studies relevant to presumed consent for organ donation.

Systematic review

- Rithalia et al. (2008) identified four methodologically robust comparative studies published prior to 2008:
 1. Abadie and Gay, 2006: included data from 22 countries over the period 1993-2002 and found that countries with presumed consent legislation had 25-30 per cent higher organ donation rates than informed consent countries.
 2. Neto et al., 2007: analysed data from 34 countries over a five year period and found that presumed consent countries produced 21-26 per cent higher organ donation rates compared to countries with informed consent legislation.
 3. Healy et al., 2005: used data from 17 countries over the period 1990-2002 and found that organ donation rates were greater by 2.7 donors per million population (PMP) in countries with presumed consent legislation compared to informed consent countries.

4. Gimbel et al., 2003: analysed data from 28 countries from the years 1995-1999 and found that countries that practiced presumed consent had, on average, and extra 6.14 donors PMP compared to countries that practiced informed consent.
- This review identified a further two methodologically robust studies published since January 2008:
 1. Bilgel, 2012: included data from 24 countries over the period 1993-2006 and estimated that countries with presumed consent legislation have on average 13-18 per cent higher organ donation rates than countries with informed consent legislation.
 2. Mossialos et al., 2012: analysed individual-level survey data from participants living in 15 European countries and found that individuals living in presumed consent countries were between 17-29 per cent more likely to report willingness to donate their own organs and 27-56 per cent more likely to report that they would be willing to consent to the donation of their relatives' organs, compared to respondents living in explicit consent countries.
 - Although six methodologically robust studies have found that opt-out systems for organ donation are associated with increased organ donation rates and increased reported willingness to donate, it cannot be inferred that this association means that presumed consent *causes* increased organ donation.

Public opinion surveys

- Recent Wales-based surveys indicate that a greater proportion of respondents support the move to an opt-out system than are against it.
- A survey of a representative sample of adults living in Wales in 2012, commissioned by the Welsh Government, found that 49 per cent of

respondents were in favour of changing to an opt-out system, while 22 per cent were against. A further 21 per cent said they 'needed more information to decide'.

- A survey of Welsh adults commissioned by BBC Wales in 2012 found that 63 per cent of respondents were in favour of adopting a system of presumed consent compared with 32 per cent against.

Experimental literature

- There is a small body of experimental literature which indicates that when the default position is to be an organ donor (as is the case in an opt-out system) there will be higher rates of effective consent. This type of research, however, is limited in the extent to which its findings could be applied to real life situations.

Evidence gaps

- There is a lack of research into whether an opt-out system has different effects on sub-groups within a population, e.g. different socio-economic and ethnic groups.
- There is very limited research on how an opt-out system is best implemented to achieve optimal organ donation rates e.g. type of registry and the extent of involvement of the family in the donation process.

Conclusions

- This paper presents three main strands of evidence:
 1. International evidence suggests that an association exists between presumed consent legislation and increased organ donation rates;

2. Recent surveys indicate that there is significant support for the introduction of an opt-out system for organ donation in Wales; and
 3. Experimental literature provides evidence for a mechanism through which presumed consent might increase organ donation, through the influence of the default position.
- In combination, these three strands of evidence provide a convincing basis for the introduction of an opt-out system in Wales. However, there can be no guarantees that this legislative change will result in increased organ donation rates.

1. Introduction

The Welsh Government plans to introduce a soft opt-out system for consent to deceased organ and tissue donation through the Human Transplantation (Wales) Bill. Under such legislation, all residents of Wales will be deemed to have given their consent to post-mortem organ donation, unless they have explicitly registered their wish to 'opt out' of being an organ donor during their lifetime. The proposed legislation also sets out safeguards, by which the family of the deceased will be involved in the organ donation decision-making process. It is hoped that this system will increase the number of organ donations in Wales and therefore, will save more lives through organ transplants.

In 2008 the UK Organ Donation Taskforce produced the report 'The potential impact of an opt out system for organ donation in the UK' (2008), commissioned by the UK government. A component of this report was the commissioning of a systematic review to be conducted by the University of York assessing the impact of opt-out systems on organ donation rates in other countries (Rithalia et al., 2008). This review identified four 'between country' comparison studies of sufficient methodological quality to provide reliable results, all of which employed regression analysis techniques that also took account of other factors that could affect organ donation rates. In all four studies, presumed consent law was associated with increased rates of organ donation, ranging from an increase of 2.7 donors per million population (pmp) in one study (Healy et al., 2005) to 6.14 donors pmp in another (Gimbel et al., 2003); and an increase of between 25-30 per cent in the third study (Abadie and Gay, 2006) and of 21-26 per cent in the fourth (Neto et al., 2007). Additionally, five 'before and after' studies based on three countries were identified, all of which demonstrated an increase in organ donation rates after the implementation of an opt-out system for organ donation. For example, in Austria, donations rates rose from 4.9 donors pmp per year to 10.1 pmp over the four year period immediately following the change in legislation (Gnant et al., 1991).

Rithalia et al's (2008) systematic review considered literature published before January 2008; the present review aims to replicate Rithalia et al's search strategy in order to provide an update covering literature published between January 2008 and July 2012. Additionally, this report also reviews recent public opinion surveys into support for opt-out systems for organ donation, along with an overview of studies which have attempted to examine the effect of defaults on decision-making related to organ donation.

2. Methods

2.1 Review methods

A review was carried out with the aim of updating an existing systematic review by Rithalia et al. (2008), which examined the impact of 'opt-out' (or 'presumed consent') legislation on organ donation rates by identifying and appraising empirical studies of relevance. The search strategy employed was designed to identify a broad range of literature on presumed consent legislation for organ donation. Citations were downloaded into Endnote Web Version 3.4. All titles and abstracts were screened. Full text manuscripts of articles considered to be potentially relevant were obtained where possible. The relevance of each paper was assessed according to Rithalia et al's inclusion criteria, detailed below.

2.2 Search strategy

The following electronic databases were searched for published and unpublished literature on presumed consent and organ donation (see Appendix 1 for further details):

- MEDLINE (medical literature)
- MEDLINE In-Process (provides rapid access to latest few weeks of the medical literature)
- EMBASE (pharmacological and biomedical literature)
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) (nursing and allied health literature)
- PsycINFO (psychological literature)
- Health Management Information Consortium (HMIC) (health management literature)
- GREYNET.org (grey literature)

Internet searches were also carried out using the specialist search engine Intute and the meta-search engine Copernic. Websites of selected organisations were browsed for additional information. The reference lists of included studies were checked for potentially relevant references.

Individual search strategies were developed for each electronic database and search engine. Where possible, searches were conducted limiting results to those published between January 2008 and July 2012.

2.3 Inclusion criteria

The primary aim of this review was to identify empirical studies that examined the impact of presumed consent legislation on organ donation rates, published since January 2008. Rithalia et al's (2008:18) inclusion criteria were used to identify those studies eligible for inclusion:

Study design: Studies comparing donation rates in a single country before and after the introduction of a presumed consent system and cross-sectional studies comparing donation rates in countries with and without presumed consent systems.

Intervention: Presumed consent systems for deceased organ donation introduced within a jurisdiction. A presumed consent system was defined as one where a deceased person is considered to be an organ donor unless he/she has made known their opposition to this prior to death. Countries were considered as presumed consent jurisdictions where such a law is in place, even if the system operated de facto requires consent of relatives.

Comparator: A system of presumed consent must have been compared with a non-presumed consent system (e.g. one in which individuals register as organ donors during their lifetime, one that requires relatives' consent, or one that requires all citizens to register their willingness or not to be an organ donor in the event of their death). This may have been within another jurisdiction or in the same jurisdiction prior to the introduction of a system of presumed consent.

Population/setting: Any jurisdiction in which a system for deceased organ donation had been introduced.

Outcomes: The primary outcome of interest was the deceased organ donation rates. Attitudes of the public, professional and other stakeholders, and any adverse consequences were also of interest and recorded where given. Any descriptive information about the context in which the system was introduced was recorded where reported, including reasons why a country has chosen to introduce or reject a presumed consent system.

2.4 Data extraction

The following information was extracted from relevant studies: country or countries studied, time period, study design, method of analysis, factors considered in analysis, other contextual factors, donation rates, and any other outcomes of interest. Data were extracted into tables in Microsoft Word.

2.5 Quality assessment

The methodological quality of the studies under review was assessed using the criteria described in Rithalia et al's (2008:19) review. This criterion was derived from the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies (National Collaborating Centre for Methods and Tools 2008).

Criteria under consideration were:

- Were appropriate countries/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?
- The appropriateness of the statistical analysis was also assessed.

3. Results

3.1 Study selection

The full literature search identified 1,524 references. The screening process reduced this number to nine potentially relevant studies (see Figure 1). Full text copies of these articles were retrieved and assessed using the inclusion criteria described previously.

Of the nine papers identified as potentially relevant, five were excluded as they did not meet the specified inclusion criteria (for details see Appendix 2). A total of four studies met the inclusion criteria.

3.2 Overview of the evidence

Table 1 provides details of the objectives and countries included in the four studies fully reviewed (for full details see data abstraction tables in Appendices 3 and 4). No 'before and after' single-jurisdiction studies were identified; all four studies identified were 'between country' comparisons.

One study examined the impact of presumed consent legislation on deceased organ donation rates, while adjusting for the effects of other potentially influencing factors, such as health expenditure and mortality due to road traffic accidents and cerebro-vascular accidents (Bilgel, 2012). This type of study has the benefit of being able to explore the between country differences in organ donation rates, considering not only the type of legislation, but also the effect that other relevant factors may be having. Two of the other studies employed a similar approach involving between country comparisons of legislation and organ donation rates, but failed to adjust for other factors that may affect organ donation rates. This weakness in analytic strategy means that any association found between presumed consent legislation and organ donation may actually be due to the effect of factors other than the countries' consent legislation, thus limiting the extent to which the findings can be

deemed trustworthy (Coppen et al., 2008; Horvat et al., 2010). The remaining study used individual-level data from persons living in 15 different European countries to examine how attitudes to organ donation differed between persons living in countries with presumed consent systems and those with explicit consent systems, while adjusting for other individual-level characteristics which may also affect one's attitude to organ donation, such as age and education (Mossialos et al., 2008). The studies used data ranging from 1993 to 2007 and the number of countries included in analyses varied between studies, as did the justification for the selection of countries under study.

The four studies were assessed for methodological quality. Two of the studies were considered to have no major methodological flaws (Mossialos et al., 2008; Bilgel, 2012) and two of the studies were identified as having limitations (Coppen et al., 2008; Horvat et al., 2010).

Figure 1: Flow of studies through review process

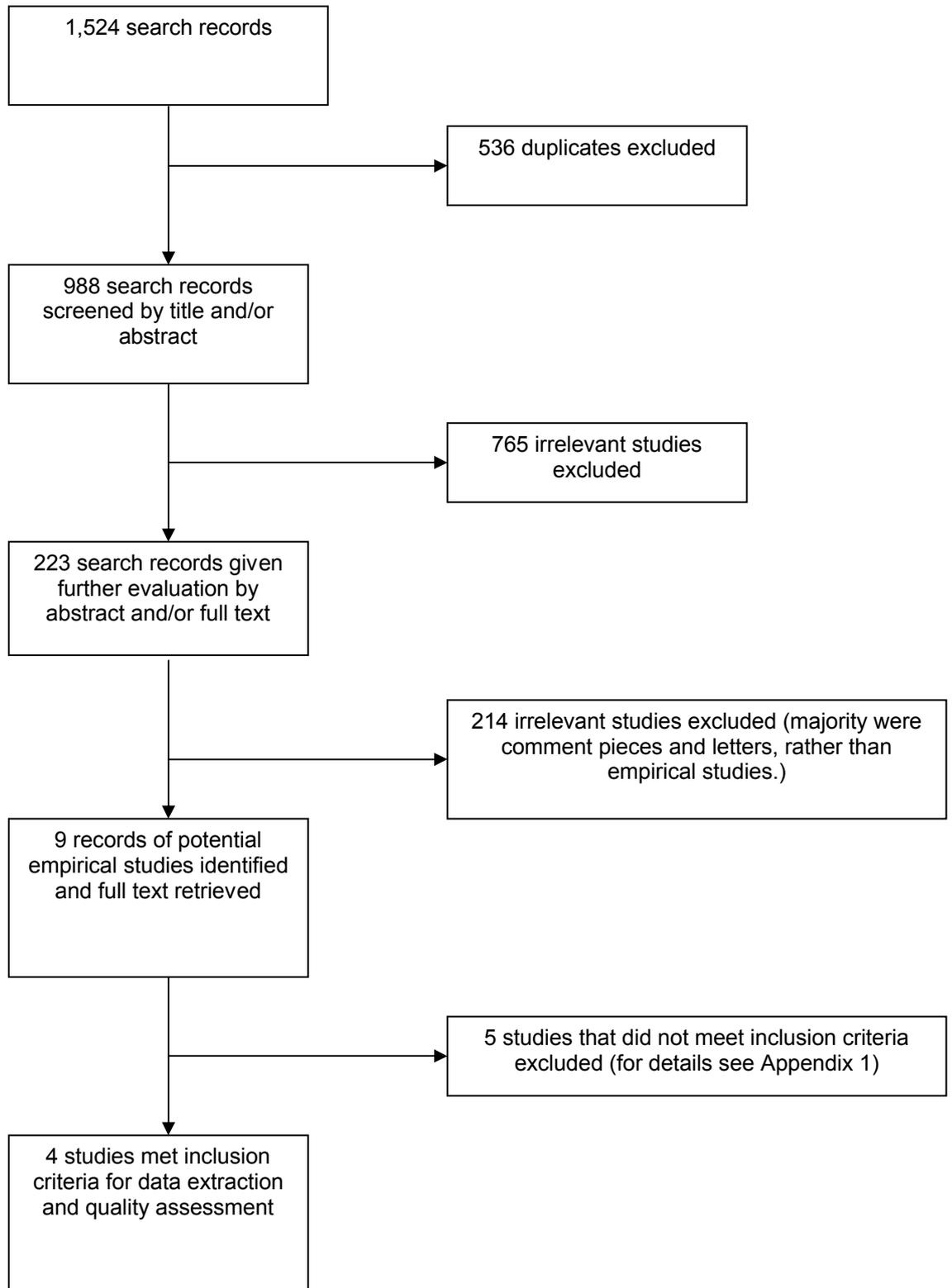


Table 1: Details of the four included studies

Author (year)	Countries included	Stated objective
Bilgel (2012)	28 countries (majority European)	To examine the interactions between a presumed consent legal regime and other customs and institutions.
Coppen et al., (2008)	10 Western European countries	To assess the impact of donor policies on donor procurement in 10 Western European countries from 1995 to 2005.
Horvat et al., (2010)	44 countries: includes European, Asian and South American countries	To compare characteristics and kidney transplantation rates for countries with presumed consent for deceased organ donation with countries with explicit consent.
Mossialos et al., (2008)	15 EU countries	To examine how country regulation, individuals' awareness of regulatory settings, social interactions and socio-demographic determinants influence individuals' willingness to donate their own organs and those of a relative.

3.3 Impact of presumed consent on donation rates

The four studies aimed to examine the impact of opt-out legislation on organ donation rates (Bilgel, 2012), kidney transplantation rates (Horvat et al., 2010), conversion rate of potential donors into actual donors (Coppen et al., 2008) and individuals' willingness to donate their organs and consent to donating those of a relative (Mossialos et al., 2008). The studies varied in their approach. While all employed statistical analysis, only two used regression techniques (Mossialos et al., 2008; Bilgel, 2012). The two studies that used regression techniques included 6-7 variables in their multivariate models.

3.4 Studies with no major methodological flaws

Bilgel (2012) analysed data from 24 countries over the period 1993-2006. This study involved a series of regression analyses estimating the impact of presumed consent legislation on organ donation rates using fixed effects vector decomposition (FEVD), a “three-stage estimator that allows estimating the impact of time-invariant variables and that is more efficient than the fixed effects model in estimating parameters of almost time-invariant variables” (p. 33).

The results of six regression models were presented, each incorporating additional variables. In all but one of these models, presumed consent legislation was shown to be associated with increased organ donation rates (statistically significant at the 5 per cent level). When adjusting for per capita health expenditure and the pool of potential donors, presumed consent legislation was associated with a 6 per cent higher organ donation rate. Presumed consent was associated with 13 per cent higher organ donation rates when the model included variables relating to: health expenditure, potential donor pool, civil liberties, legal system, role of family consent and single versus combined registry. The final model included these six explanatory variables, in addition to interaction terms between the variables: presumed consent, type of registry (combined versus single) and whether or not family consent is routinely sought. This final model found that presumed consent legislation was associated with an 18 per cent increase in organ donation rates (statistically significant at the 5 per cent level).

The first model (including only the presumed consent variable as a predictor) had an r-squared value of 0.78, which increased to 0.89 with the addition of the health expenditure and number of potential donors. As further variables were included in the model, the r-squared stayed constant at 0.89. This figure indicates that the model explained 89 per cent of the variance in organ donation rates. However, such a high r-squared value raises suspicions that the data might ‘over fit’ the model. The reason for this is unclear, given that

the study uses multiple data points for each country (from years ranging 1993-2006), the explanation that there are too few data points seems unfeasible. However, it may be that the lack of 'within country' variation throughout the years may contribute to an over-estimation of the goodness of fit of the model.

Although this study adjusted for a number of other factors likely to be related to organ donation rates, transplant capacity was not one of them. While likely to be closely correlated to health expenditure, capacity of infrastructure specific to organ donation has been found to be associated with organ donation rates in previous studies (Gimbel et al., 2003). No variables relating to education were included in the models, although previous research shows that the proportion of citizens having achieved higher education is positively associated with organ donation rates (Gimbel et al., 2003). It is possible that the inclusion of these additional factors in the model would alter the estimated impact of presumed consent legislation.

There is little information on how the 'routine family consent' variable was formed. The authors state that this variable takes the "value of 1 if next-of-kin consent is always sought in deceased donation and 0 [if] otherwise". Other studies suggest that despite the type of consent system in operation and role of the family set out in legislation, in practice, the family usually has the opportunity to take an active role in the donation decision-making process (Boyarsky et al., 2012; Rosenblum et al., 2012), though there may be subtle differences in the approach taken by medical staff. It therefore seems likely that reducing the role of the family down to a binary variable is overly simplistic.

Bilgel also conducted further analysis, focusing on the interactions between type of consent legislation, type of registry (combined versus single¹) and whether or not family consent is routinely sought. This involved dividing the countries into eight groups based on their combination of consent legislation,

¹ A combined registry refers to when persons can register their wish to opt-in or opt-out, as opposed to a single registry, which means that people are only able register a wish to opt-in or only able to register a wish to opt-out.

registry type and role of family consent, and calculating estimates of the impact of each combination versus each combination as baseline. For example, one of the estimates provided indicates that a presumed consent country which operates a combined register and routinely seeks familial consent for organ procurement produces, on average, 75 per cent higher organ donation rates than a country with informed consent legislation which operates a combined register and routinely seeks familial consent. The aim of this analytic component was to assess the effect size of these three variables, while considering their interaction with one another. However, given that this analysis only considered 24 countries and the interaction effects were estimated by dividing the countries into 8 groups, this means that on average, each group under comparison includes just 3 countries; therefore, the results of this part of the Bilgel's analysis must be interpreted with caution, given the small number of countries contributing to each estimate of effect size.

Mossialos et al. (2008) investigated the impact of presumed consent legislation on individuals' reported willingness to donate their own organs and to consent to the donation of relatives' organs, as opposed to the other studies which considered the outcome of county-level organ donation rates. Although the inclusion criteria of this review state organ donation rates to be the primary outcome of interest, attitudes of the public, professionals and other stakeholders are also of interest. While attitudes and reported intentions are correlated with actual behaviour, there is often a degree of discordance, particularly with regard to organ donation (as demonstrated by the discrepancy between reported support for donating one's organs and the actual proportion of the UK population who have signed up to the organ donation register) (Wellesley, 2011). Therefore, the results of this study must be treated with caution, particularly in terms of the extent to which the results can be extrapolated to behavioural differences in organ donation (i.e. actual organ donation rates). As with any self-reported information, issues related to social desirability bias must also be noted (i.e. respondents' tendency to report what they believe to be the most socially acceptable answer).

This study analysed data from the Eurobarometer survey (Wave 58.2); a representative sample of 16,230 individuals living in 15 European countries, surveyed through face-to-face interviews in 2002. Respondents were asked the following two questions: 1) 'Whatever the rules and regulation, would you personally be prepared to donate one of your organs to an organ donor service immediately after your death?', with answer options on a Likert scale ranging from 1 for 'yes, definitely', to 4 for 'no, definitely not', and 5 as 'don't know'. 2) 'In hospital, if you were asked, would you give your consent to the donation of an organ from a deceased relative?', with a choice of three response options: 'yes', 'no', 'don't know'. In the regression analyses any 'don't know' answers were coded as 'no', in a conservative method to maintain observations and also, because not knowing is expressing a failure to be positively certain about donating organs.

The authors present the results of two multivariate logistic regression models; one with the binary outcome of 'willingness to donate one's own organs', and the other with the binary outcome of 'willingness to donate relative's organs'. The regression models incorporated a number of individual-level explanatory factors potentially related to organ donation attitudes; self-perceived presence of serious illness, self-perceived level of health, political affiliation, age, urban or rural place of living, level of formal education, number of people respondent can count on in case of serious problems, ease of access to help from neighbours, co-operation during interview, and awareness of legislation type in their country. The country-level variable relating to type of consent legislation was classified into three categories; informed consent, presumed consent (allowing relatives to refuse donation), and enforced presumed consent (not allowing relatives to refuse donation). The validity of this classification for legislation type is somewhat questionable as by the article's own admission, and reported in other studies (Rosenblum et al, 2012), most countries consult the family regarding their relative's potential organ donation despite the legal status of the decision-making power of the family. Therefore, in practice, those countries classified as 'enforced presumed consent' may not actually be particularly different to countries classified as 'presumed consent'.

However, given that the baseline legislation is that of ‘informed consent’ (i.e. the opt-in system), the results can still be informative.

The analysis accounted for the clustering of data by country and adjusted for the factors described above. As shown in Table 2, individuals living in presumed consent countries were 1.17 times more likely to report being willing to donate their own organs and 1.27 times more likely to report willingness to donate their relatives’ organs, compared to individuals living in countries with informed consent legislation. Respondents living in countries with ‘enforced’ presumed consent legislation were found to be 1.29 times more like to express willingness to donate their own organs and 1.56 times more likely to report that they would be willing to consent to donating their relatives’ organs. This study also provided the r-squared values, indicating that the two models explained only 8.4 per cent (outcome: willingness to donate own organs) and 5.4 per cent (outcome: willingness to donate relatives’ organs) of the variance in reported willingness to donate organs, meaning that there must be other variables, not included in these models, that would also have a significant impact on individuals’ willingness to donate their own/relatives’ organs.

Table 2: Mossalios et al. (2008), odds ratios of willingness to donate own organ and relative’s organs under different consent legislation²

	Willingness to donate own organs (95% confidence interval)	Willingness to donate relative’s organs (95% confidence interval)
Informed consent	1.00	1.00
Presumed consent	1.17 (1.05–1.29)	1.27 (1.15-1.39)
Presumed consent enforced	1.29 (1.17-1.41)	1.56 (1.40-1.72)

This study provides an assessment of the association between organ donation legislation and attitudes of individuals, unlike most other studies which focus primarily on country-level organ donation rates. While it is true

² Adjusted for: health status, gender, age, political affiliation, social interactions, urban-rural living, education, and interview co-operation.

that reported intentions are unlikely translate perfectly into actual behaviour, this study provides an important insight into the differing intentions of people living in informed consent and presumed consent countries. The outcome of willingness to consent to the donation of a relative's organs is of particular relevance, given that familial consent or lack thereof, is one of the most important factors limiting organ donation rates (Barber et al, 2005).

Some limitations in this study, however, should be noted. While the sample size of individuals is relatively large at over 6,000, this only included 15 different countries, which have then been classified into three distinct types of consent system; meaning that for the explanatory variable of organ donation legislation, the sample size, and therefore the three comparative groups of countries, is quite small. Additionally, the basis for how the consent legislation type of each country was classified is not clear and given that models explain less than 9 per cent of the variation in reported willingness to donate organs, it is likely that some important explanatory factors are missing from this analysis.

3.5 Studies with limitations

Coppen et al. (2008) used data from 10 Western European countries over the period 1995-2005. The 10 countries were selected on the basis that they “share a more or less similar historical background and have more or less the same status of health systems” (p. 236), with the assumption that this would limit the number of additional factors, other than legislation type, that affect organ donation rates.

The outcome of interest was the ‘potential donor conversion rate’, which was calculated for each country using: national donation rates per million population (pmp) *divided by* national mortality rates relevant for organ donation pmp. The mortality rates judged to be relevant for organ donation were derived from Cerebral Vascular Accident (CVA) mortality and the rates of Road Traffic Accident (RTA) Mortality, as the study states that 80 per cent

of donors die from CVA or RTA and therefore, these rates serve as a good proxy for the potential donor pool. Donor conversion rates were calculated for three time frames; 1995-2005, 1995-1999, and 2000-2005.

The analysis strategy employed by this study seems to consist of plotting the potential donor conversion rates of each country against the corresponding year. The study concludes that there is “no evidence that presumed consent systems perform better than explicit consent systems”. The results described in this study appear to have been drawn primarily from visual observations of the graph, comparing countries with and without presumed consent legislation. Additionally, attention was given to observing whether a change in conversion rates occurred in the countries that introduced a change in legislation during the study period. However, the resulting conclusions seem to rely on visual observations of the graph, as opposed to any tests of statistical significance. No multivariate analysis was performed, meaning the impact of other factors on donor conversion rates was not considered. Additionally, one country, the UK, was wrongly classified as having presumed consent legislation. Given that this study only considers 10 countries (one of which has been wrongly classified) and the methodological weaknesses in the analysis strategy, the results should be interpreted with great caution.

Horvat et al. (2010) analysed data from 44 countries that had at least two years of data coverage within the study period of 1997-2007. The outcome of interest was the annual kidney transplantation rate; this only included kidneys that were successfully transplanted into a recipient and not those that were procured without subsequent transplantation. Half of the countries were classified as having presumed consent systems and the other half as having explicit consent systems.

The analysis presents the median kidney transplantation rate and corresponding inter-quartile range for countries with presumed consent, and the equivalent figures for those countries classified as having explicit consent systems. In addition, these summary statistics are also presented for the two groups of countries stratified by quartiles of the following country

characteristics; population size, percent catholic, GDP per capita, health expenditure per capita, physician density, traffic accident mortality, cerebral-vascular mortality. No multivariate analysis was conducted and no results of tests of statistical significance were presented. The results found that the median kidney transplantation rate of the 22 countries with presumed consent was 22.5 per million population (pmp) (inter-quartile range: 9.3-33.8) compared to that of the 22 explicit consent countries which had a median kidney transplantation rate of 13.9 pmp (inter-quartile range: 3.6-23.1). Given the lack of multivariate analysis, the results of this study must be interpreted with caution as there are numerous other factors which have not been adjusted for in this analysis, that could contribute to the higher median kidney transplantation rates in presumed consent countries.

3.6 Other factors influencing organ donation rates

As found in Rithalia et al's (2008) review, additional country-level factors such as increased mortality from donor-providing causes, greater health expenditure, and common law legislative system were found to be associated with higher organ donation rates in Bilgel's (2012) study, which was judged to have no major limitations.

Additionally, explored in Bilgel's study was the influence of the type of organ donation registry in place, in terms of whether persons could register their wish to opt-in or opt-out (as opposed to only being able to opt-in or only being able to opt-out), and whether family consent for donation was routinely sought.

The results from this part of the analysis are somewhat difficult to interpret; in the multivariate regression analyses which did not allow for the effect of interactions, having a combined registry was associated with 15.6 per cent lower donation rates, compared to countries that operated a single registry. Those countries that were classified as routinely seeking familial consent for organ donation were found to have 9.5 per cent lower organ donation rates

than countries that did not seek consent from the family. However, once interaction terms between the type of consent variable, the type of registry variable and the family consent variable were introduced into the model, the results indicated that countries with presumed consent legislation, a combined registry and that sought familiar consent produced 48 per cent higher organ donation rates, in comparison to countries with explicit consent legislation, a single registry and who did not seek familial consent. These interaction results must, however, be interpreted with caution; on closer inspection it seems that there are only 5 countries which fall into the former combination of policies and 3 countries which would act as the baseline in this component of the analysis, and so it is likely that such small numbers of countries bias the results.

Factors related to familial consent and type of registry were not considered in any of the studies reviewed by Rithalia et al (2008). Although Bilgel's analysis component focusing on these factors has its limitations, further robust research into their effect may provide important insights into how presumed or explicit consent systems can best be implemented to achieve optimal organ donation rates. It seems plausible that the type of register and role of family consent are both important factors in determining how well organ donation systems work to maximise donation rates, and so such analysis that investigates the wider implementation system, as opposed to just one strand of legislation, may prove valuable.

The other study judged to have produced a robust analysis was Mossialos et al's (2008) study considering individuals' reported willingness to donate their own and their relatives' organs. This study also considered other individual characteristics in the analysis and found that higher educational attainment, awareness of legislation, younger age, and greater access to social support were also associated with increased willingness to donate one's own and one's relatives' organs. This indicates that there are both country-level and individual-level factors that may be important for organ donation decisions.

3.7 Summary

In updating Rithalia et al's (2008) systematic review on the impact of presumed consent on organ donation, four studies were identified that met the inclusion criteria of this review, two were judged to have no major methodological flaws and sufficiently robust analysis to provide reliable results. The two robust studies were country comparison studies, which found presumed consent legislation to be significantly associated with higher organ donation rates (Bilgel, 2012) and greater reported willingness to donate one's own and one's relatives' organs (Mossialos et al., 2008). Bilgel (2012) found that presumed consent was associated with an up to 18 per cent increase in organ donation rates, which was statistically significant at the 5 per cent level. Mossialos et al's (2008) study found that individuals living in presumed consent or 'enforced' presumed countries were 17-29 per cent more likely to report willingness to donate their own organs and 27-56 per cent more likely to report that they would be willing to consent to the donation of their relatives' organs, compared to respondents living in explicit consent countries. These results were statistically significant at the 1 per cent level. These findings are in agreement with those reported by Rithalia et al (2008); which reported on four country comparison studies with robust methodology that found presumed consent to be associated with increased organ donation rates (statistically significant at the 5 per cent level in three of the four studies).

Combining the results of Rithalia et al's review with the present update including literature published up to July 2012, six country comparison studies employing robust methodology assessing the impact of presumed consent legislation have been identified. Estimates of the magnitude of effect of legislation vary, with studies reporting the opt-out system to be associated with increases in organ donation rates of: 13-18 per cent (Bilgel, 2012), 21-26 per cent (Neto et al., 2007), 25-30 per cent (Abadie and Gay, 2006) and an extra 2.7 donors pmp (Healy et al., 2005) and an extra 6.1 donors pmp (Gimbel et al., 2003). These five comparative studies exhibit a high degree of overlap in terms of the countries included in their analyses. Through this

duplication of data, it is likely that this selection of studies is naturally biased towards finding similar results. However, while there is overlap in the countries under study, no two studies analyse the exact same selection of countries or the same selection of factors, but all find the same association (that presumed consent is associated with higher organ donation rates) – with such replication of findings these studies could be considered to corroborate one another.

It must be noted that given that these studies are observational and not experimental, the relationships detected between organ donation legislation and the outcomes of interest can only be considered to be indicative of association and not causation.

This update did not identify any ‘before and after’ studies of single countries that introduced an opt-out system for organ donation. Rithalia et al. (2008) report on five such studies of three countries, which report increases in organ donation rates from 4.9 donors pmp to 10.1 donors pmp over a four year period immediately following the legislation change in Austria (Gnant et al., 1991), increased kidney donation rates from 18.9 pmp to 41.3 pmp during a three year period in Belgium (Roels and De Meester, 1996), and in Singapore kidney procurement rose from 4.7 per year to 31.3 per year during the three years after the change in legislation (Soh and Lim, 1992). As noted by Rithalia et al. (2008), these before and after studies included very limited investigation of other changes which occurred concurrently with the change in legislation (such as education and awareness programmes or infrastructural improvements), so limiting the extent to which the increase in organ donation rates can be directly attributed to the adoption of presumed consent legislation. An additional issue is the time period which the baseline organ donation rate is based on; in Gnant et al’s (1991) study the rate of 4.9 donors pmp is an average of annual data from a 16 year period, which may not be an appropriate baseline if there was a trend towards increasing donor rate over this long period.

The study focussing on the outcome of reported willingness to donate one's own organs and willingness to consent to the donation of relatives' organs found that respondents living in countries with presumed consent legislation were more likely to express such willingness, compared to those living in countries with explicit consent legislation (Mossialos et al., 2008). Although actual behaviour rarely reflects intentions perfectly (Radecki and Jaccard, 1999), this outcome is of interest for providing information on how legislation might affect attitudes to organ donation and potential familial consent rates to donating a relative's organ (known to be one of the major factors limiting organ donation) (Barber et al., 2005).

No studies provided evidence regarding the impact of presumed consent legislation on population sub-groups. This is an important evidence gap and there may be value in future research pursuing analyses that, in addition to assessing the effect of an opt-out system on the population as a whole, considers whether the impact of legislation differs between certain socio-economic and ethnic groups.

The studies also identified important additional factors that contribute to variation in organ donation rates between different countries. Factors identified as being statistically significantly associated with higher organ donation rates in at least one study were:

- higher mortality from road traffic accidents and cerebral-vascular accidents
- greater transplant capacity of a country
- greater GDP per capita
- higher health expenditure per capita
- common law legal system (as opposed to civil law)
- religion (specifically greater proportion of population Catholic)
- increased enrolment in higher education
- greater access to information (measured by population proportion with access to internet)

At the individual-level, factors associated with increased willingness to consent to organ donation were:

- having stayed in education for longer
- being aware of the consent legislation in place
- younger age
- greater social support (as measured through the number of people the respondents reports being able to count on and their ease in getting help from neighbours).

There are also certain factors likely to influence organ donation rates that are not included in analyses. For example, the only religion examined was Catholicism. However, other studies suggest that Islam and Judaism may have an influence on organ donation (Anbarci and Caglayan, 2005). Also, there is always the potential that countries with presumed consent may have adopted the law due to a stronger underlying commitment and favourable public attitudes to organ donation. There are difficulties in measuring and adjusting for this kind of general country commitment in quantitative analyses, meaning that separating out the effects of legislation and background attitudes is challenging.

The way in which organ donation consent law is actually implemented will likely contribute to the impact that legislation has on organ donation rates. One study reviewed by Rithalia et al. (2008) investigated the *practice* of presumed consent, rather than the legislation per se (Gimbel et al., 2003). Bilgel's (2012) study incorporated factors relating to the type of registry in operation and the role of the family in providing consent into their analyses, however the latter's component of analysis featuring these variables likely suffered from small sub-sample sizes, limiting the validity of their results. Although it seems likely that the way in which consent laws are implemented will greatly influence their effect, such factors do not appear to have been incorporated into previous research. At present, the research base considering these factors is severely limited.

While the studies presented in this review show presumed consent legislation to be associated with higher organ donation rates and greater willingness to donate organs, the evidence from these studies must be interpreted with caution. Analysis involving observational data (i.e. not experimental or interventional) can only provide information regarding associations between factors. It would be invalid to state that these findings indicate that presumed consent legislation *causes* increased organ donation rates. Moreover, each of the studies reviewed include different combinations of additional factors in their analysis, meaning that the results of each analysis are not directly comparable with one another for a) assessing the association between presumed consent and organ donation rates and b) assessing the association between other factors and organ donation rates.

4. Public opinion surveys

4.1 Introduction

In line with Rithalia et al's (2008) review, any surveys concerned with measuring public attitudes to opt-out legislation that were identified during the literature searching process have been reviewed. A survey of university students in Ireland (Healy et al., 2009), which included a question regarding attitudes to presumed consent, was identified through the literature search. Additionally, we are aware of three further Wales-specific surveys, which are of particular relevance given the proposed change to organ donation legislation in Wales; one UK-wide survey; and a series of deliberative events commissioned by the UK Organ Donation Taskforce.

4.2 Wales Omnibus Survey

The Wales Omnibus Surveys (Beaufort Research, 2012) are repeated cross-sectional studies, carried out four times a year. Conducted by Beaufort Research, the surveys use multistage, stratified, probability sampling to select a sample that is representative of the adult population resident in Wales aged 16 and over. A fresh sample of interviewing locations is selected for each wave. Interviews are conducted face-to-face with respondents using CAPI (Computer Aided Personal Interviewing) technology. The Welsh Government commissioned a number of questions to be asked on organ donation during the June 2012 wave of data collection (Welsh Government, 2012). A total of 1,006 interviews were completed and analysed.

Respondents were shown a card saying:

In Wales, the government is considering changing the organ donation procedure to a 'soft opt out' system. This will mean people will be given the opportunity to formally 'opt out' of organ donation by placing their name on a register. If they choose not to do so, having had the opportunity, then this will be treated as a decision to be a donor, and one which families will be sensitively encouraged to accept. The opportunity to 'opt in' and register a decision to be a donor will continue.

Subsequently, respondents were asked: 'Which of these statements about proposed changes to the organ donation system in Wales best reflects your view?'. Results shown in Table 3.

Table 3: Responses to attitudes to opt-out organ donation system question asked in Wales Omnibus survey

I am in favour of changing to a system where people opt out of organ donation rather than opt in	49%
I am against changing to a system where people opt out of organ donation rather than opt in	22%
I need more information to decide	21%
Don't know	8%

The results shown in Table 3 indicate that almost half (49 per cent) of the Welsh population sample report being in favour of an opt-out system for organ donation, while 22 per cent were against and 21 per cent stated that they needed more information to decide.

4.3 BBC Wales survey

BBC Wales commissioned ICM Research to conduct a telephone survey among a representative sample of 1,000 Welsh adults (ICM Research, 2012), which was carried out during February 2012. Included in the survey were attitudinal questions regarding the 'presumed consent' law for organ donation.

Respondents were asked:

The Welsh Assembly Government is planning to introduce a law to change the way organs are donated in Wales. If it's passed, the new law would presume people want to donate their organs when they die, unless they choose to opt out by taking their names off the register. This is known as "presumed consent". Are you personally...?

Results are presented in Table 4.

Table 4: Responses to attitudes to opt-out organ donation system question asked in BBC Wales commissioned survey conducted by ICM Research

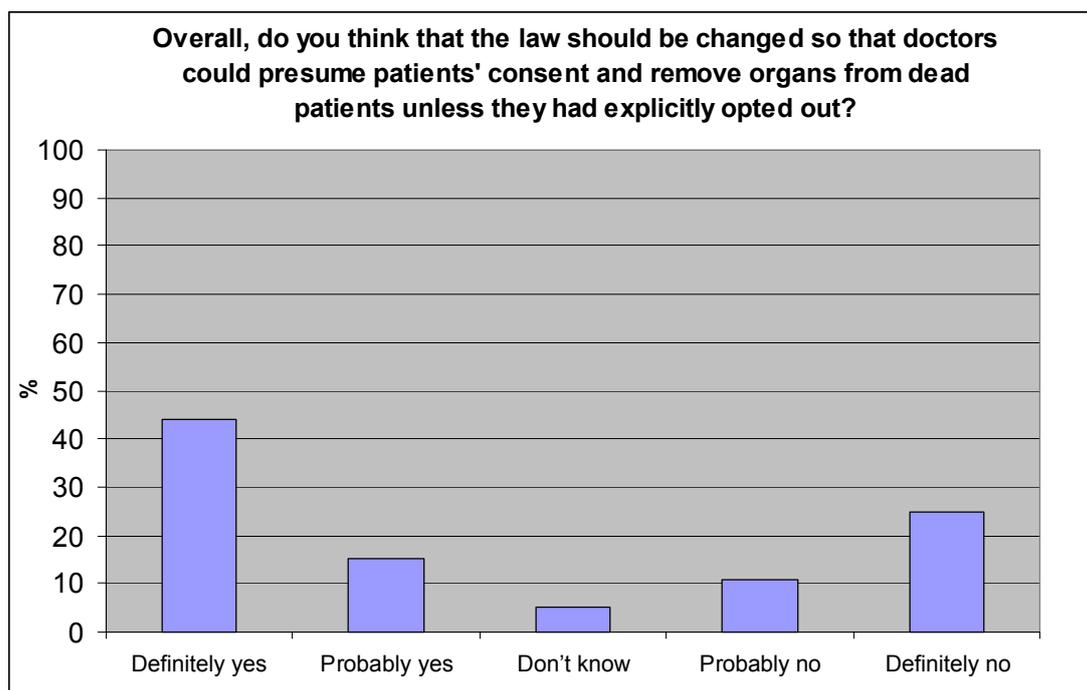
In favour of a law that presumes consent for organ donation	63%
Against a law that presumes consent for organ donation	31%
Don't know	6%

Table 4 shows that 63 per cent of the Welsh sample polled were in favour of a presumed consent law, while 31 per cent were against. These findings are broadly in line with the Wales Omnibus Survey. Unlike the BBC survey, the Wales Omnibus Survey provided an additional answer option of “I need more information to decide”. However, the proportion of respondents in favour of presumed consent is approximately double that of the proportion against in both surveys, with a ratio of around 2:1.

4.4 Opinion Research Service

Opinion Research Service from Swansea University was commissioned by the Welsh Government to conduct a telephone survey of a representative sample of the Welsh population including questions measuring organ donation attitudes (Welsh Government, 2009). A total of 385 interviews were conducted in November-December, 2008.

Figure 2: Proportion of respondents in favour and against the introduction of an opt-out system for organ donation (research conducted by Opinion Research Services, Swansea University)



As shown in Figure 2, in response to the question: “Overall, do you think that the law should be changed so that doctors could presumed patients’ consent and remove organs from dead patients unless they had explicitly opted out?”, 44 per cent of respondents said that the law should be definitely change, while 15 per cent said that it should probably be changed. The level of opposition was lower, with 25 per cent stating that the law should definitely not be changed and 11 per cent saying that it should probably not be changed. 5 per cent of respondents stated that they did not know. The overall level of support indicated by this survey is 59 per cent, meaning that all three Wales-based surveys indicate that a greater proportion of Welsh citizens support the introduction of an opt-out system, than oppose it.

4.5 Kidney Research UK

Kidney Research UK commissioned Usurv to conduct a survey investigating organ donation attitudes (Kidney Research UK, 2012). Usurv (2012) is an internet-based market research company, which recruits internet users to complete certain surveys when they log on to a partnered website. No

information is provided regarding how many respondents took part in this survey, the response rate or how representative the sample is of the UK population, therefore the extent to which these results can be considered applicable to the wider population cannot be commented on.

When asked whether they would support the introduction of an opt-out approach to organ donation in England, 54 per cent of respondents said yes, while 18 per cent said no and 27 per cent stated that they were not sure.

Despite appearing to be a more England-based survey and the lack of information regarding the characteristics of the sample, these proportions seem to be generally in line with the results reported by the Welsh surveys above.

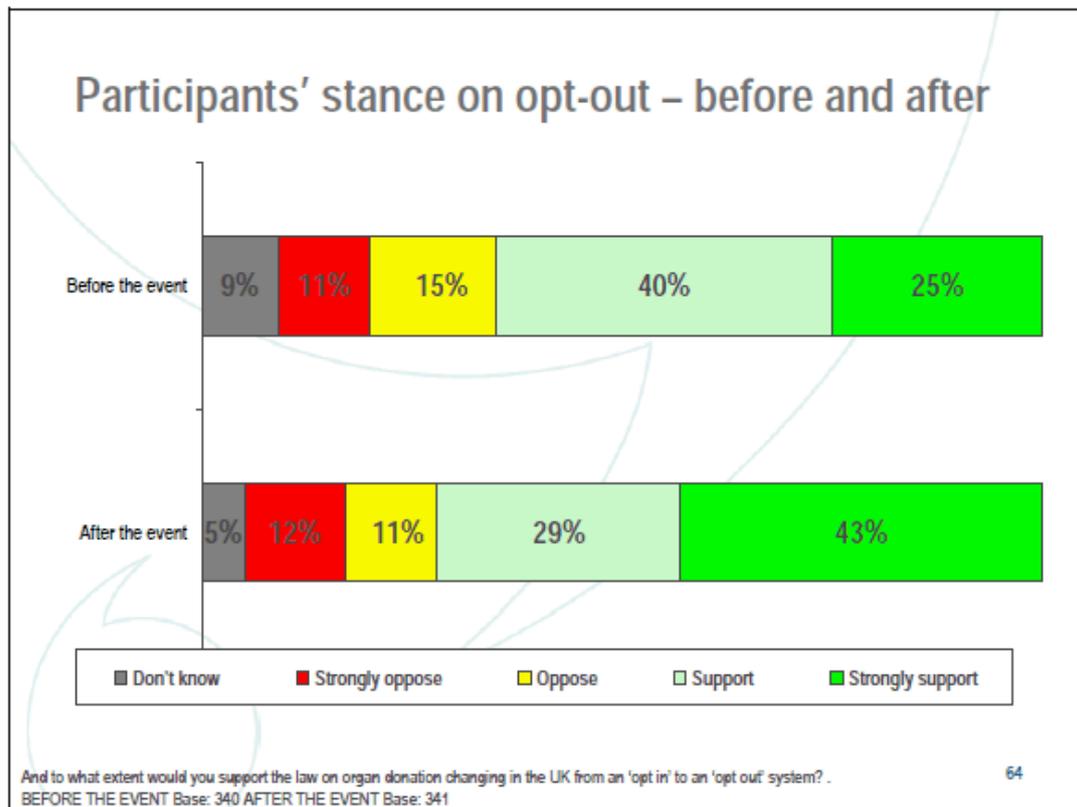
4.6 UK Organ Donation Taskforce

As part of the Organ Donation Taskforce's study into the potential impact of an opt-out system for organ donation in the UK, a research agency (Opinion Leader) was commissioned to carry out a series of deliberative events around the UK about organ donation. Events typically involved around 50 participants and were conducted in June-July, 2008, in seven locations: London, Exeter, Birmingham, Glasgow, Newcastle, Belfast, and Manchester. It is reported that "participants were recruited to ensure a regionally representative demographic spread, with some groups up-weighted in order to ensure contribution from seldom heard voices" (Opinion Leader Research, 2008) (p. 13).

At each event, participants sat at tables of approximately eight people with a facilitator who handled the overall discussion, and was responsible for handling the information provided to the participants. The events involved a mixture of materials including presentations by an Organ Donation Taskforce representative; video footage offering different views concerning opt-out and opt-in systems; information sheets about the Organ Donor Register and donor cards, and the different systems operative in other countries; scenarios to

help participants think through situations where a decision is made on donation; post-workshop questionnaires and ranking sheets to gauge people's preferences about opt-in and opt-out systems.

Figure 3: Department of Health deliberative events, 2008. Participants' responses to "And to what extent would you support the law on organ donation changing in the UK from an 'opt-in' to an 'opt-out' system?", which was asked both before and after the deliberative events. Figure from p. 43 of the Opinion Leader Research Report (Opinion Leader Research, 2008)



Of interest, are the participants' opinions regarding the introduction of an opt-out system for organ donation in the UK, both before and after involvement in the deliberative events as shown in Figure 3. These results should not be considered as representative of the UK population – they simply show how the views of participants changed before and after the events. Although the proportion who 'strongly oppose' the opt-out system remained relatively constant (11 per cent before and 12 per cent after the events) the proportion who 'strongly support' the UK adopting the opt-out system increased from 25 per cent to 43 per cent, while the total proportion supportive of a change (support or strongly support) rose from 65 per cent to 72 per cent. The

increase in (strong) support for the UK changing to an opt-out system may be indicative of the way in which equipping persons with information regarding organ donation and consent systems may change public opinion.

4.7 Healy et al, 2009

Healy et al. (2009) conducted a survey among students at the National University of Ireland, Galway, during an annual organ donation promotion week. During February 2008, respondents were asked about the opt-out system (exact question wording not reported) and 38 per cent (177/470) were in favour of changing the current “opt-in” consent methodology to presumed consent. Given that this study only surveyed students from a single university in Ireland, this study only provides information regarding the attitudes of a very specific subset of the population and therefore it is very limited in the extent to which these findings can be considered representative of a wider population. Additionally, this study was carried out during an ‘annual organ donation promotion week’, the content of which is not detailed in this article, but which may have influenced responses.

4.8 Summary

Three Wales-specific surveys, a UK-based internet survey and a study of university students in Ireland were identified, alongside a series of deliberative events commissioned by the UK Organ Donation Taskforce. Given that the Irish study only sampled students from a single university, the findings are very limited in the extent to which they can be considered representative of a wider population. The same is true for the UK-based internet survey, for which information regarding the characteristics of the sample do not appear to be published. The three Wales-based surveys, however, report that they employed sampling methods to recruit respondents that are broadly representative of the adult population resident in Wales and are of particular

relevance given that the proposed change in organ donation legislation is specific to Wales.

The Wales-based surveys indicate that a greater proportion of respondents support the move to an opt-out system than are against it. While there appears to be substantial support in Wales for the change in legislation, there is also a significant proportion of the population who oppose the change. Between 6-8 per cent report that they 'don't know' if they would support such a legislation change, while in the Wales Omnibus survey 21 per cent of respondents stated that they needed more information to decide. In combination this equates to almost 30 per cent of respondents in the Wales Omnibus Survey not being able to decide whether they support or are against the introduction of an opt-out system. The Welsh Government will seek to address this through communication campaigns to equip the Welsh population with the information that they need in order to make an informed decision. The deliberative events conducted by Opinion Leader, on behalf of the UK Department of Health, indicate that in providing information, support for a system of presumed consent may increase.

The findings of the three Wales-based and the UK internet surveys are broadly in line with the UK surveys reviewed by Rithalia et al. (2008). These indicated that the level of public support for an opt-out system for organ donation varied between surveys and over time, which could be due to a temporal change in opinions or simply differences in sampling and survey methods. The results of the surveys reviewed by Rithalia et al. (2008) are as follows:

- **1976:** UK non-random sample. 65 per cent of respondents did not agree to changing the law to one of presumed consent and 34 per cent did agree.
- **2004:** random sample of 1,009 Scottish adults. 53 per cent of respondents did not agree, and 37 per cent agreed, that doctors should

automatically be able to take organs for transplantation, unless the deceased was against it.

- **2007:** UK YouGov survey. 64 per cent of respondents stated that they did support a change to a system of presumed consent, whereby organ donation would occur unless the individual has registered an objection or that proceeding with donation would cause severe distress to the relatives.

5. Other types of evidence: Experimental literature

Not included in Rithalia et al's (2008) review were studies that take a more psychological experimental approach to examining the potential effects of presumed consent for organ donation. These studies involve presenting hypothetical scenarios to participants and asking them about their corresponding behavioural intentions. While this type of investigation is limited in the extent to which one could expect the results to be replicated in real life situations by a wider population, it can provide useful insights into possible mechanisms through which certain interventions might work – in this case, how an opt-out system might contribute to increased organ donation rates. Four studies of this kind were identified and reviewed.

Johnson and Goldstein (2003) conducted an online experiment involving 161 US resident respondents who were asked whether they would consent to being post-mortem organ donors on the basis of one of three questions with varying default positions. Participants were told to imagine they had just moved to a new state and were instructed to confirm or change their organ donation status. Respondents were asked the same questions, but allocated to one of three different defaults:

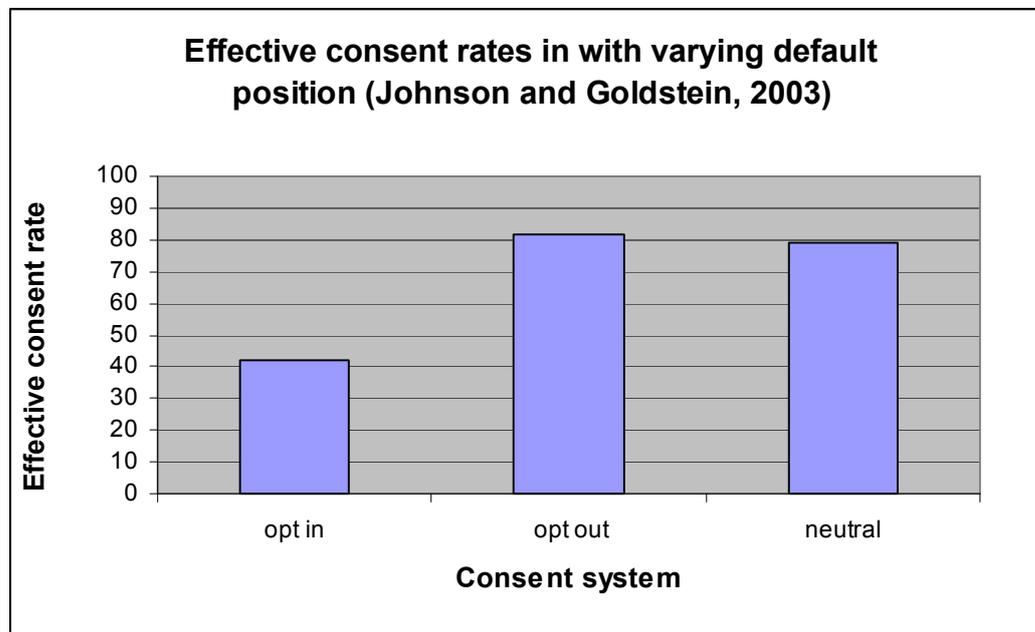
- opt-in position (the default position in the state they had just moved to was not to be an organ donor);
- opt-out position (default in new state was to be an organ donor);
- or neutral condition, which simply required respondents to choose with no prior default.

The action required for a change of choice was a mouse click, meaning differences in answers were unlikely to be based on the degree of effort required.

Effective consent rates (Figure 4) varied by default position. 82 per cent of those exposed to the opt-out default position consented to being organ donors, compared 42 per cent of the respondents who were allocated to the

opt-in default position. Of those allocated to the neutral position (no default), 79 per cent consented to be organ donors.

Figure 4: Results of Johnson and Goldstein's (2003) online experiment assessing the effect of defaults position on effective consent rates to be a post-mortem organ donor



These results suggest that the default position can have a significant impact on the choices made by respondents. While these findings are encouraging and may lend support to a change in the default position of organ donation, some weaknesses should be noted. The online experiment only had a sample size of 161, who were divided into three groups, meaning the resulting proportions will be based on the actions of just over 50 people in each hypothetical scenario. It is also unclear how these respondents were recruited and no information is provided regarding their demographic characteristics, thereby limiting our knowledge concerning the representativeness of this sample.

This kind of experiment only provides information on how people report they would behave in hypothetical situations; it is unlikely their answers would translate perfectly into actual behaviour if met with the equivalent situation in real life (Radecki and Jaccard, 1999). Also, rates of willingness to donate one's own organ is not the only factor of importance for determining actual rates of organ donation – the family of potential donors often play a critical

role in making the decision as to whether a deceased relative can be used as an organ donor or not, regardless of the type of consent system in operation (Boyarksy et al., 2012). Of particular relevance may be the differing levels of influence that the deceased wishes have on relatives agreement to consent; Coppen et al. (2010) found in their study using hypothetical scenarios that the type of consent provided by the deceased (in terms of whether it is presumed or explicit) affects the likelihood that family member will agree to organ procurement.

John et al. (2011) conducted a similar experimental study, this time involving UK resident participants. 4,000 respondents were recruited to be broadly representative of the UK population on key demographic variables and were randomly allocated to one of three groups: informed consent; presumed consent; and mandated choice. Respondents received an online survey on attitudes to organ donation, which were identical apart from the final question asking participants whether they would like to visit the national organ donation website to join the organ donation register. Each of the three groups were presented with a slightly different final question, with variations in the tick box set up as follows:

<p>Informed consent: Please take me to the NHS Organ Donation Website to join the National Organ Donor Registry</p> <p><input type="checkbox"/> (Check the box if you want to visit the site to register your name)</p>
<p>Presumed consent: Please take me to the NHS Organ Donation Website to join the National Organ Donor Registry</p> <p><input checked="" type="checkbox"/> (Uncheck the box if you DO NOT want to visit the site to register your name)</p>
<p>Mandated choice: Please take me to the NHS Organ Donation Website to join the National Organ Donor Register</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>(Please answer either 'yes' or 'no')</p>

Among those respondents assigned to the informed consent group (control), 15 per cent clicked through from the survey to visit the National Organ Donor Register website. Among the mandated choice group this percentage

increased to 20 per cent, and among the presumed consent group, to 23 per cent. The study stated that the differences between the control and the treatment groups were statistically significant, although no details of the tests carried out were provided.

While those allocated to the presumed consent group were the most likely to click through to the Organ Donor Register website, when considering how many respondents actually went on to fill in and submit the form required to register as an organ donor, less than 1 per cent of the total sample did so, with no differences observed between the three different groups.

In this study, the default setting appears to have an effect on respondents' behaviour, with the percentage clicking through the National Organ Donor Register website increasing from 15 per cent in the informed consent group to 23 per cent in the presumed consent group. However, this difference did not translate through to actual registrations on the organ donor register. Arguably, the actual organ donation registrations are the most important outcome of this study in terms of the public health impact that extra registrations could have. This particularly low rate of registrations in any of the groups could be due to a number of factors; it may simply be that once faced with a slightly more extensive online form to complete, the participants do not feel like registering at that exact time – perhaps reflective of the difference, as reported elsewhere, in the proportion of people who report that they would be willing to donate their organ and the proportion who have actually registered this wish (Wellesley, 2011). There is also the chance that respondents did not give their full attention to detail on the page in question, and therefore inadvertently found themselves re-directed to this webpage. It may therefore have been informative to inspect the length of time respondents spent on the organ donation registry page once they had been redirected.

From the results presented by this study, there is an indication of the positive effect that organ donation defaults may have, but it is not clear whether this approach would work to significantly increase actual organ donation consent

rates. As with the other experimental studies, the extent to which these results might be true in real life situations is not known.

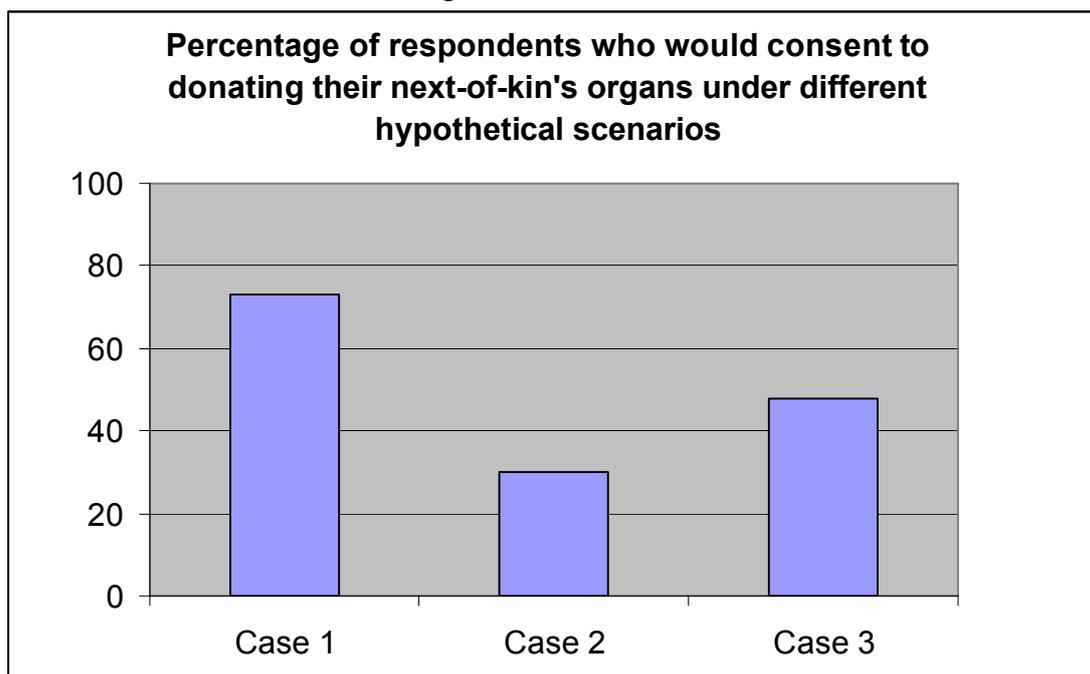
Coppen et al. (2010) conducted their study of over 600 participants via the Dutch Health Care Consumer Panel, a survey of consumers' experiences and opinions regarding health services. The questionnaire consisted of a number of hypothetical scenarios, all of which were presented to each participant. The scenarios described a situation in which a close family member had been diagnosed as brain dead, with variations in the donor status of the deceased relative as follows:

- **Scenario 1:** the deceased is registered as a donor in an explicit consent system
- **Scenario 2:** the deceased is not registered as a donor in an explicit consent system
- **Scenario 3:** the deceased is presumed to be a donor in a presumed consent system.

These scenarios were each accompanied by the question: a) *taking into account the cited (legal) conditions, would you as next of kin of the deceased agree to an organ donation procedure?*

Results (see Figure 5) showed that respondents, in their role of next of kin, were most willing to consent to the donation of a relative's organs when the deceased is registered as a donor in the context of an explicit consent system (Scenario 1: 73 per cent; 95 per cent CI: 70.3-75.6). In the cases whereby the deceased had not registered as a donor, relatives' agreement to donate was higher in the context of a presumed consent system (Scenario 3: 48 per cent; 95 per cent CI: 45.3-51.3), compared to an explicit consent system (Scenario 2: 30 per cent; 95 per cent CI: 27.7-33.1).

Figure 5: Coppen et al., 2010, results of study presenting respondents with hypothetical scenarios in which they are asked whether they would be willing to donate their deceased relative's organs.



Case	Legal conditions
1	The deceased is registered as a donor (explicit consent system)
2	The deceased is not registered as a donor (explicit consent system)
3	The deceased is (by law) presumed to be a donor (presumed consent system)

This study found that there were statistically significant differences in how people reported they would react to the question of donating their relative's organ, depending on the legal conditions relevant to organ donor consent. Figure 5 shows that the likelihood of agreement is highest when the deceased's consent has been given in the context of an explicit consent system. Where the deceased's consent has been presumed, the level of familial consent is lower than when it has been explicitly expressed. This suggests that although in a presumed consent system the pool of potential donors is larger, the likelihood in of kin consenting to procurement is lower. Whereas in an explicit consent system, the donor pool is smaller, but proportion of kin who will agree to donation is greater. Also of importance is the higher rate of familial consent in a system of presumed consent versus explicit consent system, when the potential donor has not registered their donation wishes.

As with the previous studies described, this kind of research only provides information on how respondents believe and report they would behave in hypothetical situations; it is unlikely their answers would translate perfectly into actual behaviour if met with the equivalent situation in real life. However, this study does provide interesting insights into how the Dutch public distinguish between explicit donors and presumed donors.

Davidai et al., (2012) conducted three experiments with three different samples of participants (sample sizes ranging from 43 to 163). The first two experiments involved instructing participants to read a short paragraph describing the organ donation policy of a foreign country, which either described an opt-in or opt-out policy. Respondents were then asked to consider what it means to donate one's organs in the context of the country description that they had read. Specifically, participants were instructed to evaluate the act of organ donation on seven different scales describing other acts, for example, leaving 50 per cent of one's estate to charity vs. 5 per cent, in terms of the similarity of organ donation with regard to effort and significance. Scoring was on a 1-9 continuum for each of the seven scales, and the mean score across these seven scales was then calculated for the opt-in and opt-out allocated groups and compared using the T-test.

Those allocated to the opt-out country description rated organ donation to be a significantly less substantial action, than those allocated to the opt-in scenario (mean opt out score: 4.9, mean opt-in score: 5.9, $p < 0.0001$). The third experiment involved the same rating activities in terms of the significance of organ donation compared to other activities, but involved a comparison of respondents from Austria (opt-out policy) and Germany (opt-in policy). In line with the first two experiments, those respondents from Germany, which has an opt-in policy rated organ donation to be more meaningful and substantial (akin to working overtime without compensation or giving 20% of one's annual income to charity), whereas respondents from Austria rated organ donation to be less substantial and meaningful (akin to fulfilling one's duties at work or giving 2 per cent of one's annual income to charity).

These findings lead the authors to speculate, “when citizens are presumed by the default option to be organ donors, organ donation is seen as something that one does unless some exceptional factor makes an individual particularly reluctant to participate. In contrast, when citizens are presumed by the default option not to be organ donors, organ donation is seen as something noteworthy and elective, and not something one simply does” (p. 5). The authors also suggest that this effect of default positions may be a contributing factor to the differences in organ donation rates between countries with opt-in policies and opt-out policies.

This study takes a novel approach to examining how opt-in and opt-out policies affect persons’ perceptions of organ donation. Whether such an approach is a valid method of assessment is questionable; organ donation is a unique and emotive behaviour and arguably is very difficult to compare to behaviours such as doing your job or giving money to charity. Even though the study reports that the differences in the mean scores are statistically significant, the difference was actually of only 1-point on 9-point scale, which is arguably not a particularly great difference in terms of magnitude. This study involved three distinct samples, who had been recruited in slightly different ways (approached on or near campus, completing the survey as part of a pack of questionnaires in exchange for extra credit, or online survey). These samples likely reflect the views of a very small proportion of the wider population and are very limited in terms of sample size. Overall, this study is judged to be of limited quality.

5.1 Summary

The four studies described above are essentially experiments into the effect that the legal default position for organ donation has on respondents’ reported donation intentions. This research provides insight into the mechanism by which opt-out systems might cause increase in organ donation rates; two studies suggest that when the default position is to be an organ donor, effective consent rates are higher as more individuals tend to stick with the

default position, so increasing the pool of potential donors (Johnson and Goldstein, 2003; John, 2011). Davidai et al. (2012) found that respondents' perceived organ donation to be a less substantial and meaningful act in the context of an opt-out system versus an opt-in system, possibly indicating the way in which the default position is considered as the 'norm', and so behaving in accordance with this norm (in this example, agreeing to donate organs) is no longer such an out of the ordinary behaviour.

Coppen et al's (2010) study used hypothetical scenarios to explore how family members may respond to different types of consent given by deceased relatives within different types of system. Findings indicated that when the deceased has not expressed any organ donation wishes, family members are more likely report that they would agree to organ donation in the context of a system of presumed consent, as opposed to an explicit consent system.

While these findings might be indicative of the way potential donors and their families would behave within opt-out and opt-in systems, such experimental research has limitations in the extent to which findings can be extrapolated to real life.

6. Discussion

The studies assessing the impact of opt-out systems on organ donation reviewed by Rithalia et al. (2008) and those identified by this review should be interpreted keeping in mind that these kind of studies can only be used to make inferences about *association* and *not causation*. Five comparative studies without major methodological flaws all find the association (of varying strengths) that presumed consent legislation is associated with higher organ donation rates; although the overlap in the group of countries under study likely bias the studies to show more similar results to one another.

Figure 6 presents international organ donation rates (colour coded by type of consent legislation). This illustrates that countries operating presumed consent legislation do not necessarily have the highest organ donation rates and that countries operating a system of informed consent do not necessarily have the lowest organ donation rates. However, in line with the research reviewed, there does seem to be an overall pattern whereby in general, presumed consent countries have higher organ donation rates than countries operating opt-in systems. Moreover, research suggests that in the majority of countries, regardless of whether they operate an informed consent or presumed consent system, it is the next-of-kin of the deceased that have the final say as to whether organ donation will proceed or not (Rosenblum et al., 2012). This has led authors to suggest that because the process of donation in presumed consent countries does not differ dramatically from the process in non-presumed consent countries, it seems unlikely that presumed consent alone increases donation rates (Boyarsky et al., 2012).

The single jurisdiction before and after studies identified are also limited in terms of the extent to which the observed increases in organ donation rates can be attributed solely to the change in consent legislation, due to the lack of investigation into concurrently changing factors related to organ donation. However, in comparing a country to itself a few years earlier it is likely that there will be fewer additional factors contributing to the observed differences

in organ donation rates, compared to number of potentially confounding factors present in cross country comparisons. The temporal nature of before and after studies is more useful for interpreting attribution than cross sectional studies.

Other factors that might explain the change in a country's organ donation rates before and after the introduction of an opt-out system must be factors that have also *changed* over the time period of analysis. Arguably, the additional factors that are most likely to undergo change in single country during the introduction of new organ donation legislation are those efforts directly related to that legislation, such as publicity campaigns. While such other country level factors may blur the effect, or lack thereof, of the change in legislation per se, it seems plausible that a change in legislation, in combination with communication campaigns and the inevitable extra media coverage, may be worth more than the sum of its parts in changing organ donation behaviour. Therefore, the necessity that these effects should be disentangled is questionable; any country introducing an opt-out system would have to accompany the new law with widespread communications campaigns, given the ethical requirement that every resident must be fully informed of what taking no action to record donation wishes will now mean. In reality, it is probably not possible to separate out these intertwined effects and measuring the effect of new legislation in combination with its accompanying communications campaign is more relevant for accounting for the impact of this kind of policy change in real life.

It is likely that to some extent, the success (in terms of an increase in donated organs) of a change in consent legislation to an opt-out system will depend on the level of support from the public. Where public opinion is not in favour of presumed consent law, there is a potential risk of a backlash which, if it results in the masses opting-out, could actually cause more harm than good. A commonly cited example of a failure of an opt-out system for organ donation is the case of Brazil, which in 1997 passed a law introducing presumed consent. Even before being passed, the proposed legislation change was highly criticised by medical organisations and was introduced

against a background of public distrust of the government and negative media coverage (Jensen 1999). It is reported that part of the population feared that their organs would be removed before they were clinically dead and that many rushed to register themselves as non-donors in order to avoid this perceived risk (Csillag, 1998). Brazil's presumed consent law was subsequently abolished in 1998.

The three Wales-based surveys indicate that a far greater proportion of respondents are in favour of an opt-out system for organ donation, than are against. The Wales Omnibus Survey (2012) indicates that 21 per cent need more information to decide and so, this group in particular needs to be targeted to equip them with the information required to inform their opinion. From the deliberative events conducted with 350 participants, commissioned by the UK Department of Health, there is an indication that after participants have been provided with information about organ donation and the various implementation systems in operation, opinions towards the introduction of an opt-out system in the UK become more favourable.

The experimental studies examining the effect of defaults on reported organ donation intentions are limited in the extent to which they are applicable to real life, however, they may shed light on a potential mechanism through which the opt-out system might contribute to changes in organ donation behaviour. Another potential mechanism of effect is that opt-out legislation increases family discussion about organ donation. If consent is presumed, organ donation becomes an issue that affects the entire population and so, it is possible that this encourages family members to discuss their wishes, which is of great importance given that the final donation decision is usually in the family's hands (often even if the legislation says otherwise). However, there appears to be a lack of evidence on whether presumed consent legislation affects family donation discussions in this way. Future research concerned with the mechanism of organ donation behaviour change should give focus to the role of familial discussion and how such conversations can be encouraged.

The literature reviewed indicates that there are other factors, other than consent legislation, that are associated with higher organ donation rates, such as higher GDP, religious make up of population (high proportion Catholic), and improved organ donation/transplantation infrastructure. There is a lack of evidence regarding what other factors are needed in order for opt-out legislation to have an optimal positive effect, for example, the legal role of family and the type of register (combined versus single) may be important for the functioning of an opt-out system and are factors that are more amenable to change, compared to, for example, country GDP or the religious make up of the population.

Wales' current proposal is to operate an opt-out register alongside the existing opt-in register (i.e. combined), meaning a person can either opt-in explicitly, take no action and have their consent deemed, or opt-out explicitly. This type of system does raise the question that if a person is able to explicitly opt-in for donation, does that then reduce the weight that family members (who often make the final decision) give to consent that has been deemed due to a lack of action. Coppen et al's (2010) study gives some indication of the varying levels of consideration given to different types of consent in different types of system, however none of the presented scenarios cover a situation in which a person's consent had been deemed through no action, within a system where wishes to both opt-in and opt-out can be recorded. However, according to the literature, other countries such as Belgium and Czech Republic, successfully operate a combined registry.

7. Conclusion

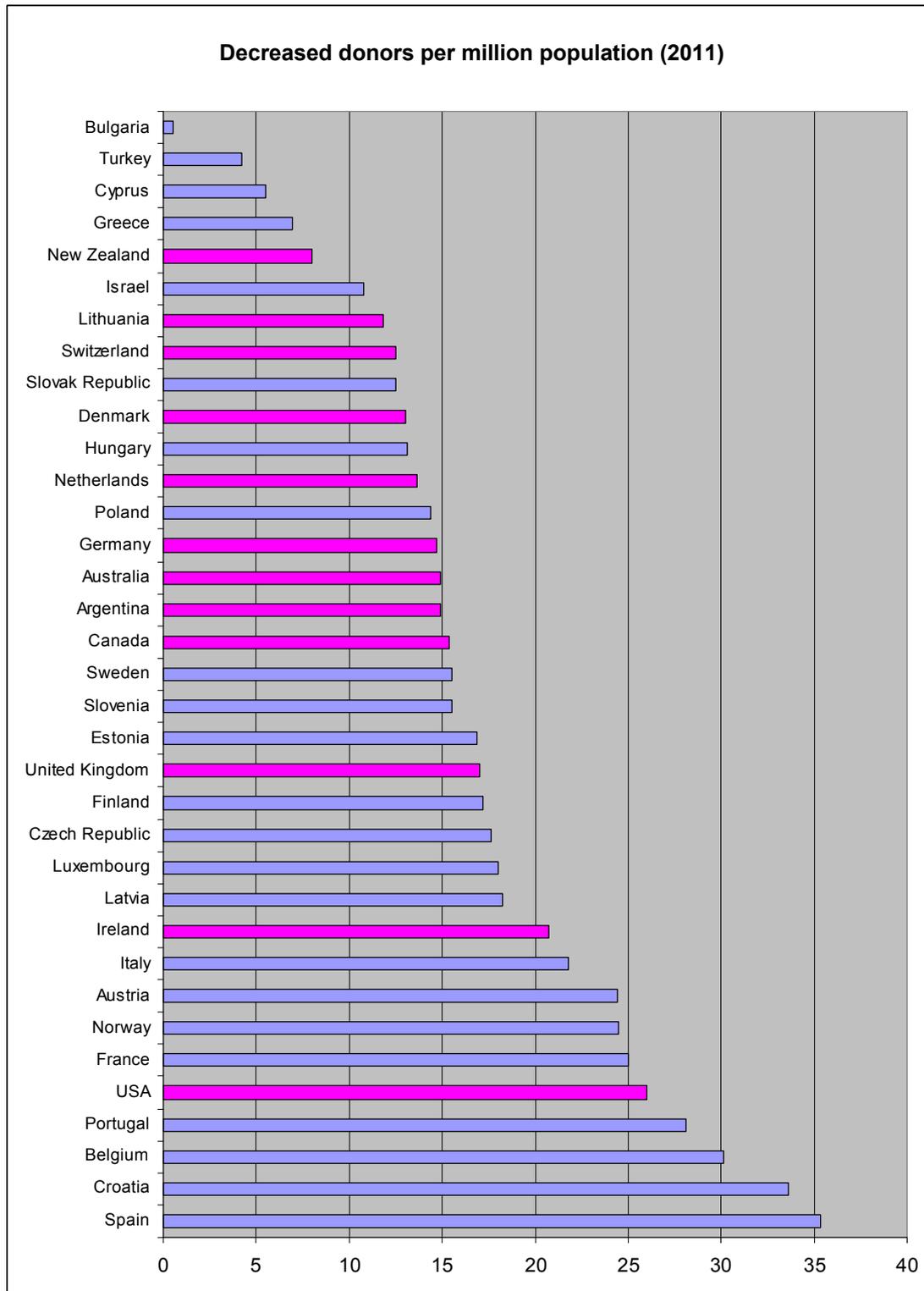
While the evidence shows presumed consent legislation to be associated with higher organ donation rates and greater willingness to donate organs, it cannot provide a definitive answer as to whether the introduction of an opt-out system in Wales will increase organ donation rates. Observational research can only provide information concerning associations; whether presumed consent systems actually *cause* increased organ donation rates cannot be inferred from the existing literature. Researchers have employed a variety of methods to investigate the impact of opt-out systems meaning that no two studies are directly comparable. Similarly, no two countries are the same and therefore, a finding that an opt-out system is associated with increased organ donation rates in one country does not mean the same relationship will exist in another.

Given the complexity of decision-making surrounding organ donation consent, it is unlikely that a single piece of legislation alone will be responsible for an increase in organ donation rates. However, it may be a contributory factor. An opt-out system changes the default position to be in line with the (reported) wishes of the majority and this may overcome the problem of inertia that limits explicit registration to opt-in, while providing a new opportunity for those who definitely do not wish to donate to record their wishes by opting out. Where legislation is changed, communications campaigns and factors related to practical implementation of the policy at the ground level will likely be important factors in the legislation's success; unfortunately the current evidence base provides little information on how these factors can be optimised.

This paper presents three main strands of evidence: 1) international evidence suggests that an association exists between presumed consent legislation and increased organ donation rates; 2) recent surveys indicate that there is significant support for the introduction of an opt-out system for organ donation in Wales; 3) experimental literature provides evidence for a mechanism

through which presumed consent might increase organ donation, through the influence of the default position. In combination, these three strands of evidence provide a convincing basis for the introduction of an opt-out system in Wales, although there can be no *guarantees* that this legislative change will result in increased organ donation rates.

Figure 6: International organ donation rates



Source: Council of Europe, International Figure on Organ Donation and Transplantation Activity (2011)

Key	
	Informed consent
	Presumed consent

Appendix 1: Details of search strategy

This review aimed to replicate the searched strategy used by Rithalia et al. (2008), while limiting dates of publication to between January 2008 and present.

One database, PAIS International, searched in Rithalia et al's (2008) could not be accessed for this update. The publication types represented by PAIS International are: 63 per cent journal articles, 25 per cent books, 11 per cent government documents, 1 per cent websites. Given the number and breadth of cover of the other databases that were possible to search, it is unlikely that our lack of access to this database has led to significant gaps in this update.

SEARCH STRATEGY

The core search strategy used for this review was as follows:

1. Presumed Consent/
2. Informed Consent/
3. (presum\$ adj3 consent\$).ti,ab.
4. (assum\$ adj3 consent\$).ti,ab.
5. (tacit adj3 consent\$).ti,ab.
6. opt out.ti,ab.
7. opting out.ti,ab.
8. or/1-8
9. Tissue Donors/
10. ((cadaver or deceased) adj2 donor\$).ti,ab.
11. ((postmortem or post mortem) adj2 donor\$).ti,ab.
12. ((deceased or dead) adj2 donor\$).ti,ab.
13. ((organ or organs) adj3 donor\$).ti,ab.
14. ((transplant or transplantation) adj donor\$).ti,ab.
15. (tissue adj3 donor\$).ti,ab.
16. "Tissue and Organ Procurement"/
17. "Tissue and Organ Harvesting"/

18. ((cadaver or deceased) adj2 (donat\$ or harvest\$)).ti,ab.
19. ((postmortem or post mortem) adj2 (donat\$ or harvest\$)).ti,ab.
20. ((deceased or dead) adj2 (donat\$ or harvest\$)).ti,ab.
21. ((organ or organs) adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
22. (tissue adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
23. or/9-22
24. 8 and 23
25. Animals/
26. Humans/
27. 25 not (25 and 26)
28. 24 not 27
29. (editorial or historical article or letter).pt.
30. 28 not 29

Ovid: EMBASE

Limited to HUMANS and PUBLICATION 2008-2013

NOT (editorial or letter.pt)

Date of search: 26/07/12

Records: 761

1. informed consent/
2. (presum\$ adj3 consent\$).ti,ab.
3. (assum\$ adj3 consent\$).ti,ab.
4. (tacit adj3 consent\$).ti,ab.
5. opt out.ti,ab.
6. opting out.ti,ab.
7. or/1-6
8. donor/ or organ donor/
9. cadaver donor/

10. ((cadaver or deceased) adj2 donor\$).ti,ab.
11. ((postmortem or post mortem) adj2 donor\$).ti,ab.
12. ((deceased or dead) adj2 donor\$).ti,ab.
13. ((organ or organs) adj3 donor\$).ti,ab.
14. ((transplant or transplantation) adj donor\$).ti,ab.
15. (tissue adj3 donor\$).ti,ab.
16. transplantation/ or organ transplantation/
17. ((cadaver or deceased) adj2 (donat\$ or harvest\$)).ti,ab.
18. ((postmortem or post mortem) adj2 (donat\$ or harvest\$)).ti,ab.
19. ((deceased or dead) adj2 (donat\$ or harvest\$)).ti,ab.
20. ((organ or organs) adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
21. (tissue adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
22. or/8-21
23. 7 and 22

Ovid: MEDLINE and MEDLINE IN PROCESS

Limited to 2008-current

Date of search: 26/07/12

Records: 364

1. Presumed Consent/
2. Informed Consent/
3. (presum\$ adj3 consent\$).ti,ab.
4. (assum\$ adj3 consent\$).ti,ab.
5. (tacit adj3 consent\$).ti,ab.
6. opt out.ti,ab.
7. opting out.ti,ab.
8. or/1-8

9. Tissue Donors/
10. ((cadaver or deceased) adj2 donor\$).ti,ab.
11. ((postmortem or post mortem) adj2 donor\$).ti,ab.
12. ((deceased or dead) adj2 donor\$).ti,ab.
13. ((organ or organs) adj3 donor\$).ti,ab.
14. ((transplant or transplantation) adj donor\$).ti,ab.
15. (tissue adj3 donor\$).ti,ab.
16. "Tissue and Organ Procurement"/
17. "Tissue and Organ Harvesting"/
18. ((cadaver or deceased) adj2 (donat\$ or harvest\$)).ti,ab.
19. ((postmortem or post mortem) adj2 (donat\$ or harvest\$)).ti,ab.
20. ((deceased or dead) adj2 (donat\$ or harvest\$)).ti,ab.
21. ((organ or organs) adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
22. (tissue adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
23. or/9-22
24. 8 and 23
25. Animals/
26. Humans/
27. 25 not (25 and 26)
28. 24 not 27
29. (editorial or historical article or letter).pt.
30. 28 not 29

Ovid: PSYCINFO
Limited 2008-current
Date of search: 26/07/12
Records: 39

1. informed consent/
2. (presum\$ adj3 consent\$).ti,ab.
3. (assum\$ adj3 consent\$).ti,ab.
4. (tacit adj3 consent\$).ti,ab.
5. opt out.ti,ab.
6. opting out.ti,ab.
7. or/1-6
8. ((cadaver or deceased) adj2 donor\$).ti,ab.
9. ((postmortem or post mortem) adj2 donor\$).ti,ab.
10. ((deceased or dead) adj2 donor\$).ti,ab.
11. ((organ or organs) adj3 donor\$).ti,ab.
12. ((transplant or transplantation) adj donor\$).ti,ab.
13. (tissue adj3 donor\$).ti,ab.
14. tissue donation/
15. ((cadaver or deceased) adj2 (donat\$ or harvest\$)).ti,ab.
16. ((postmortem or post mortem) adj2 (donat\$ or harvest\$)).ti,ab.
17. ((deceased or dead) adj2 (donat\$ or harvest\$)).ti,ab.
18. ((organ or organs) adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
19. (tissue adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
20. or/8-19
21. 7 and 20

Ovid: HMIC (Health Management Information Consortium)

Limited 2008 – current

Date of search: 26/07/12

Records: 44

1. consent/ or informed consent/

2. (presum\$ adj3 consent\$).ti,ab.
3. (assum\$ adj3 consent\$).ti,ab.
4. (tacit adj3 consent\$).ti,ab.
5. opt out.ti,ab.
6. opting out.ti,ab.
7. or/1-6
8. donors/ or organ donors/
9. ((cadaver or deceased) adj2 donor\$).ti,ab.
10. ((postmortem or post mortem) adj2 donor\$).ti,ab.
11. ((deceased or dead) adj2 donor\$).ti,ab.
12. ((organ or organs) adj3 donor\$).ti,ab.
13. ((transplant or transplantation) adj donor\$).ti,ab.
14. (tissue adj3 donor\$).ti,ab.
15. organ donation/
16. organ procurement/
17. ((cadaver or deceased) adj2 (donat\$ or harvest\$)).ti,ab.
18. ((postmortem or post mortem) adj2 (donat\$ or harvest\$)).ti,ab.
19. ((deceased or dead) adj2 (donat\$ or harvest\$)).ti,ab.
20. ((organ or organs) adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
21. (tissue adj3 (donat\$ or procure\$ or harvest\$)).ti,ab.
22. or/8-21

EBSCO: CINAHL plus

Limited: January 2008 – January 2013

Date of search: 26/07/12

Records: 315

1. Consent
2. (presume* N3 consent*) .ti,ab.

3. (assume* N3 consent*) .ti,ab.
4. (tacit* N3 consent*) .ti,ab.
5. opt out .ti,ab.
6. opting out .ti,ab.
7. or/1-6
8. Transplant Donors
9. ((cadaver or deceased) N2 donor*) .ti,ab.
10. ((postmortem or post mortem) N2 donor*) .ti,ab.
11. ((deceased or dead) N2 donor*) .ti,ab.
12. ((organ or organs) N3 donor*) .ti,ab.
13. ((transplant or transplantation) N2 donor*) .ti,ab.
14. (tissue N3 donor*) .ti,ab.
15. Organ Procurement
16. "Tissue and Organ Harvesting"
17. ((cadaver or deceased) N2 (donat* or harvest*)) .ti,ab.
18. ((postmortem or post mortem) N2 (donat* or harvest*)) .ti,ab.
19. ((deceased or dead) N2 (donat* or harvest*)) .ti,ab.
20. ((organ or organs) N3 (donat* or procure* or harvest*)) .ti,ab.
21. (tissue N3 (donat* or procure* or harvest*)) .ti,ab.
22. or/8-21
23. 7 and 22
24. (letter or editorial) .pt.
25. 23 not 24

OPEN SIGLE: link in Rithalia et al review now links to opengrey.eu

<http://www.opengrey.eu/search/>

The search function 'Browse - Communities & Collections' was used to identify the '06 - Biological and medical sciences' and the '05 - Humanities, psychology and social sciences' collections. Searches were carried out within these collections using the terms: ((donor* or donat* or harvest* or procure*) AND (tissue or organ or organs or cadaver or deceased or postmortem or "post mortem" or deceased or dead))

Once limited to 2008-2012, no records found.

Date of search: 27/07/12

Internet

INTUTE – has not been updated since July 2011 – but search function still available.

Searched using terms below, and browsed through results, no records found.

Date: 27/07/12

<http://www.intute.ac.uk/search.html>

((donor* or donat* or harvest* or procure*) AND (tissue or organ or organs or cadaver or deceased or postmortem or "post mortem" or deceased or dead))

in: Subject(s): biological sciences, law, medicine, nmah, psychology, social sciences
Resource type(s): All

Organisational websites

The following organisational websites identified by Rithalia et al (2008) as worthy of further investigation were scanned.

Department of Health - Transplantation: Internet

(<http://www.dh.gov.uk/en/Healthcare/Secondarycare/Transplantation/index.htm>
)

The Department of Health Transplantation web pages search was carried out on 27/07/2012. One potentially relevant document was downloaded for consideration.

Human Tissue Authority: Internet (http://www.hta.gov.uk/about_hta.cfm)

The Human Tissue Authority website search was carried out on 27/07/2012. No relevant documents were identified.

The Internet Journal of Law, Healthcare and Ethics: Internet

(<http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijlhc/front.xml>)

Issues of the journal, vol.1(1) 2008 onwards, were scanned for relevant material on 27/07/2012. No relevant documents were identified.

The Danish Council of Ethics: Internet (<http://www.etiskraad.dk>)

The Danish Council of Ethics website search was carried out on 27/07/2012. One potentially relevant document was downloaded for consideration.

Council of Europe: Internet (<http://www.coe.int>)

The Council of Europe website search was carried out on 27/07/2012. No relevant documents were identified.

European Society for Organ Transplantation (ESOT): Internet

(<http://www.esot.org>)

The ESOT website search was carried out on 27/07/2012. No relevant documents were identified.

European Transplant Coordinators Organization: Internet (<http://www.etco.org>)

The ETCO website search was carried out on 27/07/2012. No relevant documents were identified.

UK Transplant: Internet (<http://www.uktransplant.org.uk/ukt/>)

The UK Transplant website search was carried out on 30/07/2012. No relevant documents were identified.

**MRC Centre for Transplantation: Internet
(<http://www.kcl.ac.uk/schools/medicine/research/transplantation>)**

The MRC Centre for Transplantation web pages search was carried out on 30/07/2012. No relevant documents were identified.

**Sheffield Institute of Biotechnological Law and Ethics: Internet
(<http://www.shef.ac.uk/law/sible/index.html>)**

The SIBLE web pages search was carried out on 30/07/2012. No relevant documents were identified.

UK Clinical Ethics Network: Internet (<http://www.ethics-network.org.uk>)

The UK Clinical Ethics Network website search was carried out on 30/07/2012. No relevant documents were identified.

**World Health Organization - Transplantation: Internet
(<http://www.who.int/transplantation/en>)**

The WHO Transplantation web pages search was carried out on 30/07/2012. No relevant documents were identified.

Organizacion Nacional de Trasplantes (ONT): Internet (<http://www.ont.es>)

The ONT website search was carried out on 30/07/2012. No relevant documents were identified.

Scandiatransplant: Internet (<http://www.scandiatransplant.org>)

The Scandiatransplant website search was carried out on 30/07/2012. No relevant documents were identified.

ALLIANCE-O: Internet (<http://www.alliance-o.org>)

The ALLIANCE-O website search was carried out on 30/07/2012. No relevant documents were identified.

The Swedish National Council on Medical Ethics (SMER): Internet (<http://www.smer.se>)

The SMER website search was carried out on 30/07/2012. No relevant documents were identified.

The Norwegian Biotechnology Advisory Board: Internet (<http://www.bion.no>)

The Norwegian Biotechnology Advisory Board website search was carried out on 30/07/2012. No relevant documents were identified.

The National Advisory Board on Health Care Ethics (ETENE): Internet (<http://www.etene.org>)

The ETENE website search was carried out on 30/07/2012. No relevant documents were identified.

Nordic Committee on Bioethics: Internet (<http://www.ncbio.org>)

The Nordic Committee on Bioethics website search was carried out on 30/07/2012. No relevant documents were identified.

Belgian Advisory Committee on Bioethics: Internet (<http://www.health.fgov.be/bioeth/index.html>)

The Belgian Advisory Committee on Bioethics website search was carried out on 30/07/2012. No relevant documents were identified.

Comité Consultatif National d'Ethique (CCNE): Internet (<http://www.ccne-ethique.fr>)

The CCNE website search was carried out on 30/07/2012. No relevant documents were identified.

German Reference Centre for Ethics in the Life Sciences (DRZE): Internet
(<http://www.drze.de>)

The DRZE website search was carried out on 30/07/2012. No relevant documents were identified.

National Bioethics Committee: Internet (<http://www.palazzochigi.it/bioetica>)

The National Bioethics Committee website search was carried out on 30/07/2012. No relevant documents were identified.

Centre for Ethics and Health of the Netherlands (CEG): Internet
(<http://www.ceg.nl>)

The CEG website search was carried out on 30/07/2012. No relevant documents were identified.

National Council of Ethics for the Life Sciences (CNECV): Internet
(<http://www.cnecv.gov.pt>)

The CNECV website search was carried out on 30/07/2012. No relevant documents were identified.

European Group on Ethics in Science and New Technologies (EGE): Internet
(http://ec.europa.eu/european_group_ethics/index_en.htm)

The EGE website search was carried out on 30/07/2012. No relevant documents were identified.

Australian Health Ethics Committee (AHEC): Internet
(<http://www.nhmrc.gov.au/ethics/human/ahec/index.htm>)

The AHEC website search was carried out on 30/07/2012. No relevant documents were identified.

UNESCO International Bioethics Committee (IBC): Internet
(http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html)

The IBC website search was carried out on 30/07/2012. No relevant documents were identified.

Commission on Ethics, Science and Technology (CEST): Internet
(<http://www.ethique.gouv.qc.ca>)

The CEST website search was carried out on 30/07/2012. No relevant documents were identified.

Toi te Taiao - the Bioethics Council: Internet (<http://www.bioethics.org.nz>)

The New Zealand's Bioethics Council website search was carried out on 30/07/2012.

No relevant documents were identified.

Bioethics Advisory Committee (BAC): Internet (<http://www.bioethics-singapore.org>)

The BAC website search was carried out on 30/07/2012. No relevant documents were identified.

National Bioethics Advisory Commission (NBAC): Internet (<http://bioethics.georgetown.edu/nbac>)

The NBAC website search was carried out on 30/07/2012. No relevant documents were identified.

British Transplantation Society: Internet (<http://www.bts.org.uk>)

The British Transplantation Society website search was carried out on 30/07/2012. No relevant documents were identified.

Eurotransplant: Internet (<http://www.transplant.org>)

The Eurotransplant website search was carried out on 30/07/2012. No relevant documents were identified.

Appendix 2: Excluded studies

Studies that reached full text review, but did not meet inclusion criteria for the update of systematic review assessing the relationship between presumed consent legislation and organ donation

Potential empirical studies	Reasons for exclusion
Bird and Harris (2010)	Empirical analysis comprised of model-based estimates of how many extra organ donors the UK would have if it adopted an opt-out system, under a range of assumptions.
Lee et al. (2009)	Explored the effect of the revised Human Organ Transplant Act (HOTA) which added more organs to the organ recovery list, in the setting of Singapore; an opt-out country.
Roels et al. (2008)	Descriptive statistics based on medical records review of process from diagnosis of brain death, donor identification, to organ donation in 4 European countries. No empirical analysis of impact of type of organ donation legislation.
Coppen et al. (2010b)	Experimental study which presented a range of scenarios to a sample of respondents with the aim of assessing the extent to which explicitness of consent to organ donation by the deceased impacts on the likelihood that next of kin will agree to the procurement of their deceased relative's organs. (For a more detailed review of this study, see 'other types of evidence: experimental literature' section).
Boyarsky et al. (2012)	A qualitative study involving in-depth interviews with senior transplant physicians from 13 European presumed consent countries. No quantitative analysis of impact of legislation on organ donation.

Appendix 3: Data extraction tables for studies without major limitations

Author (year)	Country/Region included	Stated Objective	Quality assessment				
			Selection	Comparability	Data Collection	Attributable to Intervention	Appropriate Analyses
Bilgel (2012)	28 Countries: Australia; Austria, Belgium, Canada, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Luxembourg, Netherlands, Norway, New Zealand, Poland, Portugal, Slovak Republic, Slovenia, Spain, Switzerland, Sweden United Kingdom, United States.	Examining the interactions between a presumed consent legal regime and other customs and institutions	Yes - Excludes 4 of the 28 countries – explanations given below	Yes - some factors not adjusted for – see below – e.g. transplant capacity	Data sources: specified and credible? YES -->World Bank, Health, Nutrition, and Population Statistics database; Transplant Procurement Management, International Registry of Donation and Transplantation; WHO Mortality database; WHO statistical information system database; Abadie and Gay; Healy; Global Observatory on Donation and Transplantation; Personal communication with relevant persons in country of interest.	No – observational – causality cannot be presumed.	Yes – multivariate regression

Factors considered in analysis															
Presumed consent law	CVA mortality	RTA mortality	Assault	GDP	Health expenditure	Transplant capacity	Religion	Education	Legislative system	Blood donation rate	Internet access	Civil rights and liberties	Family Consent	Combined Registry	Outcome
Y: binary: 1 presumed consent, 0 informed consent	Y: potential donor pool variable: log of CVD + MVA + homicide pmp	Y	Y	N	Y: log of per capita health expenditure	N	N: considered in preliminary analysis as binary Catholicism variable but not included in final models	N	Y: binary - 1 common law, 0 civil law	N	N	Y: civil liberties index comprised of freedom of expression and belief, associational and organizational rights, rule of law, personal autonomy, and individual rights: scale 1 highest level of freedom, 4 lowest level of freedom.	Y: binary: 1 next-of-kin consent is always sought, 0 otherwise	Y: binary: 1 country maintains combined registry, 0 country maintains single registry	Deceased organ donation rates, per million population (natural log)

Results			
Description of Analysis	Presumed consent and donor rates	Other factors influencing donor rates	Quality and limitations
<ul style="list-style-type: none"> - 4 countries not included in regression analysis: Switzerland (consent legislation varies by canton), Israel (to reduce heterogeneity in social norms), Greece (low transplant rates due to low medical staff and intensive care units), Luxembourg (data inconsistencies on deceased donation rates). - Regressions performed for remaining 24 countries over period 1993-2006. - Regression estimated using Fixed Effects Vector Decomposition (FEVD) - Interactions between type of consent system (presumed vs. informed), whether family consent is routinely sought or not, and whether a combined or single option register is maintained 	<ul style="list-style-type: none"> - Results: adjusting for per capita health expenditure, potential donor pool, civil liberties, legal system - presumed consent countries have on average 5.3% higher deceased organ donation rate. - Adjusting for the above plus family consent and type of registry - presumed consent countries have on average 13.4% higher organ donation rates. - Analyses looking at consent system* family consent * registry type interaction - shows family consent approach and combined vs. single register are important in the impact that a presumed consent system has – but this component of analysis will have very small sub-sample sizes, so limiting quality of results. - e.g. a presumed consent country with routine family consent and a combined registry produces 29% higher organ donation rates compared to an informed consent country with routine family consent and a single register. - e.g. among countries that maintain combined registers and always seek family consent, those that have a presumed consent system have on average 75% higher donation rates. - e.g. within presumed consent countries, routinely seeking family consent under a single registry system leads to on average, 15% lower organ donation rate compared to those equivalent countries that do not routinely seek family consent, but if a combined registry is maintained, routinely seeking family consent is associated with 36% higher organ donation rates. - R-squared >0.8 – good 	<p>In one or more of the models the following variables were statistically significantly (at 5% level) associated with organ donation rates:</p> <p>Per capita health expenditure, potential donor pool, civil liberties, routine family consent, type of registry – combined vs. single, legislative system.</p>	<ul style="list-style-type: none"> - Small sample size – only 24 countries included in analysis - Particularly in interactions – countries split into 8 groups based on consent legislation, family consent and type of register – this means on average 3 countries per group – and while there are multiple time points to provide more data points – there is very little variation in the legislation variable over time and so, association will likely be consistent through repeated through time points. - Absence of sufficient variation in consent legislation variable within countries over time - Healy's (2005) point that presumed consent regime may be a signal of a country's commitment to donation rather than a direct cause of higher organ donation rates.

			Quality assessment				
Author (year)	Country/Region included	Stated Objective	Selection	Comparability	Data Collection	Attributable to Intervention	Appropriate Analyses
Mossialos et al., (2008)	15 EU countries: Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Germany, United Kingdom.	Examining how country regulation, individuals' awareness of regulatory settings, social interactions and socio-demographic determinants influence individuals' willingness to donate their own organs and those of a relative.	Individual-level data from 15 EU countries which Eurobarometer survey includes. 15 is small n – this is effectively a multi-level dataset.	Potential confounders discussed and analysed – but – it is not entirely clear whether results shown in table are adjusted for everything else in table – I think they are.	Used data from the Eurobarometer survey 58.2, a cross-national comparative survey that includes a representative national sample of 15 EU countries: Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Germany, United Kingdom. Data collected Oct-Nov 2002. Respondents: resident citizens aged 15 and over: n = 16230. Multistage random sampling, total survey sample is representative of the whole territory of the 15 countries surveyed. Face-to-face interviews.	No - observational	Logistic regression to identify determinants of individuals' willingness to become cadaveric organ donors and to permit the donation of relatives' organs. Clustered data by country accounting for country of residence specific effects – rather than treating all observations as independent.

Factors considered in analysis																Outcome
Presumed consent law	CVA mortality	RTA mortality	Assault	GDP	Health expenditure	Transplant capacity	Religion	Education	Legislative system	Blood donation rate	Internet access	Civil rights and liberties	Family Consent	Combined Registry		
Y	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	<p>Reported willingness to donate one's own organs.</p> <p>Reported willingness to donate relatives' organs.</p> <p>However, individual attitudes regarding donations are not always aligned with behaviour – well demonstrated by the high proportion of the British public who state they are in favour of organ donation and would donate their organs but of whom only ~20% are signed up to the organ donation register.</p> <p>Questions: 'Whatever the rules and regulation, would you personally be prepared to donate one of your organs to an organ donor service immediately after your death?' Response options: 1 'yes definitely', to 4 'no, definitely not', and 5 'don't know'.</p> <p>'In hospital, if you were asked, would you give your consent to the donation of an organ from a deceased relative' – responses: yes, no, don't know.</p> <p>In regression – treated 'don't know' answers as 'no' – conservative method to maintain observations and because it is expressing a failure to be positively certain about donating organs.</p>	

Description of Analysis	Results		
	Presumed consent and donor rates	Other factors influencing donor rates	Quality and limitations
<p>Logistic regression to identify determinants of individuals' willingness to become cadaveric organ donors and to permit the donation of relatives' organs.</p> <p>Clustered data by country accounting for country of residence specific effects – rather than treating all observations as independent.</p> <p>Variables included in models: Illness, health, gender, age, political identification, social support, help from neighbours, urban-rural, educational attainment, awareness of country legislation, consent legislation, cooperation in interview.</p>	<p>60.1% willing to be organ donors 48.4% willing to consent to donation of relative's organs 31% expressed awareness of their country's type of organ donation legislation.</p> <p>Presumed consent countries: 0.64 willing donate own organs, 0.51 willing donate relatives' organs Presumed consent enforced countries: 0.60 willing donate own organs, 0.51 willing donate relatives' organs Informed consent countries: 0.57 willing donate own organs, 0.44 willing donate relatives' organs.</p> <p>Proportions differed significantly by country – gives examples, but not for all countries.</p> <p>From regression analysis: Willingness to donate own organs: Baseline: informed consent Presumed consent: OR 1.17 Presumed consent enforced: OR 1.29</p> <p>Willingness to donate relatives' organs: Baseline: informed consent Presumed consent: OR 1.27 Presumed consent enforced: OR 1.56 All above p<0.01</p> <p>Interaction between awareness and consent legislation Interaction only significant between awareness and <i>enforced</i> presumed consent OR: 1.48 own organs, OR: 1.20 relatives' organs.</p> <p>Those who are willing to donate their own organ more likely to be willing to donate their relatives' organs – but more uncertainty regarding relatives' organs.</p> <p>Pseudo R-squared: 0.084 and 0.054 – not so good.</p>	<ul style="list-style-type: none"> - Educational attainment - Awareness of legislation 1.91 greater odds of willing to donate own organs; 1.74 greater odds donating family's organs (p<0.01). - Age – over 60s less willing to donate own and relatives' organs. - Social interactions/support – those who report having fewer people they can count on less likely to be willing to donate organs – sense of inclusion influencing feelings of reciprocity? 	<p>Analysis fine as long as the results do control for every other variable in table.</p> <p>Country-level legislation factors and individual level awareness of legislation and other potential relevant factors. Country level clustering accounting for in analysis apparently.</p> <p>Outcome is self-reported hypothetical behaviour. This may not translate directly into behaviour, but is likely a proxy of some degree.</p> <p>Should probably go in 'attitudes' section rather than impact of presumed consent section.</p> <p>Splits presumed consent countries into 'presumed consent' (with family refusal allowed) and 'enforced presumed consent' with no family refusal allowed – BUT – this study admits (as reported by other studies) that in practice, most families are consulted with regard to organ donation. It is not clear how this study defined informed consent, presumed consent and enforced presumed consent. Not certain where splitting presumed consent countries into 'enforced' and not makes sense.</p>

Appendix 4: Data extraction tables for studies with limitations

Author (year)	Country/Region included	Stated Objective	Selection	Quality assessment			
				Comparability	Data Collection	Attributable to Intervention	Appropriate Analyses
Coppen et al., (2008)	10 Western European countries	To assess the impact of donor policies on donor procurement in 10 Western European countries from 1995 to 2005.	“Number of confounding factors between countries restricted by analysing on countries which share a more or less similar historical background and have more or less the same status of health systems.”	<p>No – only accounts for mortality relevant to potential donor pool.</p> <p>Argues chosen 10 countries that are similar to reduce confounding. Not convincing that they are similar enough to assume no other differences.</p>	<p>Data for CVA and RTA mortality rates from the WHO Health for All Database. Where some countries had data missing for certain years, estimates for missing values were derived from trend line.</p> <p>Data for countries’ organ donation rates – authors asked national transplant centres to send their ‘numbers of post mortal organ donors of whom at least one solid organ had been successfully transplanted per year’ – accounts for differences between countries in the quality of procured organs. France and Sweden provided data in response to ‘numbers of post mortal organ donors of whom at least one solid organ had been recovered for the purpose of organ transplantation’.</p> <p>From countries that provided data according to both definitions – difference between rates no more than 5% overall – so acceptable to France and Sweden data as trends remain the same. Rates PMI calculated using mid-year population from WHO.</p>	No	<p>No -</p> <p>Calculates potential donor conversion rate using calculation described below.</p> <p>Looks at 10 countries from 1995 – 2005.</p> <p>Analysis consists of graphs. No multivariate regression.</p> <p>Conclusions seem to be based on visual observations on graphs, with no tests of statistical significance.</p>

Factors considered in analysis															
Presumed consent law	CVA mortality	RTA mortality	Assault	GDP	Health expenditure	Transplant capacity	Religion	Education	Legislative system	Blood donation rate	Internet access	Civil rights and liberties	Family Consent	Combined Registry	Outcome
Yes – classification based on legal analysis by Gevers et al, 2004. But not sure how valid this is – they classified UK as presumed consent/	Yes – by using this as denominator in donor conversion rate calculation	Yes – by using this as denominator in donor conversion rate calculation	N	N	N	N	N	N	N	N	N	N	N	N	<p>Conversion of potential donors into actual donors.</p> <p>National Cerebral Vascular Accident (CVA) and Road Traffic Accident (RTA) mortality rates used as proxies for the number of potential donors per country.</p> <p>Study cites research claiming that approximately 80% of organ donors die from a CVA or RTA.</p> <p>Restricted proxy to mortality among those under 65 years – because older – more CVA mortality but does not lead to a matching increase in donors.</p> <p>Conversion rate: (national donation rates PMI / national mortality rates relevant for organ donation OMI) * 100</p> <p>Donor efficiency rates calculated for three time frames (1995-2005, 1995-1999, 2000-2005).</p>

Description of Analysis	Results		
	Presumed consent and donor rates	Other factors influencing donor rates	Quality and limitations
<p>Calculates potential donor conversion rate using calculation described above.</p> <p>Looks at 10 countries from 1995 – 2005.</p> <p>3 countries defined as explicit consent – although 4 if change classification of UK.</p> <p>Analysis consists of graphs. No multivariate regression analyses.</p> <p>Conclusions seem to be based on visual observations on graphs, with no tests of statistical significance. Only comparing 10 countries – very small n.</p>	<p>Conclusion based on observations from graphs so validity cannot be established.</p> <p>2 countries in time frame changed legislation from explicit consent to presumed consent:</p> <ul style="list-style-type: none"> - Italy – changed to presumed consent in 1998, donor efficiency rate was increasing 1995-1999 and continues to increase post 1999, slope looks slightly steeper after 1999 but no indication as to whether this is a statistically significant change. - Sweden – changed to presumed consent 1996 – in 1998 rate peaks at just under 6%, and then decreases again 1998-2002 toward pre-change in legislation rate. 	<p>None examined, although outcome of conversion rates takes into account potential donor pool from donor-providing deaths.</p>	<p>Use of conversion rates is good. However, analysis quality is flawed – only 10 countries, misclassification of UK as presumed consent country, according to Rithalia (2008) Sweden not presumed consent, results based on visible patterns in graph rather than regression, many potential confounders ignored by claiming that they chose 10 countries that they believe to be similar enough to one another to make confounding factors not an issue.</p>

Author (year)	Country/Region included	Stated Objective	Quality assessment				
			Selection	Comparability	Data Collection	Attributable to Intervention	Appropriate Analyses
Horvat et al., (2010)	<p>Eligible for analysis if:</p> <ul style="list-style-type: none"> - Nation has deceased donor transplantation programme, with surgeries performed within country and not abroad - 2 or more years of data within period of study - Organ donor consent legislation that was consistent across the nation and the period of study - No government-regulated paid organ donation program <p>44 countries: 22 with presumed consent, 22 with explicit consent. Includes European, Asian and South American countries</p> <p>1997-2007</p>	To compare characteristics and kidney transplantation rates for countries with presumed consent for deceased organ donation with countries with explicit consent.	44 countries	Poor - no multivariate analyses – basically descriptive statistics	<p>Sources specified and seem credible.</p> <p>Data from: national and regional renal or transplantation registries, national health ministries, transplantation centers, online databases, and literature, and were verified by country representatives. Legislation types classified according to WHO International Digest of Health Legislation, national health ministries, and available literature – where unclear representatives were contacted. Country characteristics from US Census Bureau International Database, UN Statistics division, WHO and CIA World Factbook.</p>	No – observational data and no multivariate analysis	No – groups 22 countries as presumed consent and other 22 as explicit consent – then compares median rates and inter-quartile ranges of each groups of countries' organ donation rates, and also stratifies results by Catholicism, GDP per capita, health expenditure per capita physician density, traffic accident mortality, cerebrovascular mortality.

Factors considered in analysis															
Presumed consent law	CVA mortality	RTA mortality	Assault	GDP	Health expenditure	Transplant capacity	Religion	Education	Legislative system	Blood donation rate	Internet access	Civil rights and liberties	Family Consent	Combined Registry	Outcome
Y	Y	Y		Y	Y	Y	Y	N	N	N	N		N	N	<p>Annual kidney transplantation rate per million population: calculated by number of kidney transplantations performed in a nation in a given year divided by the total mid year population of the nation as of 1st July of that year. Kidney transplantation rates sent to country representatives for verification and then averaged across all available years of data.</p> <p>Deceased and living transplantation examined separately.</p> <p>Deceased kidney transplantation was counted if a kidney was successfully transplanted in a recipient but not if it was procured without transplantation.</p>

Description of Analysis	Results		
	Presumed consent and donor rates	Other factors influencing donor rates	Quality and limitations
Groups 22 countries as presumed consent and other 22 as explicit consent – then compares median rates and inter-quartile ranges of each groups of countries' organ donation rates, and also stratifies results by Catholicism, GDP per capita, health expenditure per capita physician density, traffic accident mortality, cerebrovascular mortality.	Higher median kidney transplantation rates (deceased donors) in countries with presumed consent 22.6 vs. 13.9 – but analysis not good enough to infer anything.	Analysis quality lacking to infer – patterns of kidney transplant rates suggest relationship with GDP, health expenditure, physician density.	Poor quality. Does not meet York Review criteria. No multivariate regression analysis.

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