Consent to organ donation should not be presumed before exploring regional variations

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Consent to organ donation should not be presumed before exploring regional variations

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Objectives: To explore regional variations in donation of cadaveric solid organs and tissues across the four devolved health administrations of the UK (England, Scotland, Wales & Northern Ireland).

Design: A secondary analysis of databases from NHS Blood & Transplant (1990-2009) and from the National Organ Procurement Service for the Republic of Ireland, Eurotransplant International Foundation and Scandiatransplant.

Results: Statistically significant differences were found for the cornea between England and Scotland as well as England and Northern Ireland for every year of the nineteen years investigated and between Wales and Northern Ireland for all but two years. The fewest significant differences occurred between Scotland and Northern Ireland. For around half of the years or more, statistically significant differences were evident in kidney and liver donations between Scotland and Wales and England and Wales. For both regional pairs (Scotland/England, England/Wales), the pattern of kidney and liver donations were matched over most years. Comparison of Northern Ireland with Scotland and England showed 8/19 years for which kidney donations were significantly higher than for both Scotland and England. Fewer differences were found for liver donations: Scotland and Northern Ireland (6/19); England and Northern Ireland (5/19). Between Scotland and England there were very few significant differences in kidney and liver donations and there were no significant differences for any year between Wales and Northern Ireland for kidney and liver donations. In the case of lung and heart donations, there were very few significant differences between any of the regions.

Conclusion: Data across the UK show patterns of similarities and differences in donation rate that vary with type of organ donated. Further exploration of underlying regional differences, organisational issues and practices and attitudes that may affect organ donation, particularly with respect to certain organs, should be undertaken before legislative measures are considered.

Article focus:

- To investigate organ donation of cadaveric solid organs and tissues across the four devolved health administrations of the UK;
- To consider reasons for regional variations and those related to organ type, drawing on regional differences in culture and practice and on findings in other EU countries.

Key messages:

- organ donation and registration rates vary across the four regions of UK;
- variations depend on the type of organ donated;
- recognition of regional variations in donation and registration rates and the underlying reasons are required before attempts to introduce presumed consent legislation nationally.

Strengths & limitations: The strengths of this article are its novelty, as this is the first article that has analysed data across the UK and shown differences in donation rates in the four regions; its timeliness given the shortfall in organ donations and the continuing debate about altering legislation to permit presumed consent and its importance in highlighting that regional differences need to be considered before any national changes to legislation are made. The limitation of this work was that data from other EU countries, for the entire time period investigated, were not available.

Introduction

Approximately 80-90% of the UK population support the principle of organ donation[1], yet, only 28% of the population carry an organ donor card (Pocock P. 2010). Despite advances in transplantation medicine, organ shortage is the single most limiting factor preventing potential recipients from receiving the benefits of transplantation.[2] If the overwhelming support for organ donation could be directly translated into a willingness to donate, this should bode well for a presumed consent system, (allowing organs to be used for transplantation unless the individual has explicitly objected). However, interpretation of these findings is far from simple. The authors argue that before considering a presumed consent system, differences in donation and registration rates for different organs in the four regions of the UK need to be investigated and reasons for any differences explored. Without such research, a nationally imposed system for all organs may fail or create regional inequalities. This paper presents an analysis of data of organ donation and registration in the four regions of the UK for five organ types: kidney, liver, heart, lung and cornea in order to determine whether significant differences exist across the four regions and whether these vary depending on the organ. Comparisons are made to European nations that have adopted presumed consent as well as to those that have not.

Methods

Information about all organ donations and registration in the four regions of the UK: England, Scotland, Wales and Northern Ireland was obtained from NHS Blood & Transplant for all available years: from 1990-2009.[3] Data from other European nations was provided from the National Organ Procurement Service for the Republic of Ireland, Eurotransplant International Foundation and Scandiatransplant. Statistical analysis of the data was conducted using the z-test for independent proportions which is appropriate for dealing with data from whole populations.[4]

Results and Discussion

Regional variations in registration and donation

The UK currently operates a system of informed consent requiring individuals who wish to donate, to formally register their intention on a centralised register and to carry an organ donor card. Figure 1a shows that since the organ donor register was first launched in 1994, Wales has consistently outperformed other parts of the UK in terms of the percentage of population registered, with Scotland in second position, England third and Northern Ireland last. (A caveat is that although records are updated periodically to remove those who have died subsequent to being registered, organ donor registration rates may still include some entries of deceased individuals. This should not, however, affect regional variations.)

When the registration rates are compared to donation rates, the trends are somewhat different.[3] The rate of organ donation is consistently higher in Wales than the UK average for the majority of the last 20 years (Figure 1b). Donation rates in Northern Ireland are the second highest, achieving a higher than UK average in 13 of those years, with Scotland achieving this in 6 years and England capable of achieving this in only 3 years. So whilst registration and donation are both highest in Wales, amongst the other parts of the UK registration and donation do not follow similar trends. In Northern Ireland, for example, where willingness to register as an organ donor is lower than any other UK region, the organ donation rate is generally higher than in England or Scotland. It is also notable that whilst England exhibits the least variation in organ donation over the last two decades, Scotland shows an overall decrease in donation with trends in Wales and Northern Ireland varying from year to year with the greatest fluctuations in the latter (Pocock P. 2010).

Variations in donation according to organ type

Masked by general variations in donation are the figures for individual organs. Table 1 shows the rate of donation for each region of the UK for different organs (Pocock P. 2010). The rate of kidney donation has been consistently highest in Wales for most of the past 20 years. Northern Ireland contributed the second highest rate of donation followed by England and Scotland respectively. Similar regional variations in donation are seen for the liver. With respect to heart donation, Wales was the region with the highest overall donation rate until 1998 when it was overtaken by Scotland and/or Northern Ireland with the exception of 2006-2007. Northern Ireland had the second highest rate of donation, Scotland third and England the lowest rate. The overall rate of heart donation has fallen dramatically over the twenty year period for Wales, Scotland and England; Northern Ireland shows fluctuations with no consistent trend.

In contrast to falling heart donation rates, the rate of lung donation has risen since 1990, with Northern Ireland being the greatest contributor over most of this period (Pocock P. 2010). The overall numbers, however, are low and comparable to those of heart donation. The pattern for corneal donations shows a greater consistency for most regions except Wales which contributed significantly more corneal tissue than the other regions between 1995 and 2005 but subsequently decreased to levels comparable to pre-1995. England has the second highest donation rate and Northern Ireland is the lowest for every year over the last two decades.

	Kidney				Heart				Lung				Liver				Cornea			
Year	E	S	W	NI	E	S	W	NI	E	S	W	NI	E	S	W	NI	E	S	W	NI
90-91	14.6	17.4	19.0	19.2	3.9	3.9	5.4	1.9	0.0	0.0	0.0	0.0	6.0	8.2	8.6	7.1	27.8	11.4	16.7	9.9
91-92	13.9	14.7	21.2	25.5	3.8	3.7	6.8	5.7	0.2	0.4	0.0	0.0	7.3	7.4	12.2	14.7	29.6	12.3	29.3	14.0
92-93	13.7	19.4	14.4	15.3	3.8	5.7	6.3	3.8	0.1	0.2	0.0	0.0	8.1	12.0	12.2	7.6	33.1	21.9	24.3	16.2
93-94	12.9	17.3	17.6	10.8	3.9	3.9	5.0	4.5	0.2	0.2	0.0	0.6	9.8	12.0	13.5	8.9	37.5	21.0	23.9	12.7
94-95	13.5	15.1	25.7	19.8	4.0	4.3	6.8	5.1	0.3	0.2	0.0	0.0	10.7	11.0	18.0	12.1	37.5	21.4	28.6	15.3
95-96	12.8	15.1	17.6	16.6	3.7	5.7	2.7	3.8	0.4	0.0	0.5	0.6	10.9	11.4	16.7	11.5	34.5	19.7	85.4	13.4
96-97	12.8	10.5	20.0	23.8	3.3	3.3	6.8	4.5	0.6	0.2	0.4	0.6	10.9	8.2	20.4	17.5	33.0	17.1	80.7	12.2
97-98	11.7	12.5	18.7	16.5	2.9	3.9	5.3	4.9	0.6	0.0	0.4	0.0	11.0	10.2	18.0	14.6	26.2	14.8	48.2	5.8
98-99	11.0	13.7	16.2	12.1	2.4	4.3	2.6	3.6	0.6	0.2	0.4	0.0	10.5	12.0	13.2	11.5	26.0	13.1	46.9	6.0
99-00	11.7	13.1	15.0	13.3	2.0	3.9	2.2	2.4	2.0	0.4	0.4	0.0	11.2	12.0	16.3	10.2	27.1	15.6	52.0	4.8
00-01	11.6	9.5	13.7	12.7	2.3	1.4	1.3	1.8	2.3	0.8	1.3	1.2	11.1	9.8	14.5	12.1	30.2	16.2	31.9	7.8
01-02	10.4	9.8	14.5	18.7	2.1	1.4	2.2	3.0	2.1	1.6	0.4	1.2	10.5	11.4	13.2	16.3	25.1	10.4	42.3	7.8
02-03	11.0	7.9	14.2	18.5	1.6	1.6	2.7	4.2	1.6	1.8	1.8	1.8	11.6	10.0	14.2	16.1	25.4	12.8	51.3	7.7
03-04	10.7	7.7	18.8	17.2	1.7	1.2	1.8	1.2	1.7	1.8	0.9	1.8	11.1	8.7	19.6	15.4	28.5	8.9	62.1	8.9
04-05	9.8	8.3	16.5	16.0	1.3	1.6	3.6	4.7	1.3	0.8	1.3	1.2	10.3	10.7	16.5	17.2	27.0	15.0	51.3	4.1
05-06	9.4	5.5	14.7	10.1	1.2	1.8	0.9	1.8	1.2	1.8	2.2	1.8	10.4	8.5	14.3	10.1	31.1	12.7	26.6	8.9
06-07	8.5	6.5	15.2	16.4	1.5	1.6	4.5	2.3	1.5	0.8	0.9	2.9	10.6	6.9	17.9	19.7	32.8	15.2	36.1	8.8
07-08	7.2	4.7	9.6	8.7	1.1	1.8	1.3	1.7	1.1	0.8	1.3	1.2	10.6	8.3	14.0	10.5	34.3	18.6	27.5	4.7
08-09	8.2	9.0	7.9	8.7	1.3	1.0	1.3	2.3	1.3	2.2	1.8	3.5	11.2	10.8	12.2	12.2	34.4	21.1	24.0	4.1

Table 1: UK Donor rates (deceased donors per million population) by organ type 1990-2009 (Pocock P. 2010). (E = England S = Scotland W = Wales NI = Northern Ireland)

Table 1 shows 95 combinations of year and organ. For each combination and pair of regions, the differences in the proportions of donors (per million population x 10^{-6}) were tested for statistical significance at the 5% level using the appropriate z test for independent proportions.[4] Certain clear patterns were detected. With regards to the cornea, statistically significant differences were found between England and Scotland as well as England and Northern Ireland for all years and between Wales and Northern Ireland for all but two years (Table 2). The fewest significant differences in corneal donations occurred between Scotland and Northern Ireland. The patterns seen with corneal donations may reflect attitudes based on culture and tradition as well as on lack of awareness of what eye donation involves. In Northern Ireland, and to a lesser extent in Scotland, the tradition of wakes and burial remains strong. Disfiguring the face of a deceased loved one before burial by removing the eyeballs, is unlikely to be accepted.[5] There is no eye bank or retrieval centre in Northern Ireland and information regarding the effect of collecting eye tissue on facial appearance is not well explained. In Wales and England, where over 70% of deaths result in cremations (compared to around 60% of deaths in Scotland and 15% in Northern Ireland)[6], the issue of the facial appearance of the deceased is less important.

For around half of the years or more, statistically significant differences are evident in kidney and liver donations between Scotland and Wales (kidney: 11/19; liver: 9/19) and England and Wales (kidney: 10/19; liver 11/19) with the greater donations from Wales compared with the other two regions (Table 2). For both regional pairs (Scotland/England, England/Wales), the pattern of kidney and liver donations (i.e. whether differences are significant or not) were matched over most years. Comparison of Northern Ireland with Scotland and England showed 8/19 years for which kidney donations were significantly higher than for both Scotland and England. Fewer differences were found for liver donations: Scotland and Northern Ireland (6/19); England and Northern Ireland (5/19). Between Scotland and England

there were very few significant differences in kidney and liver donations and there were no significant differences for any year between Wales and Northern Ireland for kidney and liver donations. Similar trends in Northern Ireland and Wales and differences between these regions and England and Scotland, in particular with regard to kidney donations, may reflect the way in which the regions approach the raising of public awareness. Bodies such as Donate Wales, Kidney Wales and the Northern Ireland Kidney Research Fund, actively promote kidney and organ donations in general. There is no comparable body for England alone; the various UK bodies (e.g. UK National Kidney Federation, British Liver Trust) and the Scottish Kidney Federation offer a great deal of support to patient groups and promote research activities but there appears to be less focus on raising awareness of organ donation than in Wales and Northern Ireland. It is also possible that awareness of the importance of donating these organs is highlighted when a kidney or liver donation is needed (and in the case of these organs may also be provided from a living donor who is most likely to be a relative), in the more tight-knit communities with family-based and kinship networks found in Northern Ireland and Wales.[7]

In the case of lung and heart donations, there were very few significant differences between any of the regions over the nineteen year period (Table 2). Lung and heart donations have been very low in number in all regions across all the years and this may reflect the fact that heart beating donors, on which heart and most lung transplants depend have been decreasing for around a decade across the UK.[3]

Year	Kidney						Heart					
	zEW	zES	zEN	zWS	zWN	zSN	zEW	zES	zEN	zWS	zWN	zSN
90-91	-1.66	-1.56	-1.47	0.47	-0.04	-0.47	-1.10	0.00	1.26	0.89	1.68	1.18
91-92	-2.81	-0.46	-3.78	1.98	-0.86	-2.84	-2.20	0.11	-1.19	1.79	0.42	-1.07
92-93	-0.28	-3.25	-0.53	-1.47	-0.22	1.05	-1.84	-2.05	0.00	0.31	1.04	0.91
93-94	-1.89	-2.59	0.72	0.09	1.70	1.79	-0.81	0.00	-0.37	0.66	0.22	-0.33
94-95	-4.75	-0.93	-2.10	3.08	1.17	-1.28	-2.01	-0.32	-0.68	1.38	0.66	-0.41
95-96	-1.94	-1.37	-1.30	0.78	0.23	-0.42	0.76	-2.18	-0.06	-1.70	-0.59	0.91
96-97	-2.90	1.39	-3.74	3.23	-0.78	-3.95	-2.74	0.00	-0.81	2.08	0.91	-0.69
97-98	-2.98	-0.50	-1.75	2.05	0.51	-1.21	-2.04	-1.25	-1.46	0.84	0.17	-0.55
98-99	-2.29	-1.73	-0.42	0.82	1.05	0.49	-0.19	-2.54	-0.97	-1.10	-0.56	0.38
99-00	-2.98	-0.50	-1.77	2.05	0.51	-1.22	0.98	1.30	0.42	-0.11	-0.40	-0.37
00-01	-0.91	1.34	-0.41	1.60	0.27	-1.12	-0.10	1.06	-0.78	0.78	-0.49	-1.34
01-02	-1.86	0.40	-3.22	1.76	-1.02	-2.88	-1.26	0.00	-2.54	0.99	-0.80	-1.95
02-03	-1.41	2.04	-2.84	2.52	-1.05	-3.66	-0.11	0.83	0.49	0.64	0.47	0.00
03-04	-3.57	1.99	-2.52	4.15	0.37	-3.37	-2.85	-0.56	-3.66	1.67	-0.53	-2.26
04-05	-3.09	1.03	-2.51	3.11	0.12	-2.71	0.40	-1.15	-0.69	-0.91	-0.78	0.00
05-06	-2.50	2.78	-0.29	3.97	1.27	-2.01	-3.44	-0.17	-0.83	2.29	1.15	-0.59
06-07	-3.31	1.49	-3.41	3.58	-0.30	-3.72	-0.28	-1.40	-0.73	-0.49	-0.33	0.09
07-08	-1.31	2.04	-0.72	2.47	0.29	-1.90	0.00	0.57	-1.12	0.36	-0.75	-1.28
08-09	0.16	-0.60	-0.23	-0.47	-0.28	0.11	-0.28	-1.40	-0.73	-0.49	-0.33	0.09

	Lung						Liver					
	zEW	zES	zEN	zWS	zWN	zSN	zEW	zES	zEN	zWS	zWN	zSN
90-91	0.00	0.00	0.00	0.00	0.00	0.00	-1.53	-1.90	-0.55	0.17	0.51	0.43
91-92	0.66	-0.92	0.56	-0.94	0.00	0.79	-2.60	-0.08	-3.52	2.00	-0.66	-2.64
92-93	0.47	-0.65	0.40	-0.67	0.00	0.56	-2.08	-2.88	0.22	0.07	1.37	1.46
93-94	0.67	0.00	-1.07	-0.67	-1.15	-0.81	-1.71	-1.49	0.36	0.53	1.30	1.01
94-95	0.82	0.40	0.69	-0.67	0.00	0.56	-3.20	-0.20	-0.53	2.40	1.43	-0.36
95-96	-0.23	1.43	-0.39	1.60	-0.13	-1.75	-2.53	-0.32	-0.22	1.83	1.31	-0.03
96-97	0.38	1.15	0.00	0.49	-0.28	-0.81	-4.12	1.78	-2.44	4.40	0.63	-3.16
97-98	0.38	1.76	0.99	1.44	0.80	0.00	-3.07	0.52	-1.35	2.76	0.81	-1.46
98-99	0.38	1.15	0.99	0.49	0.81	0.57	-1.22	-0.99	-0.39	0.43	0.47	0.16
99-00	1.70	2.53	1.82	0.00	0.81	0.81	-2.22	-0.51	0.38	1.48	1.61	0.59
00-01	0.98	2.20	0.93	0.64	0.09	-0.47	-2.28	-0.58	0.34	1.48	1.61	0.59
01-02	1.76	0.75	0.79	-1.36	-0.91	0.37	-1.22	-0.60	-2.25	0.65	-0.80	-1.55
02-03	-0.23	-0.34	-0.20	0.00	0.00	0.00	-1.12	1.02	-1.66	1.57	-0.48	-2.01
03-04	0.91	-0.16	-0.10	-0.91	-0.78	0.00	-3.68	1.56	1.64	3.91	0.98	-2.34
04-05	0.00	0.96	0.11	0.64	0.09	-0.47	-2.79	-0.27	-2.72	2.05	-0.17	-2.08
05-06	-1.31	-1.15	-0.69	0.36	0.28	0.00	-1.76	1.27	0.12	2.25	1.17	-0.60
06-07	0.72	1.25	-1.44	0.14	-1.48	-2.05	-3.24	2.48	-3.52	4.28	-0.41	-4.53
07-08	-0.28	0.62	-0.12	0.64	0.09	-0.48	-1.54	1.54	0.04	2.26	0.98	-0.84
08-09	-0.80	-1.89	-2.63	-0.35	-1.06	-0.93	-0.44	0.26	-0.38	0.52	0.00	-0.48

	Cornea					
	zEW	zES	zEN	zWS	zWN	zSN
90-91	3.09	6.88	4.22	1.83	1.75	0.49
91-92	0.08	7.04	3.55	5.06	3.05	-0.52
92-93	25.08	38.24	21.66	0.63	1.70	1.38
93-94	1.00	2.69	3.51	0.77	2.45	2.08
94-95	2.13	5.77	4.51	1.84	2.65	1.50
95-96	-12.24	5.53	4.47	12.98	9.26	1.62
96-97	-11.74	6.09	4.51	13.11	9.08	1.34
97-98	-6.22	4.91	5.05	8.38	7.46	2.81
98-99	-5.95	5.57	5.02	8.74	7.34	2.35
99-00	-6.91	4.85	5.50	8.82	8.16	3.36
00-01	-0.46	5.61	5.23	4.29	5.06	2.50
01-02	-4.99	6.50	4.43	8.90	6.42	0.93
02-03	-7.41	5.51	4.50	9.72	7.45	1.68
03-04	-8.99	8.13	4.75	13.20	8.34	0.00
04-05	-6.72	5.05	5.71	8.85	8.32	3.50
05-06	1.19	7.27	5.15	4.21	3.99	1.25
06-07	-0.84	6.76	5.42	5.60	5.43	1.95
07-08	1.73	5.89	6.61	2.42	5.37	4.06
08-09	2.64	4.97	6.76	0.78	5.02	4.70

Key

zEW is the z score for the difference between the proportions in England and Wales (a negative score indicates that the proportion was greater in Wales)

zES = England with Scotland
zEN = England with N. Ireland
zWS = Wales with Scotland
zWN = Wales with N. Ireland
zSN = Scotland with N. Ireland

An absolute value for z > 1.96 indicates that the difference between two independent proportions is significant at 0.05 level (two-tailed test).

Table 2 Statistical analyses using z-scores comparing differences in organ donation between each of the four regions: England, Scotland, Wales and Northern Ireland for five organs

Can parallels be drawn from the EU?

It has been suggested that at least 20-30 deceased donors per million population would be necessary to meet the UK's increasing demands.[8] The British Medical Association called for changes in legislation, suggesting a system of presumed consent that allows for objections of relatives.[9] The Organ Donation Taskforce was commissioned in 2008 to consider the potential effects of such legislation and concluded that a change to presumed consent at this time was unlikely to increase organ donation rates, may incur prohibitive costs and could result in a backlash; other factors needed to be considered before introducing legislative change.[10]

Bird and Harris modelled situations with varying relative refusal rates and drew on comparisons with EU countries that already adopted presumed consent systems.[11] However, presumed consent for organ donation has been implemented with varying effect in the EU. Adoption and successful implementation of laws in one country should not be taken as a guarantee of similar success in another. Hence, though Sweden applies presumed consent, its donation rate in 2009, at 13.8 deceased donors per million population,[12] was comparable to that of Germany (14.5 deceased donors per million population) and Denmark (14.0 deceased donors per million population) (Sønder S. 2010); both of which require informed consent (Figure 2). The figures available for Ireland, where informed consent is needed, were 21.2 deceased donors per million population in 2009.[13] The nation with the highest donor rate (34.4 deceased donors per million population in 2009)[14], and one often cited as evidence of successful implementation of presumed consent legislation[15], is Spain which operates a "soft" form of presumed consent where next of kin can object to organ

donation[14-15]. Yet, the impact of the legislation has been questioned and the high rate of donor activity attributed to the "Spanish Model"[14-15] that demands an integrated approach with dedicated transplant co-ordinators, mainly intensive care physicians, involved in procurement[15]. This highly coordinated network and the respect for autonomy given to the individual and relatives, is credited with improving donation rates of 14.3 deceased donors per million population in 1989 to rates of 33-35 deceased donors per million population in recent years.[14-15] The majority of donations in Spain are from heart-beating donors in intensive care; live organ donation and that from non-heart beating donors is relatively low[15]. The converse is true in the UK and estimates suggest that even if a theoretical upper limit were reached, with present facilities and practices, heart beating donor numbers in the UK would only reach half of those in Spain.[15] Given that Spain introduced presumed consent in 1979[2], it is clear that a legislative change alone was not sufficient to improve donation rates. It is notable that Spain achieves a significantly higher rate of donation than does Austria [12] which relies upon a "hard" approach in which views of relatives are not routinely sought.

Comparisons across the EU further indicate that whilst a country may have relatively low overall donation rates, for certain organs the trend may be reversed. Sweden lags behind countries like Austria, Belgium, Germany and the Netherlands with regard to overall deceased donations but has had the highest kidney donation rate for the majority of the past 13 years (Sønder S. 2010).[12]

Conclusions

Data from the four UK regions show patterns of similarities and differences that vary with type of organ donated. Further exploration of underlying regional differences, organisational issues and practices and attitudes that may affect organ donation, particularly with respect to

certain organs, should be undertaken before legislative measures are considered. Comparison of EU nations, and particularly Spain, indicates that improvement of donation rates is unlikely to be achieved by introducing new legislation alone.

Provenance/Contributorship: Barbara Pierscionek is a Professor of Vision Science at the School of Biomedical Science, University of Ulster. She is qualified in science and law, teaches ethics and law and researches the biology and physics of ageing as well as healthcare ethics and presumed consent. Gordon Rae is a Professor of Psychology at the School of Psychology, University of Ulster, trained in mathematics and statistics as well as psychology and his research interests include applying statistical methods to psychology and medicine. Carol McClenahan is a lecturer in Psychology at the School of Psychology, University of Ulster. Her research expertise is in attitude and behavioural change in relation to health. She also has an interest in ethics in psychology and health. Donal McGlade is currently undertaking a PhD on attitudes that determine behaviour with respect to organ donation. All authors were involved in preparation of the manuscript. Barbara Pierscionek is the guarantor.

"All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) (URL) and declare that all authors had: (1) No financial support for the submitted work from anyone other than their employer; (2) No financial relationships with commercial entities that might have an interest in the submitted work; (3) No spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work; (4) No Non-financial interests that may be relevant to the submitted work."

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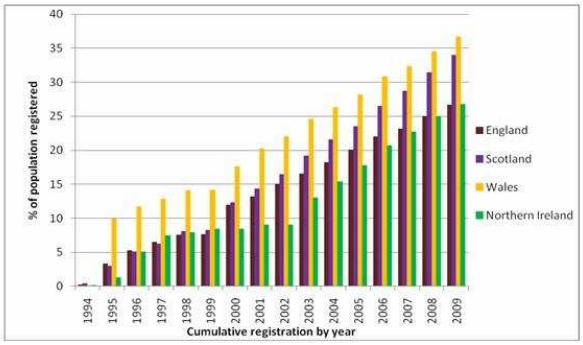
Figure captions

Figure 1: a) Organ donor registration rates in England, Wales, Scotland and Northern Ireland 1994-2009 (Pocock P. 2010) b) Organ donation rates in England, Wales, Scotland and Northern Ireland 1990-2009 (Pocock P. 2010)

Figure 2: Organ donor rates in selected EU countries 1997-2009.[13] (SØnder S. 2010)

a)



b)

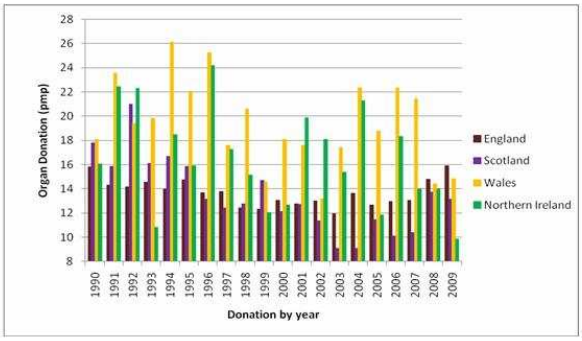


Figure 1

254x190mm (96 x 96 DPI)

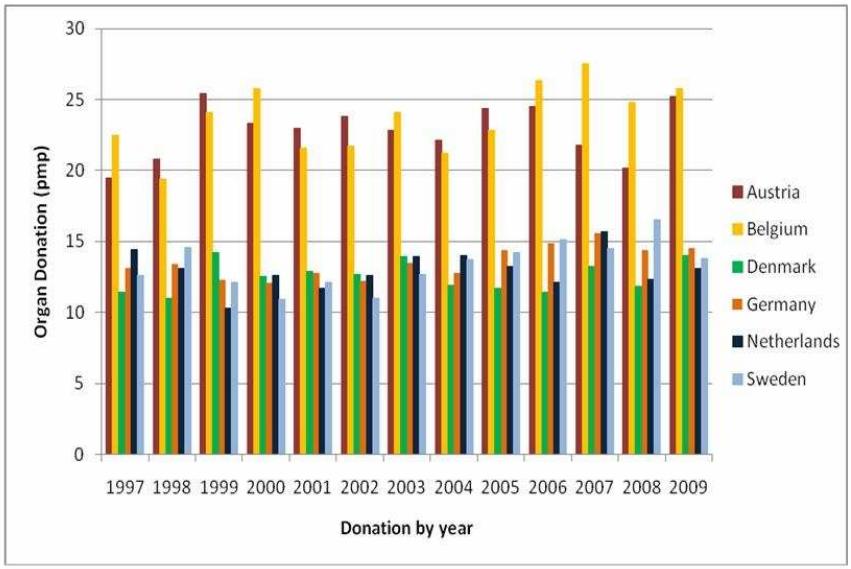


Figure 2

254x190mm (96 x 96 DPI)

Research review guidelines : modified from RATS guidelines

	ASK THIS OF THE MANUSCRIPT	THIS SHOULD BE INCLUDED IN THE MANUSCRIPT	✓ <>
R	**Relevance of study question**		
	Is the research question interesting?	Research question explicitly stated	✓
	Is the research question relevant to clinical practice, public health, or policy? *It is relevant to policy*	Research question justified and linked to the existing knowledge base (empirical research, theory, policy)	✓
A	**Appropriateness of the method**		
	Is the methodology used the best approach for the study aims?	Study design described and justified : *data for all organ donations and registrations was required in order to compare trends across the four UK regions.*	✓
T	**Transparency of procedures**		
	Data collection		
	Was collection of data systematic and comprehensive?	Method (s) outlined : *all available data from centralized sources collected*	✓
	Why and when was data collection stopped, and is this reasonable?	End of data collection justified and described: *all available complete data was collected*	✓
S	**Soundness of interpretive approach**		
	Analysis		
	Is the type of analysis appropriate for the type of study?	Analytic approach described in depth and justified	✓
	Are the interpretations clearly presented and adequately supported by the evidence?	Statistical analysis conducted using appropriate test Analysis, presentation and interpretation provided	✓
	Discussion and presentation		

Is adequate account taken of previous knowledge and how the findings add?	Findings presented with reference to existing literature, and how they contribute	✓
Is the manuscript well written and accessible?	Evidence of following guidelines (format, word count) Written for a health sciences audience	✓

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Consent to organ donation should not be presumed before exploring regional variations

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Consent to organ donation should not be presumed before exploring regional variations

(secondary analysis of databases)

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Key words: *organ donation, presumed consent, UK regional variations, EU organ donation*

Word count: 2138 words

Objectives: To explore regional variations in donation of cadaveric solid organs and tissues across the four devolved health administrations of the UK (England, Scotland, Wales & Northern Ireland).

Design: A secondary analysis of databases from NHS Blood & Transplant (1990-2009) and from the National Organ Procurement Service for the Republic of Ireland, Eurotransplant International Foundation and Scandiatransplant.

Results: Statistically significant differences using Chi-square and post hoc analyses were found for the cornea between England and Scotland as well as England and Northern Ireland for every year of the nineteen years investigated and between Wales and Northern Ireland for all but five years. The fewest significant differences occurred between Scotland and Northern Ireland. Whilst Chi-square analysis showed differences across the four regions in kidney and liver donation rates over 10 out the 19 years (kidney) and 7 out of the 19 years (liver), very few of these resulted in statistical significance following post hoc comparisons. There were no significant post hoc differences between any of the regions for lung and heart donations.

Conclusion: Temporal variations in organ donation rates over the last two decades vary in the four UK regions with type of organ donated. For heart, lung, kidney and liver the differences in any given year were not statistically significant. Corneal donation rates show highly significant regional variations with the greatest number of differences occurring between England and Northern Ireland and England and Scotland. The lowest number of differences was found between Northern Ireland and Scotland. Further exploration of underlying factors, organisational issues and practices and attitudes that may affect corneal donation, needs to be undertaken.

Article focus:

- To investigate organ donation of cadaveric solid organs and tissues across the four devolved health administrations of the UK and how they vary with time;
- To consider reasons for regional variations and those related to organ type, drawing on regional differences in culture and practice and on findings in other EU countries.

Key messages:

- organ donation and registration rates vary with time across the four regions of UK;
- for any given year, statistically significant differences in corneal donation rates exist across the four regions;
- Scotland and Northern Ireland show the fewest differences in corneal donation rates

Strengths & limitations:

The strengths of this article are its novelty, as this is the first article that has analysed data across the UK and shown patterns in donation rates in the four regions over the last two decades; its timeliness given the shortfall in organ donations and the continuing debate about altering legislation to permit presumed consent and its importance in investigating for which organs regional differences exist and for which organs donation rates are similar. The limitation of this work was that data from other EU countries, for the entire time period investigated, were not available.

Introduction

Approximately 80-90% of the UK population support the principle of organ donation[1], yet, only 28% of the population carry an organ donor card.[2] Despite advances in transplantation medicine, organ shortage is the single most limiting factor preventing potential recipients from receiving the benefits of transplantation.[3] If the overwhelming support for organ donation could be directly translated into a willingness to donate, this should bode well for a presumed consent system (allowing organs to be used for transplantation unless the individual has explicitly objected). However, interpretation of these findings is far from simple. The authors argue that before considering a presumed consent system, differences in donation and registration rates for different organs in the four regions of the UK need to be investigated and reasons for any differences explored. Without such research, a nationally imposed system for all organs may fail or create regional inequalities. This paper presents an analysis of data of organ donation and registration in the four regions of the UK for five organ types: kidney, liver, heart, lung and cornea in order to determine whether significant differences exist across the four regions and whether these vary depending on the organ. Comparisons are made to European nations that have adopted presumed consent as well as to those that have not.

Methods

Information about all organ donations and registration in the four regions of the UK: England, Scotland, Wales and Northern Ireland was obtained from NHS Blood & Transplant for all available years: from 1990-2009.[2] Data from other European nations was provided from the National Organ Procurement Service for the Republic of Ireland [4], Eurotransplant International Foundation [5] and Scandiatransplant [6]. Statistical analysis of the data was conducted using a procedure developed by Zar.[7]

Results and Discussion

Regional variations in registration and donation

The UK currently operates a system of informed consent requiring individuals who wish to donate, to formally register their intention on a centralised register and to carry an organ donor card. Figure 1a shows that since the organ donor register was first launched in 1994, Wales has consistently outperformed other parts of the UK in terms of the percentage of population registered, with Scotland in second position, England third and Northern Ireland last. (A caveat is that although records are updated periodically to remove those who have died subsequent to being registered, organ donor registration rates may still include some entries of deceased individuals. This should not, however, affect regional variations.)

When the registration rates are compared to donation rates, the trends are somewhat different.[2] The rate of organ donation is consistently higher in Wales than the UK average for the majority of the last 20 years (Figure 1b). Donation rates in Northern Ireland are the second highest, achieving a higher than UK average in 13 of those years, with Scotland achieving this in 6 years and England capable of achieving this in only 3 years. So whilst registration and donation are both highest in Wales, amongst the other parts of the UK registration and donation do not follow similar trends. In Northern Ireland, for example, where willingness to register as an organ donor is lower than any other UK region, the organ donation rate is generally higher than in England or Scotland. It is also notable that whilst England exhibits the least variation in organ donation over the last two decades, Scotland shows an overall decrease in donation with trends in Wales and Northern Ireland varying from year to year with the greatest fluctuations in the latter.[2]

Variations in donation according to organ type

Masked by general variations in donation are the figures for individual organs. Table 1 shows the rate of donation for each region of the UK for different organs.[2] The rate of kidney donation has been consistently highest in Wales for most of the past 20 years. Northern Ireland contributed the second highest rate of donation followed by England and Scotland respectively. Similar regional variations in donation are seen for the liver. With respect to heart donation, Wales was the region with the highest overall donation rate until 1998 when it was overtaken by Scotland and/or Northern Ireland with the exception of 2006-2007. Northern Ireland had the second highest rate of donation, Scotland third and England the lowest rate. The overall rate of heart donation has fallen dramatically over the twenty year period for Wales, Scotland and England; Northern Ireland shows fluctuations with no consistent trend.

In contrast to falling heart donation rates, the rate of lung donation has risen since 1990, with Northern Ireland being the greatest contributor over most of this period.[2] The overall numbers, however, are low and comparable to those of heart donation. The pattern for corneal donations shows a greater consistency for most regions except Wales which contributed significantly more corneal tissue than the other regions between 1995 and 2005 but subsequently decreased to levels comparable to pre-1995. England has the second highest donation rate and Northern Ireland is the lowest for every year over the last two decades.

	Kidney				Heart				Lung				Liver				Cornea			
Year	E	S	W	NI	E	S	W	NI	E	S	W	NI	E	S	W	NI	E	S	W	NI
90-91	14.6	17.4	19.0	19.2	3.9	3.9	5.4	1.9	0.0	0.0	0.0	0.0	6.0	8.2	8.6	7.1	27.8	11.4	16.7	9.9
91-92	13.9	14.7	21.2	25.5	3.8	3.7	6.8	5.7	0.2	0.4	0.0	0.0	7.3	7.4	12.2	14.7	29.6	12.3	29.3	14.0
92-93	13.7	19.4	14.4	15.3	3.8	5.7	6.3	3.8	0.1	0.2	0.0	0.0	8.1	12.0	12.2	7.6	33.1	21.9	24.3	16.2
93-94	12.9	17.3	17.6	10.8	3.9	3.9	5.0	4.5	0.2	0.2	0.0	0.6	9.8	12.0	13.5	8.9	37.5	21.0	23.9	12.7
94-95	13.5	15.1	25.7	19.8	4.0	4.3	6.8	5.1	0.3	0.2	0.0	0.0	10.7	11.0	18.0	12.1	37.5	21.4	28.6	15.3
95-96	12.8	15.1	17.6	16.6	3.7	5.7	2.7	3.8	0.4	0.0	0.5	0.6	10.9	11.4	16.7	11.5	34.5	19.7	85.4	13.4
96-97	12.8	10.5	20.0	23.8	3.3	3.3	6.8	4.5	0.6	0.2	0.4	0.6	10.9	8.2	20.4	17.5	33.0	17.1	80.7	12.2
97-98	11.7	12.5	18.7	16.5	2.9	3.9	5.3	4.9	0.6	0.0	0.4	0.0	11.0	10.2	18.0	14.6	26.2	14.8	48.2	5.8
98-99	11.0	13.7	16.2	12.1	2.4	4.3	2.6	3.6	0.6	0.2	0.4	0.0	10.5	12.0	13.2	11.5	26.0	13.1	46.9	6.0
99-00	11.7	13.1	15.0	13.3	2.0	3.9	2.2	2.4	2.0	0.4	0.4	0.0	11.2	12.0	16.3	10.2	27.1	15.6	52.0	4.8
00-01	11.6	9.5	13.7	12.7	2.3	1.4	1.3	1.8	2.3	0.8	1.3	1.2	11.1	9.8	14.5	12.1	30.2	16.2	31.9	7.8
01-02	10.4	9.8	14.5	18.7	2.1	1.4	2.2	3.0	2.1	1.6	0.4	1.2	10.5	11.4	13.2	16.3	25.1	10.4	42.3	7.8
02-03	11.0	7.9	14.2	18.5	1.6	1.6	2.7	4.2	1.6	1.8	1.8	1.8	11.6	10.0	14.2	16.1	25.4	12.8	51.3	7.7
03-04	10.7	7.7	18.8	17.2	1.7	1.2	1.8	1.2	1.7	1.8	0.9	1.8	11.1	8.7	19.6	15.4	28.5	8.9	62.1	8.9
04-05	9.8	8.3	16.5	16.0	1.3	1.6	3.6	4.7	1.3	0.8	1.3	1.2	10.3	10.7	16.5	17.2	27.0	15.0	51.3	4.1
05-06	9.4	5.5	14.7	10.1	1.2	1.8	0.9	1.8	1.2	1.8	2.2	1.8	10.4	8.5	14.3	10.1	31.1	12.7	26.6	8.9
06-07	8.5	6.5	15.2	16.4	1.5	1.6	4.5	2.3	1.5	0.8	0.9	2.9	10.6	6.9	17.9	19.7	32.8	15.2	36.1	8.8
07-08	7.2	4.7	9.6	8.7	1.1	1.8	1.3	1.7	1.1	0.8	1.3	1.2	10.6	8.3	14.0	10.5	34.3	18.6	27.5	4.7
08-09	8.2	9.0	7.9	8.7	1.3	1.0	1.3	2.3	1.3	2.2	1.8	3.5	11.2	10.8	12.2	12.2	34.4	21.1	24.0	4.1

Table 1: UK Donor rates (deceased donors per million population) by organ type 1990-2009.[2]
(E = England S = Scotland W = Wales NI = Northern Ireland)

Table 1 shows 95 combinations of year and organ. For each combination and pair of regions, the differences in the proportions of donors were tested for statistical significance. The sample sizes used to obtain these proportions is obtained by multiplying the entries in Table 1 by the size of each country's population in millions for the relevant year.[2] In order to reduce a proliferation of Type I errors the procedure described by Zar [7] was adopted. The first step of this procedure involved carrying out a Chi-square test to test the null hypothesis: that the population proportions for each country are equal. If the null hypothesis is rejected, Tukey's HSD (Honestly Significant Difference) is applied to pairs of proportions after carrying out a Freeman-Tukey averaged double arcsine transformation. In order to obtain a balance between Type I and Type II errors, the significance level adopted for both the Chi-square test and the Studentised range statistic (q) was 0.01. As noted in Table 2, using this two stage procedure it is possible for the Chi-square test to be significant but for none of the subsequent post hoc comparison tests to be significant due to the conservative nature of the latter. (In Table 2, a row of six Xs for any combination of organ and year denotes comparisons where Chi-square indicated significance but each of the post hoc analyses showed no significance).

Certain clear patterns were detected. With regards to the cornea, statistically significant differences were found between England and Scotland as well as England and Northern Ireland for all years and between Wales and Northern Ireland for all but five years (Table 2). Where significance was found, Scotland and Northern Ireland had lower donation rates than England and Wales and the fewest significant differences in corneal donations occurred between Scotland and Northern Ireland (4 out of the 19 years).

The patterns seen with corneal donations may reflect attitudes based on culture and tradition as well as on lack of awareness of what eye donation involves. In Northern Ireland, and to a lesser extent in Scotland, the tradition of wakes and burial remains strong. Disfiguring the face of a deceased loved one before burial by removing the eyeballs, is unlikely to be accepted.[8] There is no eye bank or retrieval centre in Northern Ireland and information regarding the effect of collecting eye tissue on facial appearance is not well explained. In Wales and England, where over 70% of deaths result in cremations (compared to around 60% of deaths in Scotland and 15% in Northern Ireland)[9], the issue of the facial appearance of the deceased is less important.

Whilst for 10 out of the 19 years, Chi-squared analysis indicated significance in kidney donation rates (Table 2) further application of post hoc test showed far fewer statistically significant differences. These occurred between Wales and Scotland (in 2003-2004, 2005-2006 and 2006-2007) between Scotland and Northern Ireland (in 1996-1997, 2002-2003, 2003-2004 and 2006-2007) between England and Wales (in 1994-1995 and 2003-2004) and between England and Northern Ireland (in 1991-1992 and 1996-1997). Similarly for liver donation rates, Chi-squared analysis showed statistical differences across the regions for 7 out of the 19 years but following post hoc tests, statistical significance was only evident between Wales and Scotland for 3 out of the 19 years (1996-1997, 2003-2004 and 2006-2007) between England and Wales (in 1996-1997 and 2003-2004) and between Scotland and Northern Ireland in 2006-2007 (Table 2). There were no significant differences for any year between Wales and Northern Ireland for kidney and liver donations.

In the case of lung and heart donations, there were no significant post hoc differences between any of the regions over the two decades (Table 2). Lung and heart donations have

been very low in number in all regions across all the years and this may reflect the fact that heart beating donors, on which heart and most lung transplants depend have been decreasing for around a decade across the UK.[10]

Year	Kidney						Heart					
	qEW	qES	qEN	qWS	qWN	qSN	qEW	qES	qEN	qWS	qWN	qSN
90-91	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
91-92	X	X	**-4.70**	X	X	X	N/A	N/A	N/A	N/A	N/A	N/A
92-93	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
93-94	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
94-95	**-5.84**	X	X	X	X	X	N/A	N/A	N/A	N/A	N/A	N/A
95-96	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
96-97	X	X	**-4.65**	X	X	**5.13**	N/A	N/A	N/A	N/A	N/A	N/A
97-98	X	X	X	X	X	X	N/A	N/A	N/A	N/A	N/A	N/A
98-99	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
99-00	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
00-01	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
01-02	X	X	X	X	X	X	N/A	N/A	N/A	N/A	N/A	N/A
02-03	X	X	X	X	X	**-4.77**	N/A	N/A	N/A	N/A	N/A	N/A
03-04	**-4.51**	X	X	**5.53**	X	**-4.43**	N/A	N/A	N/A	N/A	N/A	N/A
04-05	X	X	X	X	X	X	X	X	X	X	X	X
05-06	X	X	X	**5.28**	X	X	N/A	N/A	N/A	N/A	N/A	N/A
06-07	X	X	X	**4.79**	X	**-4.83**	X	X	X	X	X	X
07-08	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
08-09	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Lung						**Liver**					
	qEW	qES	qEN	qWS	qWN	qSN	qEW	qES	qEN	qWS	qWN	qSN
90-91	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
91-92	N/A	N/A	N/A	N/A	N/A	N/A	X	X	X	X	X	X
92-93	N/A	N/A	N/A	N/A	N/A	N/A	X	X	X	X	X	X
93-94	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
94-95	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
95-96	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
96-97	N/A	N/A	N/A	N/A	N/A	N/A	**-5.10**	X	X	**5.84**	X	X
97-98	N/A	N/A	N/A	N/A	N/A	N/A	X	X	X	X	X	X
98-99	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
99-00	X	X	X	X	X	X	N/A	N/A	N/A	N/A	N/A	N/A
00-01	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
01-02	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
02-03	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
03-04	N/A	N/A	N/A	N/A	N/A	N/A	**-4.63**	X	X	**5.24**	X	X
04-05	N/A	N/A	N/A	N/A	N/A	N/A	X	X	X	X	X	X
05-06	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
06-07	N/A	N/A	N/A	N/A	N/A	N/A	X	X	X	**5.70**	X	**-5.81**
07-08	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
08-09	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

	Cornea					
	qEW	qES	qEN	qWS	qWN	qSN
90-91	**4.77**	**11.45**	**7.22**	X	X	X
91-92	X	**11.68**	**5.76**	**6.72**	X	X
92-93	X	**6.47**	**5.90**	X	X	X
93-94	**5.0**	**9.31**	**8.78**	X	X	X
94-95	X	**9.04**	**7.58**	X	X	X
95-96	**-13.93**	**8.66**	**7.57**	**16.90**	**15.05**	X
96-97	**-13.40**	**9.71**	**7.71**	**17.06**	**14.80**	X
97-98	**-7.66**	**7.70**	**9.39**	**11.00**	**12.34**	X
98-99	**-7.37**	**8.92**	**9.26**	**11.47**	**12.05**	X
99-00	**-8.42**	**7.58**	**10.57**	**11.58**	**13.76**	**5.40**
00-01	X	**8.90**	**9.50**	**5.78**	**7.81**	X
01-02	**-6.29**	**10.79**	**7.76**	**11.63**	**10.18**	X
02-03	**-8.91**	**8.83**	**7.93**	**12.72**	**12.05**	X
03-04	**-10.58**	**14.19**	**8.34**	**17.25**	**13.50**	X
04-05	**-8.20**	**7.95**	**11.22**	**11.60**	**14.11**	**5.70**
05-06	X	**12.13**	**9.21**	**5.64**	**5.96**	X
06-07	X	**11.01**	**9.81**	**7.46**	**8.40**	X
07-08	X	**9.33**	**13.22**	X	**8.50**	**6.71**
08-09	X	**7.68**	**13.76**	X	**7.92**	**8.05**

Key

qEW is the Studentised range statistic for the difference between the proportions in England and Wales (a negative score indicates that the proportion was greater in Wales)

qES = England with Scotland
qEN = England with N. Ireland
qWS = Wales with Scotland
qWN = Wales with N. Ireland
qSN = Scotland with N. Ireland

Cells marked N/A indicate the Chi-square test was not significant ($p > 0.01$) and hence no post hoc comparison tests were carried out. Values in bold indicate that the difference between two independent proportions is significant at 0.01 level (two-tailed test) using the Tukey HSD test whilst an X indicates it was not ($p > 0.01$). A row of six cells marked X for any combination of organ and year indicates that the Chi-square test was significant ($p < 0.01$) but the post hoc comparison test for a particular pair of countries was not ($p > 0.01$).

Table 2: Statistical analyses using Chi-square and Tukey's HSD test comparing differences in organ donation between each of the four regions: England, Scotland, Wales and Northern Ireland for five organs

Can parallels be drawn from the EU?

It has been suggested that at least 20-30 deceased donors per million population would be necessary to meet the UK's increasing demands.[11] The British Medical Association called for changes in legislation, suggesting a system of presumed consent that allows for objections of relatives.[12] The Organ Donation Taskforce was commissioned in 2008 to consider the potential effects of such legislation and concluded that a change to presumed consent at this time was unlikely to increase organ donation rates, may incur prohibitive costs and could result in a backlash; other factors needed to be considered before introducing legislative change.[13]

Bird and Harris modelled situations with varying relative refusal rates and drew on comparisons with EU countries that already adopted presumed consent systems.[14] However, presumed consent for organ donation has been implemented with varying effect in the EU. Adoption and successful implementation of laws in one country should not be taken as a guarantee of similar success in another. Hence, though Sweden applies presumed consent, its donation rate in 2009, at 13.8 deceased donors per million population,[6] was comparable to that of Germany (14.5 deceased donors per million population) and Denmark (14.0 deceased donors per million population);[5] both of which require informed consent (Figure 2). The figures available for Ireland, where informed consent is needed, were 21.2 deceased donors per million population in 2009.[4] The nation with the highest donor rate (34.4 deceased donors per million population in 2009)[15], and one often cited as evidence of successful implementation of presumed consent legislation[16], is Spain which operates a "soft" form of presumed consent where next of kin can object to organ donation[15-16]. Yet, the impact of the legislation has been questioned and the high rate of donor activity attributed to the "Spanish Model"[15-16] that demands an integrated approach with dedicated transplant co-ordinators, mainly intensive care physicians, involved in procurement[16]. This

highly coordinated network and the respect for autonomy given to the individual and their relatives, is credited with improving donation rates of 14.3 deceased donors per million population in 1989 to rates of 33-35 deceased donors per million population in recent years.[15-16] The majority of donations in Spain are from heart-beating donors in intensive care; live organ donation and that from non-heart beating donors is relatively low[16]. The converse is true in the UK and estimates suggest that even if a theoretical upper limit were reached, with present facilities and practices, heart beating donor numbers in the UK would only reach half of those in Spain.[16] Given that Spain introduced presumed consent in 1979[3], it is clear that a legislative change alone was not sufficient to improve donation rates. It is notable that Spain achieves a significantly higher rate of donation than does Austria [5] which relies upon a "hard" approach in which views of relatives are not routinely sought.

Comparisons across the EU further indicate that whilst a country may have relatively low overall donation rates, for certain organs the trend may be reversed. Sweden lags behind countries like Austria, Belgium, Germany and the Netherlands with regard to overall deceased donations but has had the highest kidney donation rate for the majority of the past 13 years.[5-6]

Conclusions

Data from the four UK regions show that organ donation rates vary over the last two decades but that few significant differences exist in organ donation rates for most organs investigated with the cornea a notable exception. From these findings, the introduction of presumed consent legislation across the UK should not result in discrepancies arising from regional variations. However, shortfalls in Scotland and Northern Ireland in corneal donation rates need to be addressed. Further exploration of underlying regional differences, organisational

issues and practices and attitudes that may affect corneal donation needs to be undertaken. Comparison of EU nations, and particularly Spain, indicates that improvement of donation rates is unlikely to be achieved by introducing new legislation alone.

Provenance/Contributorship: Barbara Pierscionek is a Professor of Vision Science at the School of Biomedical Science, University of Ulster. She is qualified in science and law, teaches ethics and law and researches the biology and physics of ageing as well as healthcare ethics and presumed consent. Gordon Rae is a Professor of Psychology at the School of Psychology, University of Ulster, trained in mathematics and statistics as well as psychology and his research interests include applying statistical methods to psychology and medicine. Carol McClenahan is a lecturer in Psychology at the School of Psychology, University of Ulster. Her research expertise is in attitude and behavioural change in relation to health. She also has an interest in ethics in psychology and health. Donal McGlade is currently undertaking a PhD on attitudes that determine behaviour with respect to organ donation. All authors were involved in preparation of the manuscript. Barbara Pierscionek is the guarantor.

"All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) (URL) and declare that all authors had: (1) No financial support for the submitted work from anyone other than their employer; (2) No financial relationships with commercial entities that might have an interest in the submitted work; (3) No spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work; (4) No Non-financial interests that may be relevant to the submitted work."

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Figure captions

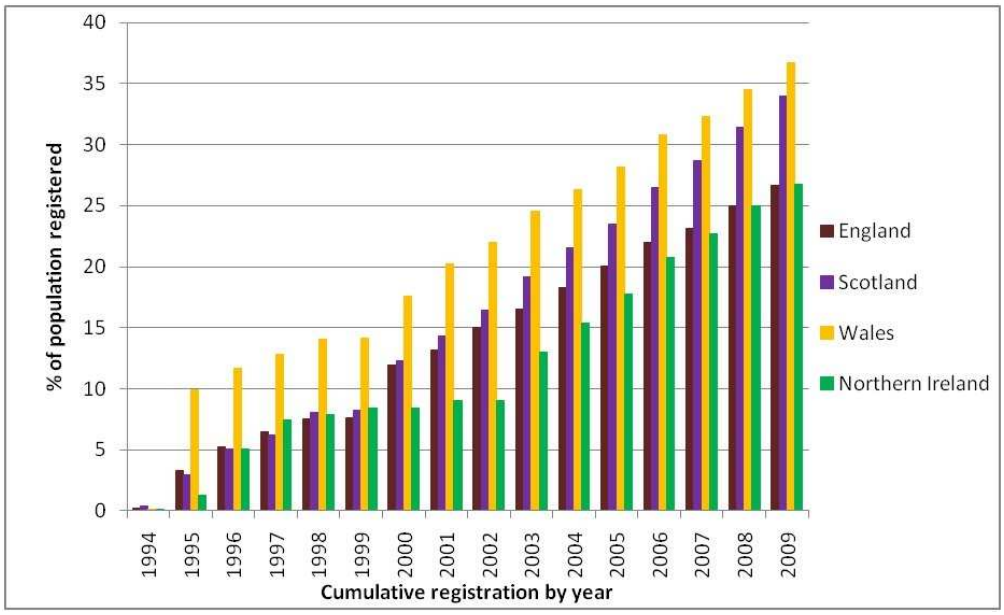
Figure 1: a) Organ donor registration rates in England, Wales, Scotland and Northern Ireland 1994-2009.[2] b) Organ donation rates in England, Wales, Scotland and Northern Ireland 1990-2009.[2]

Figure 2: Organ donor rates in selected EU countries 1997-2009.[13-14]

Research review guidelines : modified from RATS guidelines

	ASK THIS OF THE MANUSCRIPT	THIS SHOULD BE INCLUDED IN THE MANUSCRIPT	✓ <>
R	**Relevance of study question**		
	Is the research question interesting?	Research question explicitly stated	✓
	Is the research question relevant to clinical practice, public health, or policy? *It is relevant to policy*	Research question justified and linked to the existing knowledge base (empirical research, theory, policy)	✓
A	**Appropriateness of the method**		
	Is the methodology used the best approach for the study aims?	Study design described and justified : *data for all organ donations and registrations was required in order to compare trends across the four UK regions.*	✓
T	**Transparency of procedures**		
	Data collection		
	Was collection of data systematic and comprehensive?	Method (s) outlined : *all available data from centralized sources collected*	✓
	Why and when was data collection stopped, and is this reasonable?	End of data collection justified and described: *all available complete data was collected*	✓
S	**Soundness of interpretive approach**		
	Analysis		
	Is the type of analysis appropriate for the type of study?	Analytic approach described in depth and justified	✓
	Are the interpretations clearly presented and adequately supported by the evidence?	Statistical analysis conducted using appropriate test Analysis, presentation and interpretation provided	✓
	Discussion and presentation		

Is adequate account taken of previous knowledge and how the findings add?	Findings presented with reference to existing literature, and how they contribute	✓
Is the manuscript well written and accessible?	Evidence of following guidelines (format, word count) Written for a health sciences audience	✓



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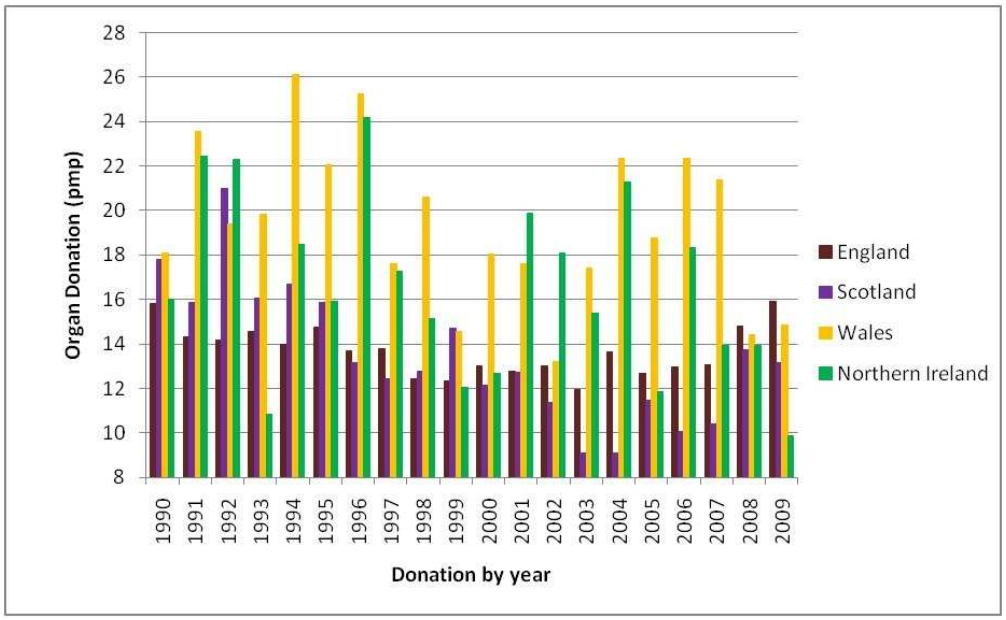

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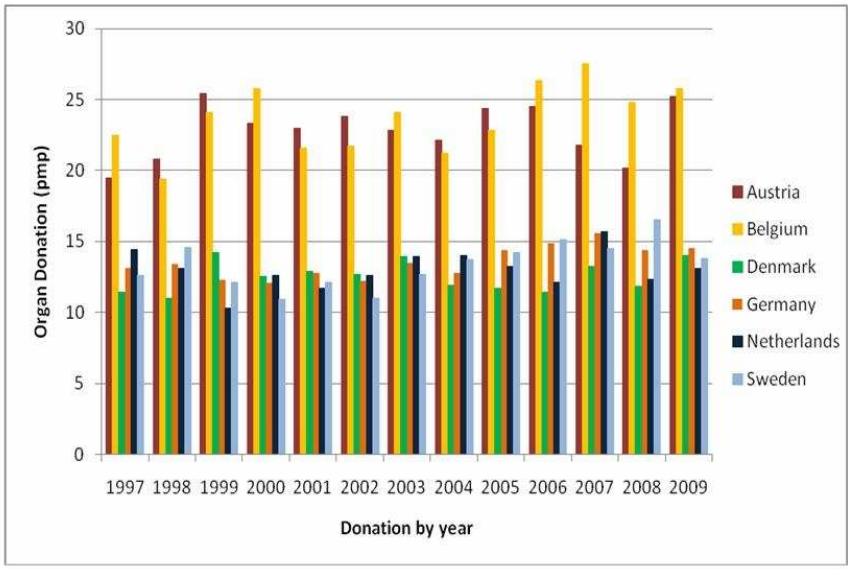

Figure 2

254x190mm (96 x 96 DPI)

Regional and temporal variations in organ donation across the UK

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Regional and temporal variations in organ donation across the UK

(secondary analysis of databases)

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Key words: *organ donation, presumed consent, UK regional variations, EU organ donation*

Word count: 2478 words

Objectives: To explore regional variations in donation of cadaveric solid organs and tissues across the four devolved health administrations of the UK (England, Scotland, Wales & Northern Ireland).

Design: A secondary analysis of databases from NHS Blood & Transplant (1990-2009) and from the National Organ Procurement Service for the Republic of Ireland, Eurotransplant International Foundation and Scandiatransplant.

Results: After adjusting for time, statistically significant differences were found among the four regions ($p<0.001$) for liver donations. The only exceptions were between England and Scotland and between Wales and Northern Ireland where the differences were not significant following a Bonferroni correction ($p>0.008$). England had significantly fewer heart donations than both Wales ($p<0.001$) and Northern Ireland ($p = 0.005$). There were no significant differences among the four regions for lung donations. Regional variations in kidney and corneal donations were moderated by time. Northern Ireland, however, has had consistently lower corneal donation rates than the other three regions.

Conclusion: Organ donation rates over the last two decades vary in the four UK regions and this variation depends on the type of organ donated. Further exploration of underlying factors, organisational issues, practices and attitudes to organ donation in the four regions of the UK, taking into account findings from EU countries with varying approaches to presumed consent, needs to be undertaken before such legislation is introduced across the UK.

Article focus:

- To investigate organ donation of cadaveric solid organs and tissues across the four devolved health administrations of the UK and how they vary with time;
- To consider reasons for regional variations and those related to organ type, drawing on regional differences in culture and practice and on findings in other EU countries.

Key messages:

- organ donation and registration rates vary with time across the four regions of UK;
- heart and liver donations are highest in Wales and Northern Ireland;
- the significance of regional variations on kidney and corneal donation rates is moderated by the effect of changes over time; Northern Ireland consistently has the lowest corneal donation rate;
- the reasons for regional variations require further investigation as well as comparisons with practices and attitudes in other EU states

Strengths & limitations:

The strengths of this article are a) its novelty, as this is the first article that has analysed data across the UK and shown patterns in donation rates in the four regions over the last two decades; b) its timeliness given the shortfall in organ donations and the continuing debate about altering legislation to permit presumed consent and its importance in investigating for which organs regional differences exist and for which organs donation rates are similar. The limitation of this work was that data from other EU countries, for the entire time period investigated, were not available.

Introduction

Approximately 80-90% of the UK population support the principle of organ donation[1], yet, only 28% of the population carry an organ donor card.[2] Despite advances in transplantation medicine, organ shortage is the single most limiting factor preventing potential recipients from receiving the benefits of transplantation.[3] If the overwhelming support for organ donation could be directly translated into a willingness to donate, this should bode well for a presumed consent system (allowing organs to be used for transplantation unless the individual has explicitly objected). However, interpretation of these findings is far from simple. The authors argue that before considering a presumed consent system, differences in donation and registration rates for different organs in the four regions of the UK need to be investigated and reasons for any differences explored. Without such research, a nationally imposed system for all organs may fail or create regional inequalities. This paper presents an analysis of data of organ donation and registration in the four regions of the UK for five organ types: kidney, liver, heart, lung and cornea in order to determine whether significant differences exist across the four regions and whether these vary depending on the organ. Comparisons are made to European nations that have adopted presumed consent as well as to those that have not.

Methods

Information about all organ donations and registration in the four regions of the UK: England, Scotland, Wales and Northern Ireland was obtained from NHS Blood & Transplant for all available years: from 1990-2009.[2] Data from other European nations was provided from the National Organ Procurement Service for the Republic of Ireland [4], Eurotransplant International Foundation [5] and Scandiatransplant [6]. Statistical analyses were carried out

using Poisson regression (SPSS version 17). Bonferroni corrections were used to control for Type I errors when making inter-regional comparisons.

Results and Discussion

Regional variations in registration and donation

The UK currently operates a system of informed consent requiring individuals who wish to donate, to formally register their intention on a centralised register and to carry an organ donor card. Figure 1a shows that since the organ donor register was first launched in 1994, Wales has consistently outperformed other parts of the UK in terms of the percentage of population registered, with Scotland in second position, England third and Northern Ireland last. (A caveat is that although records are updated periodically to remove those who have died subsequent to being registered, organ donor registration rates may still include some entries of deceased individuals. This should not, however, affect regional variations).

When the registration rates are compared to donation rates, the trends are somewhat different.[2] The rate of organ donation is consistently higher in Wales than the UK average for the majority of the last 20 years (Figure 1b). Donation rates in Northern Ireland are the second highest, achieving a higher than UK average in 13 of those years, with Scotland achieving this in 6 years and England capable of achieving this in only 3 years. So whilst registration and donation are both highest in Wales, amongst the other parts of the UK registration and donation do not follow similar trends. In Northern Ireland, for example, where willingness to register as an organ donor is lower than any other UK region, the organ donation rate is generally higher than in England or Scotland. It is also notable that whilst England exhibits the least variation in organ donation over the last two decades, Scotland

shows an overall decrease in donation with trends in Wales and Northern Ireland varying from year to year with the greatest fluctuations in the latter.[2]

Variations in donation according to organ type

Masked by general variations in donation are the figures for individual organs. Table 1 shows the rate of donation for each region of the UK for different organs.[2] Poisson regression analyses were carried out on the numbers of organ donations (entries in Table 1 x the population for each country in that year expressed in millions) using the Generalized Linear Models program in SPSS Version 17. The offset was the natural logarithm of the total population for each country, which varied slightly from year to year. Separate analyses were carried out for each organ because it was deemed highly probable that donors often give more than one organ and hence a single model analysis would violate the assumption of independent observations. Four different models were considered: the intercept only model, M0, which included no explanatory variables; model M1, which included the explanatory variable year (as well as the intercept); model M2 which included the explanatory variables year and country; and the full or saturated model M3 which includes the explanatory variables year and country and their interaction. Pairs of models were compared using the differences between their deviance values (ΔD). This statistic is a large-sample chi-squared statistic with degrees of freedom equal to the difference between the residual df values for the two models. Table 2 shows that for all organs, model M1 was a statistically significant improvement over model M0 and model M2 was a significant improvement over model M1 (in all cases the value of ΔD was significant at $p < 0.001$). In the case of liver, lung and heart, model M2 was not statistically significantly different from the saturated model M3. Since the two models have comparable fit, the former was selected on the grounds that it is the more parsimonious (requires fewer parameters to be estimated). Applying model M2 for the liver, Wales had significantly higher counts than England and Scotland (Wald chi-square 90.23, df

= 1, p< 0.001; 65.12, df = 1, p< 0.001 respectively) and Northern Ireland had significantly higher counts than England and Scotland (Wald chi-square 21.34, df = 1, p< 0.001; 19.04, df = 1, p< 0.001, respectively). After a Bonferroni correction (six comparisons carried out, original alpha = 0.05, adjusted significance level = 0.05/6 = 0.008) there was no statistically significant difference between England and Scotland nor between Wales and Northern Ireland (Wald chi-square 0.506, df = 1, p = 0.477; 5.76, df = 1, p = 0.016). For the lung there were no statistically significant differences between the regions. In the case of the heart, England had significantly fewer donations than Wales and Northern Ireland (Wald chi-square 19.86, df = 1, p<0.001; 8.06, df = 1, p = 0.005, respectively). There were no significant differences between Scotland and the other three regions after applying a Bonferroni correction.

For the cornea and kidney, model M2 was a significantly poorer fit than the saturated model. (There was also substantial overdispersion as indicated by the values of D/df shown in Table 2 which was not corrected using a negative binomial as an alternative model). These findings suggest that for these organs the effect of country was moderated by year. For example, in the case of the cornea the donor rates per million for Scotland and Northern Ireland were quite close in 1991-92 (12.3 and 14.0 respectively) whereas in 2008-9 there was a substantial discrepancy (21.1 and 4.1 respectively). Inspection of the Poisson interaction term indicated that the difference between Scotland and Northern Ireland in 2008-9 (17.0) was significantly greater (p<0.001) than the difference between the two regions in 1991-92.

	Kidney				Heart				Lung				Liver				Cornea			
Year	E	S	W	NI	E	S	W	NI	E	S	W	NI	E	S	W	NI	E	S	W	NI
90-91	14.6	17.4	19.0	19.2	3.9	3.9	5.4	1.9	0.0	0.0	0.0	0.0	6.0	8.2	8.6	7.1	27.8	11.4	16.7	9.9
91-92	13.9	14.7	21.2	25.5	3.8	3.7	6.8	5.7	0.2	0.4	0.0	0.0	7.3	7.4	12.2	14.7	29.6	12.3	29.3	14.0
92-93	13.7	19.4	14.4	15.3	3.8	5.7	6.3	3.8	0.1	0.2	0.0	0.0	8.1	12.0	12.2	7.6	33.1	21.9	24.3	16.2
93-94	12.9	17.3	17.6	10.8	3.9	3.9	5.0	4.5	0.2	0.2	0.0	0.6	9.8	12.0	13.5	8.9	37.5	21.0	23.9	12.7
94-95	13.5	15.1	25.7	19.8	4.0	4.3	6.8	5.1	0.3	0.2	0.0	0.0	10.7	11.0	18.0	12.1	37.5	21.4	28.6	15.3
95-96	12.8	15.1	17.6	16.6	3.7	5.7	2.7	3.8	0.4	0.0	0.5	0.6	10.9	11.4	16.7	11.5	34.5	19.7	85.4	13.4
96-97	12.8	10.5	20.0	23.8	3.3	3.3	6.8	4.5	0.6	0.2	0.4	0.6	10.9	8.2	20.4	17.5	33.0	17.1	80.7	12.2
97-98	11.7	12.5	18.7	16.5	2.9	3.9	5.3	4.9	0.6	0.0	0.4	0.0	11.0	10.2	18.0	14.6	26.2	14.8	48.2	5.8
98-99	11.0	13.7	16.2	12.1	2.4	4.3	2.6	3.6	0.6	0.2	0.4	0.0	10.5	12.0	13.2	11.5	26.0	13.1	46.9	6.0
99-00	11.7	13.1	15.0	13.3	2.0	3.9	2.2	2.4	2.0	0.4	0.4	0.0	11.2	12.0	16.3	10.2	27.1	15.6	52.0	4.8
00-01	11.6	9.5	13.7	12.7	2.3	1.4	1.3	1.8	2.3	0.8	1.3	1.2	11.1	9.8	14.5	12.1	30.2	16.2	31.9	7.8
01-02	10.4	9.8	14.5	18.7	2.1	1.4	2.2	3.0	2.1	1.6	0.4	1.2	10.5	11.4	13.2	16.3	25.1	10.4	42.3	7.8
02-03	11.0	7.9	14.2	18.5	1.6	1.6	2.7	4.2	1.6	1.8	1.8	1.8	11.6	10.0	14.2	16.1	25.4	12.8	51.3	7.7
03-04	10.7	7.7	18.8	17.2	1.7	1.2	1.8	1.2	1.7	1.8	0.9	1.8	11.1	8.7	19.6	15.4	28.5	8.9	62.1	8.9
04-05	9.8	8.3	16.5	16.0	1.3	1.6	3.6	4.7	1.3	0.8	1.3	1.2	10.3	10.7	16.5	17.2	27.0	15.0	51.3	4.1
05-06	9.4	5.5	14.7	10.1	1.2	1.8	0.9	1.8	1.2	1.8	2.2	1.8	10.4	8.5	14.3	10.1	31.1	12.7	26.6	8.9
06-07	8.5	6.5	15.2	16.4	1.5	1.6	4.5	2.3	1.5	0.8	0.9	2.9	10.6	6.9	17.9	19.7	32.8	15.2	36.1	8.8
07-08	7.2	4.7	9.6	8.7	1.1	1.8	1.3	1.7	1.1	0.8	1.3	1.2	10.6	8.3	14.0	10.5	34.3	18.6	27.5	4.7
08-09	8.2	9.0	7.9	8.7	1.3	1.0	1.3	2.3	1.3	2.2	1.8	3.5	11.2	10.8	12.2	12.2	34.4	21.1	24.0	4.1

Table 1: UK Donor rates (deceased donors per million population) by organ type 1990-2009.[2]
(E = England S = Scotland W = Wales NI = Northern Ireland)

The results show certain regional differences in donation for four of the organs. With regards to the liver, the Poisson analysis indicated that Wales and Northern Ireland had statistically significantly higher donor rates than England and Scotland. The rate of liver donation has been consistently highest in Wales for the past twenty years and Northern Ireland has contributed the second highest rate of donation for most of the years examined. Heart donations were also statistically significantly higher in Wales and Northern Ireland compared to England. With respect to heart donation, in the first decade examined, with the exception of 1995-6, Wales was the region with the highest overall donation rate until 1998 when it was overtaken by Scotland and/or Northern Ireland. One or both of these regions dominated in heart donations over most of the second decade studied (with the exception of 2003-4 and 2006-7 where Wales had the highest donations). The overall rate of heart donations has fallen over the twenty year period for Wales, Scotland and England; Northern Ireland shows fluctuations with no consistent trend.

In contrast to falling heart donation rates, the rate of lung donation has risen since 1990, with Northern Ireland being the greatest contributor over most of this period.[2] This notwithstanding, there were no statistically significant regional variations in lung donations. It should be noted that lung as well as heart donations have been very low in number in all regions across all the years compared to other organs and this may reflect the fact that heart beating donors, on which heart and most lung transplants depend, have been decreasing for around a decade across the UK.[7]

Kidney and corneal donations showed significant regional differences but these were not consistent across the time period investigated, as indicated by the need to add an interaction

term to the models. No discernable pattern emerges from the kidney donation data although it is perhaps worth noting that for most of the first decade examined, England was the lowest contributor; in the second decade, with the exception of one year (2008-09), the lowest contributions came from Scotland.

The pattern for corneal donations shows a greater consistency for most regions except Wales, which contributed significantly more corneal tissue than the other regions between 1995 and 2005 but subsequently decreased to levels comparable to pre-1995 and to those of England. There is no obvious reason for this trend. Perhaps the most striking picture to emerge from the data shown in Table 1 is the low rate of corneal donations in Northern Ireland, particularly when compared with those of England and Wales. Scotland and Northern Ireland were very similar in corneal donations in the early part of the first decade examined but subsequently the gap increased.

The patterns seen with corneal donations may reflect attitudes based on culture and tradition as well as on lack of awareness of what eye donation involves. In Northern Ireland, and to a lesser extent in Scotland, the tradition of wakes and burial remains strong. Disfiguring the face of a deceased loved one before burial by removing the eyeballs, is unlikely to be accepted.[8] There is no eye bank or retrieval centre in Northern Ireland and information regarding the effect of collecting eye tissue on facial appearance is not sufficiently well explained. In Wales and England, where over 70% of deaths result in cremations (compared to around 60% of deaths in Scotland and 15% in Northern Ireland) [9], the issue of the facial appearance of the deceased may be of less importance. The presence of an eye bank with dedicated staff is the most likely means of increasing corneal donations although it has been shown that retrieval rates can be raised effectively by implementing an active policy for

corneal donation in accident and emergency departments [10]. This approach would also apply to other organs.

	Kidney						Heart					
Model	Deviance (D)	df	D/df	ΔD	Δdf	Sig.	Deviance (D)	df	D/df	ΔD	Δdf	Sig.
M0: Intercept only	716.34	75	9.55				600.86	75	8.01			
M1: Intercept + year	225.75	57	3.96				87.03	57	1.53			
M1-M0				490.59	18	<.001				513.84	18	<.001
M2: Intercept + year + country	109.52	54					58.55	54	1.08			
M2-M1				116.23	3	<.001				28.48	3	<.001
M3 (Full) –M2				109.52	54	<.001				58.55	54	.312
	Lung						**Liver**					
Model	Deviance (D)	df	D/df	ΔD	Δdf	Sig.	Deviance (D)	df	D/df	ΔD	Δdf	Sig.
M0: Intercept only	683.13	75	9.11				385.34	75	5.14			
M1: Intercept + year	72.99	57	1.28				169.45	57	2.97			
M1-M0				610.14	18	<.001				215.89	18	<.001
M2: Intercept + year + country	63.26	54	1.17				69.58	54	1.29			
M2-M1				9.73	3	.021				99.87	3	<.001
M3 (Full) –M2				63.26	54	.182				69.58	54	.075
	Cornea											
Model	Deviance (D)	df	D/df	ΔD	Δdf	Sig.						
M0: Intercept	2528.01	75	33.71									
M1: Intercept + year	2040.97	57	35.81									

Key

Sig = significance level

ΔD = difference between the deviances of the two models being

M1-M0				487.03	18	<.001
M2: Intercept + year + country	461.11	54	8.54			
M2-M1				1579.87	3	<.001
M3 (Full)–M2				461.11	54	<.001

compared

Δdf = difference between the degrees of freedom of the two models being compared

M3 (Full) = model including intercept, year, country, and year x country interaction

Table 2: Poisson regression analysis of number of organ donations under a variety of models

Can parallels be drawn from the EU?

It has been suggested that at least 20-30 deceased donors per million population would be necessary to meet the UK's increasing demands.[11] The British Medical Association called for changes in legislation, suggesting a system of presumed consent that allows for objections of relatives.[12] The Organ Donation Taskforce was commissioned in 2008 to consider the potential effects of such legislation and concluded that a change to presumed consent at this time was unlikely to increase organ donation rates, may incur prohibitive costs and could result in a backlash; other factors needed to be considered before introducing legislative change.[13]

Bird and Harris modelled situations with varying relative refusal rates and drew on comparisons with EU countries that already adopted presumed consent systems.[14] However, presumed consent for organ donation has been implemented with varying effect in the EU. Adoption and successful implementation of laws in one country should not be taken as a guarantee of similar success in another. Hence, though Sweden applies presumed consent, its donation rate in 2009, at 13.8 deceased donors per million population,[6] was comparable to that of Germany (14.5 deceased donors per million population) and Denmark (14.0 deceased donors per million population);[5] both of which require informed consent (Figure 2). The figures available for Ireland, where informed consent is needed, were 21.2 deceased donors per million population in 2009.[4] The nation with the highest donor rate (34.4 deceased donors per million population in 2009)[15], and one often cited as evidence of successful implementation of presumed consent legislation[16], is Spain which operates a "soft" form of presumed consent where next of kin can object to organ donation[15-16]. Yet, the impact of the legislation has been questioned and the high rate of donor activity attributed to the "Spanish Model"[15-16] that demands an integrated approach with dedicated transplant co-ordinators, mainly intensive care physicians, involved in procurement[16]. This

highly coordinated network and the respect for autonomy given to the individual and their relatives, is credited with improving donation rates of 14.3 deceased donors per million population in 1989 to rates of 33-35 deceased donors per million population in recent years.[15-16] The majority of donations in Spain are from heart-beating donors in intensive care; live organ donation and that from non-heart beating donors is relatively low[16]. The converse is true in the UK and estimates suggest that even if a theoretical upper limit were reached, with present facilities and practices, heart beating donor numbers in the UK would only reach half of those in Spain.[16] Given that Spain introduced presumed consent in 1979[3], it is clear that a legislative change alone was not sufficient to improve donation rates. It is notable that Spain achieves a significantly higher rate of donation than does Austria [5] which relies upon a "hard" approach in which views of relatives are not routinely sought.

Comparisons across the EU further indicate that whilst a country may have relatively low overall donation rates, for certain organs the trend may be reversed. Sweden lags behind countries like Austria, Belgium, Germany and the Netherlands with regard to overall deceased donations but has had the highest kidney donation rate for the majority of the past 13 years.[5-6]

Conclusions

Data from the four UK regions show that organ donation rates vary over the last two decades and that for two of the organs, kidney and cornea, the significance of regional variations is moderated by variations in time. The cornea, in particular, shows shortfalls in donation rates from Northern Ireland. Further exploration of underlying regional differences and temporal variations in organ donation as well as organisational issues, practices and attitudes that may affect organ donation, needs to be undertaken before considering legislation to admit

presumed consent. Comparison of EU nations, and particularly Spain, indicates that improvement of organ donation rates is unlikely to be achieved by introducing new legislation alone.

Provenance/Contributorship: Barbara Pierscionek is a Professor of Vision Science at the School of Biomedical Science, University of Ulster. She is qualified in science and law, teaches ethics and law and researches the biology and physics of ageing as well as healthcare ethics and presumed consent. Gordon Rae is a Professor of Psychology at the School of Psychology, University of Ulster, trained in mathematics and statistics as well as psychology and his research interests include applying statistical methods to psychology and medicine. Carol McClenahan is a lecturer in Psychology at the School of Psychology, University of Ulster. Her research expertise is in attitude and behavioural change in relation to health. She also has an interest in ethics in psychology and health. Donal McGlade is currently undertaking a PhD on attitudes that determine behaviour with respect to organ donation. All authors were involved in preparation of the manuscript. Barbara Pierscionek is the guarantor.

"All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) (URL) and declare that all authors had: (1) No financial support for the submitted work from anyone other than their employer; (2) No financial relationships with commercial entities that might have an interest in the submitted work; (3) No spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work; (4) No Non-financial interests that may be relevant to the submitted work."

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Figure captions

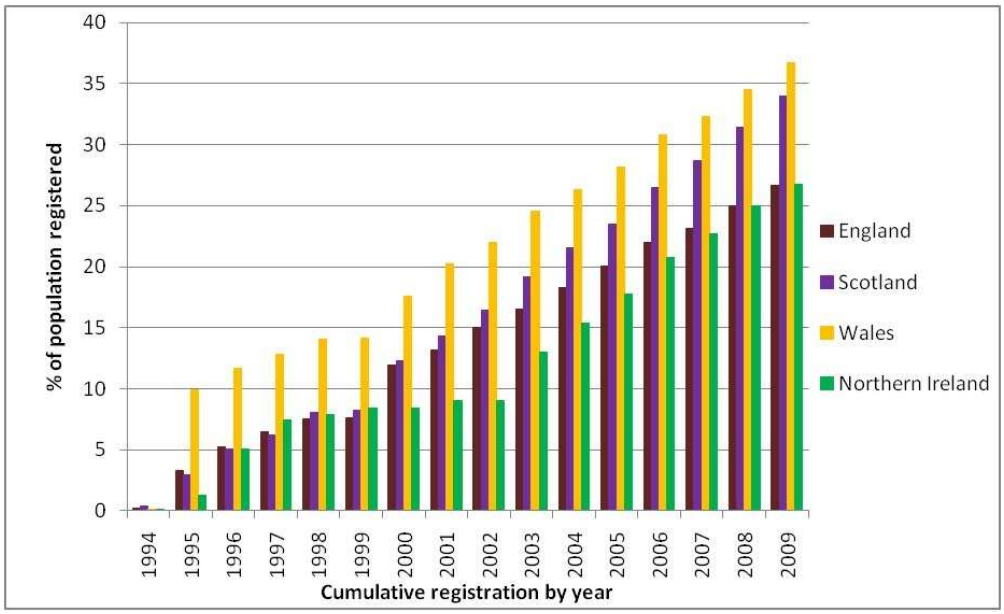
Figure 1: a) Organ donor registration rates in England, Wales, Scotland and Northern Ireland 1994-2009.[2] b) Organ donation rates in England, Wales, Scotland and Northern Ireland 1990-2009.[2]

Figure 2: Organ donor rates in selected EU countries 1997-2009.[5-6]

Research review guidelines : modified from RATS guidelines

	ASK THIS OF THE MANUSCRIPT	THIS SHOULD BE INCLUDED IN THE MANUSCRIPT	✓ <>
R	**Relevance of study question**		
	Is the research question interesting?	Research question explicitly stated	✓
	Is the research question relevant to clinical practice, public health, or policy? *It is relevant to policy*	Research question justified and linked to the existing knowledge base (empirical research, theory, policy)	✓
A	**Appropriateness of the method**		
	Is the methodology used the best approach for the study aims?	Study design described and justified : *data for all organ donations and registrations was required in order to compare trends across the four UK regions.*	✓
T	**Transparency of procedures**		
	Data collection		
	Was collection of data systematic and comprehensive?	Method (s) outlined : *all available data from centralized sources collected*	✓
	Why and when was data collection stopped, and is this reasonable?	End of data collection justified and described: *all available complete data was collected*	✓
S	**Soundness of interpretive approach**		
	Analysis		
	Is the type of analysis appropriate for the type of study?	Analytic approach described in depth and justified	✓
	Are the interpretations clearly presented and adequately supported by the evidence?	Statistical analysis conducted using appropriate test Analysis, presentation and interpretation provided	✓
	Discussion and presentation		

Is adequate account taken of previous knowledge and how the findings add?	Findings presented with reference to existing literature, and how they contribute	✓
Is the manuscript well written and accessible?	Evidence of following guidelines (format, word count) Written for a health sciences audience	✓



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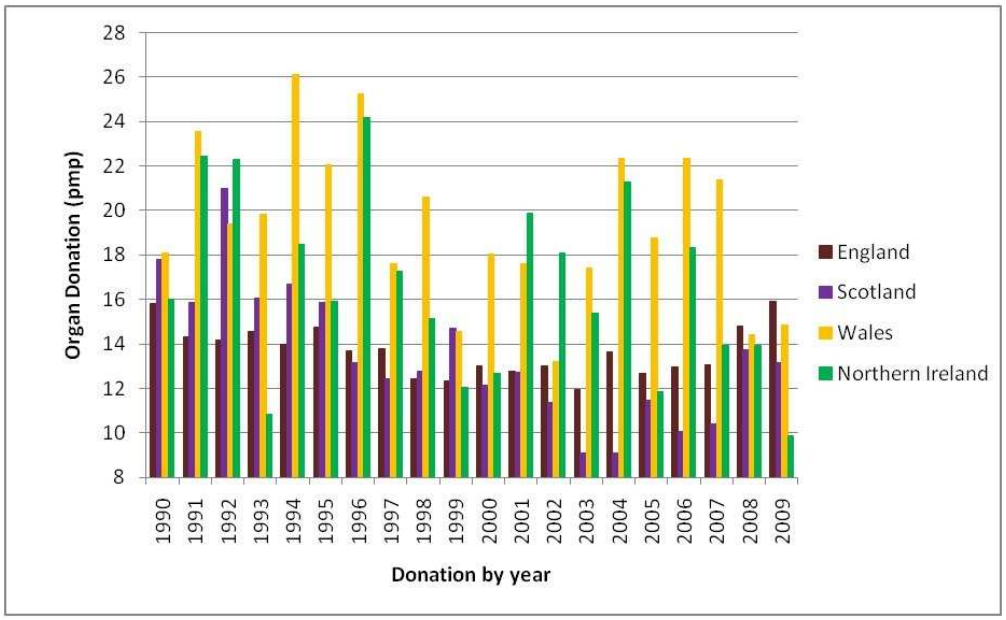

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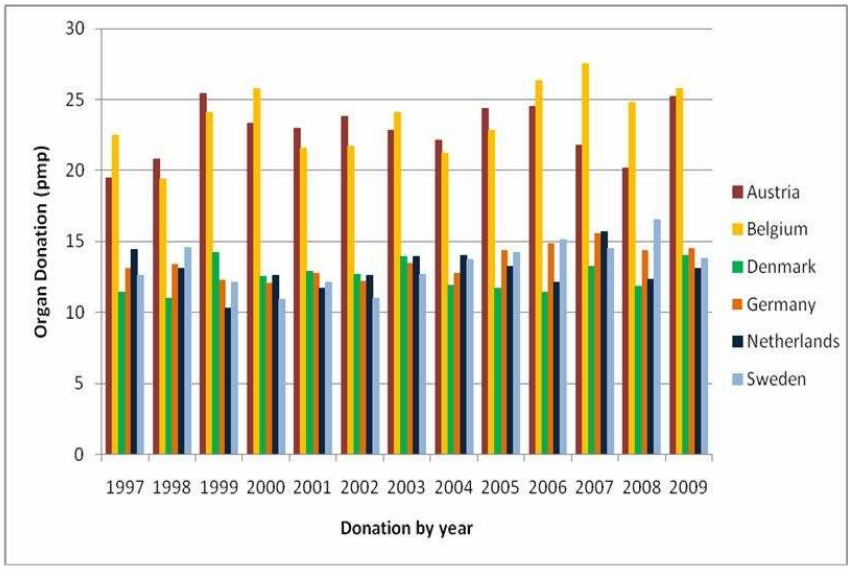

Figure 2

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Regional and temporal variations in organ donation across the UK: secondary analysis of databases

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Regional and temporal variations in organ donation across the UK

(Research: secondary analysis of databases)

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Key words: *organ donation, presumed consent, UK regional variations, EU organ donation*

Word count: 2621 words

Objectives: To explore regional variations in donation of cadaveric solid organs and tissues across the four devolved health administrations of the UK (England, Scotland, Wales & Northern Ireland).

Design: A secondary analysis of databases from NHS Blood & Transplant (1990-2009) and from the National Organ Procurement Service for the Republic of Ireland, Eurotransplant International Foundation and Scandiatransplant.

Results: After adjusting for time, statistically significant differences were found among the four regions ($p<0.001$) for liver donations. The only exceptions were between England and Scotland and between Wales and Northern Ireland where the differences were not significant following a Bonferroni correction ($p>0.008$). England had significantly fewer heart donations than both Wales ($p<0.001$) and Northern Ireland ($p = 0.005$). There were no significant differences among the four regions for lung donations. Regional variations in kidney and corneal donations were moderated by time. Northern Ireland, however, has had consistently lower corneal donation rates than the other three regions.

Conclusion: Organ donation rates over the last two decades vary in the four UK regions and this variation depends on the type of organ donated. Further exploration of underlying factors, organisational issues, practices and attitudes to organ donation in the four regions of the UK, taking into account findings from EU countries with varying approaches to presumed consent, needs to be undertaken before such legislation is introduced across the UK.

Article focus:

- To investigate organ donation of cadaveric solid organs and tissues across the four devolved health administrations of the UK and how they vary with time;

- To consider reasons for regional variations and those related to organ type, drawing on regional differences in culture and practice and on findings in other EU countries.

Key messages:

- organ donation and registration rates vary with time across the four regions of UK;
- heart and liver donations are highest in Wales and Northern Ireland;
- the significance of regional variations on kidney and corneal donation rates is moderated by the effect of changes over time; Northern Ireland consistently has the lowest corneal donation rate;
- the reasons for regional variations require further investigation as well as comparisons with practices and attitudes in other EU states

Strengths & limitations:

The strengths of this article are:

- its novelty, as this is the first article that has analysed data across the UK and shown patterns in donation rates in the four regions over the last two decades;
- its timeliness given the shortfall in organ donations, the continuing debate about presumed consent and its importance in investigating regional differences

The limitation of this article is:

- data from other EU countries, for the entire time period investigated, were not available

Introduction

Approximately 80-90% of the UK population support the principle of organ donation[1], yet only 29% of the population carry an organ donor card.[2] Despite advances in transplantation medicine, organ shortage is the single most limiting factor preventing potential recipients from receiving the benefits of transplantation.[3] If the overwhelming support for organ donation could be directly translated into a willingness to donate, this should bode well for a presumed consent system (allowing organs to be used for transplantation unless the individual has explicitly objected). However, interpretation of these findings is far from simple. This paper presents an analysis of data of organ donation and registration in the four regions of the UK for five organ types: kidney, liver, heart, lung and cornea in order to determine whether significant differences exist across the four regions and whether these vary depending on the organ. Any variations may be influenced by factors that could subsequently affect whether or not a presumed consent system, especially one that included the consent of relatives, were to be successful or whether it may create regional inequalities. Comparisons are made to European nations that have adopted presumed consent as well as to those that have not in order to see whether such factors may be discernable.

Methods

Information about all organ donations and registration in the four regions of the UK: England, Scotland, Wales and Northern Ireland was obtained from NHS Blood & Transplant for all available years: from 1990-2009. Data from other European nations was provided from the National Organ Procurement Service for the Republic of Ireland [4], Eurotransplant International Foundation [5] and Scandiatransplant [6]. Statistical analyses were carried out using Poisson regression (SPSS version 17). Bonferroni corrections were used to control for Type I errors when making inter-regional comparisons.

Results and Discussion

Regional variations in registration and donation

The UK currently operates a system of informed consent requiring individuals who wish to donate, to formally register their intention on a centralised register. Figure 1a shows that since the organ donor register was first launched in 1994, Wales has consistently outperformed other parts of the UK in terms of the percentage of population registered, with Scotland in second position, England third and Northern Ireland last. (A caveat is that although records are updated periodically to remove those who have died subsequent to being registered, organ donor registration rates may still include some entries of deceased individuals. This should not, however, affect regional variations).

When the registration rates are compared to donation rates, the trends are somewhat different. The rate of organ donation is consistently higher in Wales than the UK average for the majority of the last 20 years (Figure 1b). Donation rates in Northern Ireland are the second highest, achieving a higher than UK average in 13 of those years, with Scotland achieving this in 6 years and England capable of achieving this in only 3 years. So whilst registration and donation are both highest in Wales, amongst the other parts of the UK registration and donation do not follow similar trends. In Northern Ireland, for example, where willingness to register as an organ donor is lower than any other UK region, the organ donation rate is generally higher than in England or Scotland. It is also notable that whilst England exhibits the least variation in organ donation over the last two decades, Scotland shows an overall decrease in donation with trends in Wales and Northern Ireland varying from year to year with the greatest fluctuations in the latter.

Variations in donation according to organ type

Masked by general variations in donation are the figures for individual organs. Table 1 shows the rate of donation for each region of the UK for different organs. Poisson regression analyses were carried out on the numbers of organ donations (entries in Table 1 x the population for each country in that year expressed in millions) using the Generalized Linear Models program in SPSS Version 17. The offset was the natural logarithm of the total population for each country, which varied slightly from year to year. Separate analyses were carried out for each organ because donors may donate more than one organ and hence a single model analysis would violate the assumption of independent observations. Four different models were considered: the intercept only model, M0, which included no explanatory variables; model M1, which included the explanatory variable year (as well as the intercept); model M2 which included the explanatory variables year and country; and the full or saturated model M3 which includes the explanatory variables year and country and their interaction. Pairs of models were compared using the differences between their deviance values (ΔD). This statistic is a large-sample chi-squared statistic with degrees of freedom equal to the difference between the residual df values for the two model. Model M1 was a statistically significant improvement over model M0 and model M2 was a significant improvement over model M1 (in all cases the value of ΔD was significant at $p < 0.001$). In the case of liver, lung and heart, model M2 was not statistically significantly different from the saturated model M3. Since the two models have comparable fit, the former was selected on the grounds that it is the more parsimonious (requires fewer parameters to be estimated). Applying model M2 for the liver, Wales had significantly higher counts than England and Scotland (Wald chi-square 90.23, df = 1, $p< 0.001$; 65.12, df = 1, $p< 0.001$ respectively) and Northern Ireland had significantly higher counts than England and Scotland (Wald chi-square 21.34, df = 1, $p< 0.001$; 19.04, df = 1, $p< 0.001$, respectively). After a Bonferroni correction (six comparisons carried out, original alpha = 0.05, adjusted significance level = 0.05/6 =

0.008) there was no statistically significant difference between England and Scotland nor between Wales and Northern Ireland (Wald chi-square 0.506, df = 1, p = 0.477; 5.76, df = 1, p = 0.016). For the lung there were no statistically significant differences between the regions. In the case of the heart, England had significantly fewer donations than Wales and Northern Ireland (Wald chi-square 19.86, df = 1, p<0.001; 8.06, df = 1, p = 0.005, respectively). There were no significant differences between Scotland and the other three regions after applying a Bonferroni correction.

For the cornea and kidney, model M2 was a significantly poorer fit than the saturated model. (There was also substantial overdispersion as indicated by the values of D/df which was not corrected using a negative binomial as an alternative model). These findings suggest that for these organs the effect of country was moderated by year. For example, in the case of the cornea the donor rates per million for Scotland and Northern Ireland were quite close in 1991-92 (12.3 and 14.0 respectively) whereas in 2008-9 there was a substantial discrepancy (21.1 and 4.1 respectively). Inspection of the Poisson interaction term indicated that the difference between Scotland and Northern Ireland in 2008-9 (17.0) was significantly greater (p<0.001) than the difference between the two regions in 1991-92.

	Kidney				Heart				Lung				Liver				Cornea			
Year	E	S	W	NI	E	S	W	NI	E	S	W	NI	E	S	W	NI	E	S	W	NI
90-91	14.6	17.4	19.0	19.2	3.9	3.9	5.4	1.9	0.0	0.0	0.0	0.0	6.0	8.2	8.6	7.1	27.8	11.4	16.7	9.9
91-92	13.9	14.7	21.2	25.5	3.8	3.7	6.8	5.7	0.2	0.4	0.0	0.0	7.3	7.4	12.2	14.7	29.6	12.3	29.3	14.0
92-93	13.7	19.4	14.4	15.3	3.8	5.7	6.3	3.8	0.1	0.2	0.0	0.0	8.1	12.0	12.2	7.6	33.1	21.9	24.3	16.2
93-94	12.9	17.3	17.6	10.8	3.9	3.9	5.0	4.5	0.2	0.2	0.0	0.6	9.8	12.0	13.5	8.9	37.5	21.0	23.9	12.7
94-95	13.5	15.1	25.7	19.8	4.0	4.3	6.8	5.1	0.3	0.2	0.0	0.0	10.7	11.0	18.0	12.1	37.5	21.4	28.6	15.3
95-96	12.8	15.1	17.6	16.6	3.7	5.7	2.7	3.8	0.4	0.0	0.5	0.6	10.9	11.4	16.7	11.5	34.5	19.7	85.4	13.4
96-97	12.8	10.5	20.0	23.8	3.3	3.3	6.8	4.5	0.6	0.2	0.4	0.6	10.9	8.2	20.4	17.5	33.0	17.1	80.7	12.2
97-98	11.7	12.5	18.7	16.5	2.9	3.9	5.3	4.9	0.6	0.0	0.4	0.0	11.0	10.2	18.0	14.6	26.2	14.8	48.2	5.8
98-99	11.0	13.7	16.2	12.1	2.4	4.3	2.6	3.6	0.6	0.2	0.4	0.0	10.5	12.0	13.2	11.5	26.0	13.1	46.9	6.0
99-00	11.7	13.1	15.0	13.3	2.0	3.9	2.2	2.4	2.0	0.4	0.4	0.0	11.2	12.0	16.3	10.2	27.1	15.6	52.0	4.8
00-01	11.6	9.5	13.7	12.7	2.3	1.4	1.3	1.8	2.3	0.8	1.3	1.2	11.1	9.8	14.5	12.1	30.2	16.2	31.9	7.8
01-02	10.4	9.8	14.5	18.7	2.1	1.4	2.2	3.0	2.1	1.6	0.4	1.2	10.5	11.4	13.2	16.3	25.1	10.4	42.3	7.8
02-03	11.0	7.9	14.2	18.5	1.6	1.6	2.7	4.2	1.6	1.8	1.8	1.8	11.6	10.0	14.2	16.1	25.4	12.8	51.3	7.7
03-04	10.7	7.7	18.8	17.2	1.7	1.2	1.8	1.2	1.7	1.8	0.9	1.8	11.1	8.7	19.6	15.4	28.5	8.9	62.1	8.9
04-05	9.8	8.3	16.5	16.0	1.3	1.6	3.6	4.7	1.3	0.8	1.3	1.2	10.3	10.7	16.5	17.2	27.0	15.0	51.3	4.1
05-06	9.4	5.5	14.7	10.1	1.2	1.8	0.9	1.8	1.2	1.8	2.2	1.8	10.4	8.5	14.3	10.1	31.1	12.7	26.6	8.9
06-07	8.5	6.5	15.2	16.4	1.5	1.6	4.5	2.3	1.5	0.8	0.9	2.9	10.6	6.9	17.9	19.7	32.8	15.2	36.1	8.8
07-08	7.2	4.7	9.6	8.7	1.1	1.8	1.3	1.7	1.1	0.8	1.3	1.2	10.6	8.3	14.0	10.5	34.3	18.6	27.5	4.7
08-09	8.2	9.0	7.9	8.7	1.3	1.0	1.3	2.3	1.3	2.2	1.8	3.5	11.2	10.8	12.2	12.2	34.4	21.1	24.0	4.1

Table 1: UK Donor rates (deceased donors per million population) by organ type 1990-2009.
(E = England S = Scotland W = Wales NI = Northern Ireland)

The results show certain regional differences in donation for four of the organs. With regards to the liver, the Poisson analysis indicated that Wales and Northern Ireland had statistically significantly higher donor rates than England and Scotland. The rate of liver donation has been consistently highest in Wales for the past twenty years and Northern Ireland has contributed the second highest rate of donation for most of the years examined. Heart donations were also statistically significantly higher in Wales and Northern Ireland compared to England. With respect to heart donation, in the first decade examined, with the exception of 1995-6, Wales was the region with the highest overall donation rate until 1998 when it was overtaken by Scotland and/or Northern Ireland. One or both of these regions dominated in heart donations over most of the second decade studied (with the exception of 2003-4 and 2006-7 where Wales had the highest donations). The overall rate of heart donations has fallen over the twenty year period for Wales, Scotland and England; Northern Ireland shows fluctuations with no consistent trend.

In contrast to falling heart donation rates, the rate of lung donation has risen since 1990, with Northern Ireland being the greatest contributor over most of this period. This notwithstanding, there were no statistically significant regional variations in lung donations. It should be noted that lung as well as heart donations have been very low in number in all regions across all the years compared to other organs and this may reflect the fact that heart beating donors, on which heart and most lung transplants depend, have been decreasing for around a decade across the UK.[7]

Kidney and corneal donations showed significant regional differences but these were not consistent across the time period investigated, as indicated by the need to add an interaction term to the models. No discernable pattern emerges from the kidney donation data although it

is perhaps worth noting that for most of the first decade examined, England was the lowest contributor; in the second decade, with the exception of one year (2008-09), the lowest contributions came from Scotland.

The pattern for corneal donations shows a greater consistency for most regions except Wales, which contributed significantly more corneal tissue than the other regions between 1995 and 2005 but subsequently decreased to levels comparable to pre-1995 and to those of England. There is no obvious reason for this trend. Perhaps the most striking picture to emerge from the data shown in Table 1 is the low rate of corneal donations in Northern Ireland, particularly when compared with those of England and Wales. Scotland and Northern Ireland were very similar in corneal donations in the early part of the first decade examined but subsequently the gap increased.

The patterns seen with corneal donations may reflect attitudes based on culture and tradition as well as on lack of awareness of what eye donation involves. In Northern Ireland, and to a lesser extent in Scotland, the tradition of wakes and burial remains strong. Disfiguring the face of a deceased loved one before burial by removing the eyeballs, is unlikely to be accepted.[8] There is no eye bank or retrieval centre in Northern Ireland; if such as centre is ever established the effect of collecting eye tissue on facial appearance will require comprehensive explanation as studies show that procuring corneal tissue is erroneously considered to be a procedure that leads to disfigurement.[8-10] In Wales and England, where over 70% of deaths result in cremations (compared to around 60% of deaths in Scotland and 15% in Northern Ireland) [11], the issue of the facial appearance of the deceased may be of less importance. The presence of an eye bank would make it possible to procure corneal tissue locally, however, it has been found that appropriately trained and dedicated staff are

the most likely means of increasing corneal donations.[12-13] Co-ordinated organisation and appropriate policies and staff training would also improve consent to donation of other organs.[14-15]

It should be noted that in addition to differences in rates of donation of different organs, there are variations in their health status and in time limitations permitted for maintaining a status that is suitable for transplantation. For example, in the years 2009 to 2010, an average of 11% of all organs retrieved were not subsequently transplanted.[7] This applied particularly to the retrieval of lungs and liver. Although approximately 33% of all corneas recovered during the same period were deemed unsuitable for transplantation,[7] the cornea is more viable than the heart and lungs due to its ability to survive for an extended period of time in appropriate medium before transplantation. A confidential audit of deaths in England and Wales showed that approximately 92% of donors had a suitable cornea for donation, while 65% had a suitable heart for donation and only 31 per cent had suitable lungs for donation.[16]

Can parallels be drawn from the EU?

It has been suggested that at least 20-30 deceased donors per million population would be necessary to meet the UK's increasing demands.[17] The British Medical Association called for changes in legislation, suggesting a system of presumed consent that allows for objections of relatives.[18] The Organ Donation Taskforce was commissioned in 2008 to consider the potential effects of such legislation and concluded that a change to presumed consent at this time was unlikely to increase organ donation rates, may incur prohibitive costs and could result in a backlash; other factors needed to be considered before introducing legislative change.[19]

Bird and Harris modelled situations with varying relative refusal rates and drew on comparisons with EU countries that already adopted presumed consent systems.[20] However, presumed consent for organ donation has been implemented with varying effect in the EU. Adoption and successful implementation of laws in one country should not be taken as a guarantee of similar success in another. Hence, though Sweden applies presumed consent, its donation rate in 2009, at 13.8 deceased donors per million population,[6] was comparable to that of Germany (14.5 deceased donors per million population) and Denmark (14.0 deceased donors per million population);[5] both of which require informed consent (Figure 2). The figures available for Ireland, where informed consent is needed, were 21.2 deceased donors per million population in 2009.[4] The nation with the highest donor rate (34.4 deceased donors per million population in 2009) [21], and one often cited as evidence of successful implementation of presumed consent legislation [22], is Spain which operates a "soft" form of presumed consent where next of kin can object to organ donation.[21-22] Yet, the impact of the legislation has been questioned and the high rate of donor activity attributed to the "Spanish Model"[21-22] that demands an integrated approach with dedicated transplant co-ordinators, mainly intensive care physicians, involved in procurement.[22] This highly coordinated network and the respect for autonomy given to the individual and their relatives, is credited with improving donation rates of 14.3 deceased donors per million population in 1989 to rates of 33-35 deceased donors per million population in recent years.[21-22] The majority of donations in Spain are from heart-beating donors in intensive care; live organ donation and that from non-heart beating donors is relatively low.[22] The converse is true in the UK and estimates suggest that even if a theoretical upper limit were reached, with present facilities and practices, heart beating donor numbers in the UK would only reach half of those in Spain.[22] Given that Spain introduced presumed consent in 1979[3], it is clear that a legislative change alone was not sufficient to improve donation rates. It is notable that Spain achieves a significantly higher rate of donation than does

Austria [5] which relies upon a "hard" approach in which views of relatives are not routinely sought.

Comparisons across the EU further indicate that whilst a country may have relatively low overall donation rates, for certain organs the trend may be reversed. Sweden lags behind countries like Austria, Belgium, Germany and the Netherlands with regard to overall deceased donations but has had the highest kidney donation rate for the majority of the past 13 years.[5-6]

Conclusions

Data from the four UK regions show that organ donation rates vary over the last two decades and that for two of the organs, kidney and cornea, the significance of regional variations is moderated by variations in time. The cornea, in particular, shows shortfalls in donation rates from Northern Ireland. Further exploration of underlying regional differences and temporal variations in organ donation as well as organisational issues, practices and attitudes that may affect organ donation, needs to be undertaken before considering legislation to admit presumed consent. Comparison of EU nations, and particularly Spain, indicates that improvement of organ donation rates is unlikely to be achieved by introducing new legislation alone.

Provenance/Contributorship: Barbara Pierscionek is a Professor of Vision Science at the School of Biomedical Science, University of Ulster and is qualified in science and law. Gordon Rae is a Professor of Psychology at the School of Psychology, University of Ulster, and is trained in mathematics and statistics as well as psychology. Carol McClenahan is a lecturer in Psychology at the School of Psychology, University of Ulster and her expertise is in attitude and behavioural change in relation to health. Donal McGlade is currently

undertaking a PhD on attitudes that determine behaviour with respect to organ donation. All authors were involved in preparation of the manuscript. Barbara Pierscionek is the guarantor.

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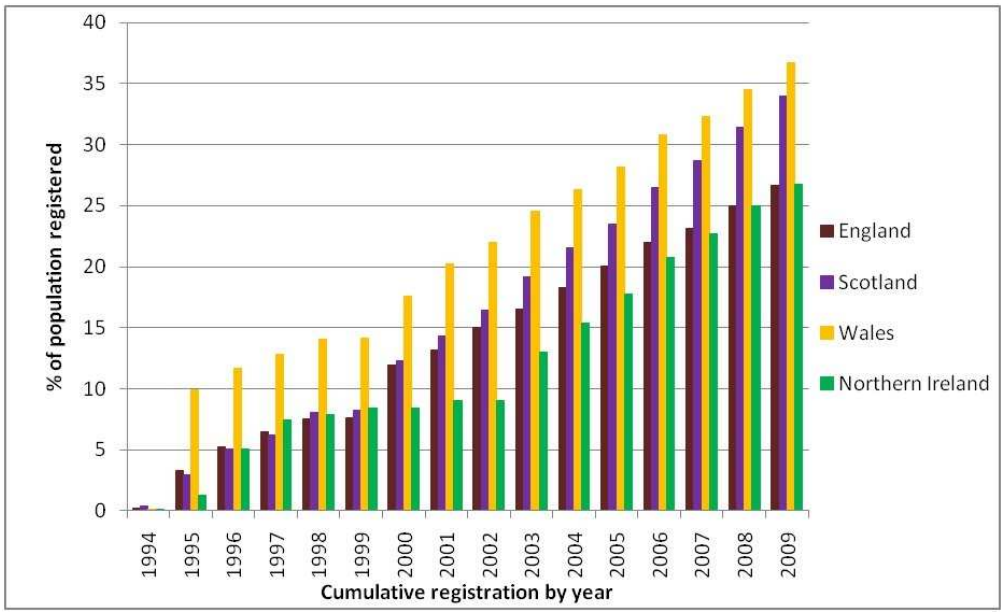
Figure captions

Figure 1: a) Organ donor registration rates in England, Wales, Scotland and Northern Ireland 1994-2009. b) Organ donation rates in England, Wales, Scotland and Northern Ireland 1990-2009.

Figure 2: Organ donor rates in selected EU countries 1997-2009.[5-6]



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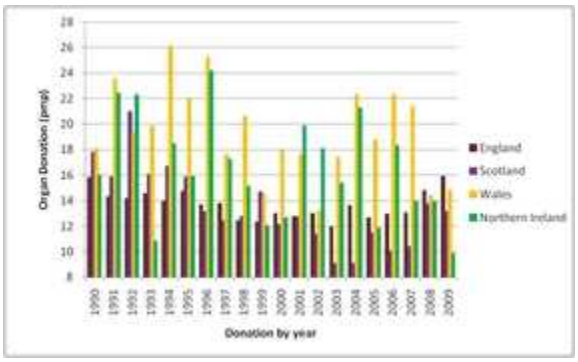

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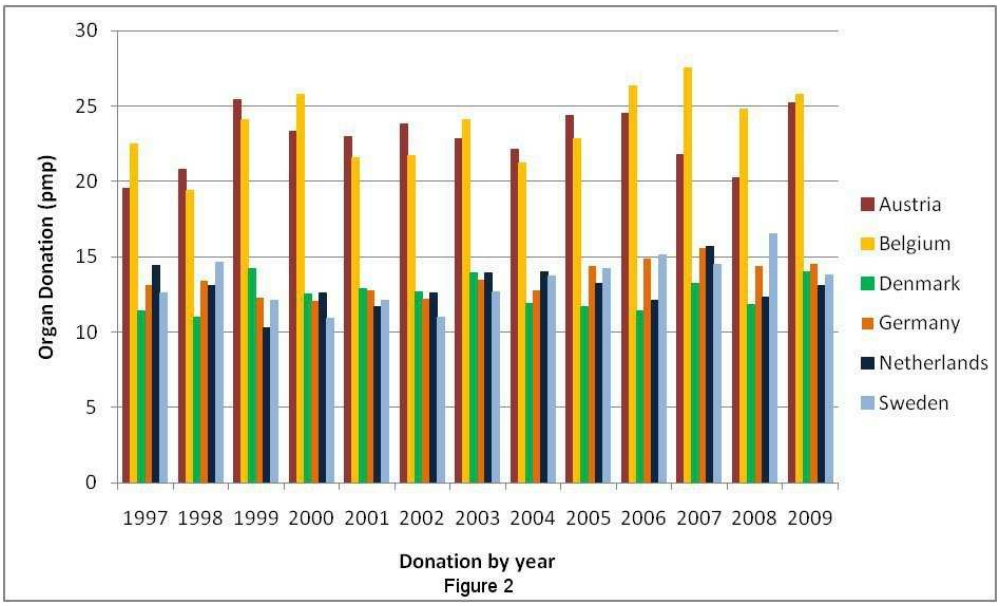

Figure 2

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Research review guidelines : modified from RATS guidelines

	ASK THIS OF THE MANUSCRIPT	THIS SHOULD BE INCLUDED IN THE MANUSCRIPT	✓ <>
R	**Relevance of study question**		
	Is the research question interesting?	Research question explicitly stated	✓
	Is the research question relevant to clinical practice, public health, or policy? *It is relevant to policy*	Research question justified and linked to the existing knowledge base (empirical research, theory, policy)	✓
A	**Appropriateness of the method**		
	Is the methodology used the best approach for the study aims?	Study design described and justified : *data for all organ donations and registrations was required in order to compare trends across the four UK regions.*	✓
T	**Transparency of procedures**		
	Data collection		
	Was collection of data systematic and comprehensive?	Method (s) outlined : *all available data from centralized sources collected*	✓
	Why and when was data collection stopped, and is this reasonable?	End of data collection justified and described: *all available complete data was collected*	✓
S	**Soundness of interpretive approach**		
	Analysis		
	Is the type of analysis appropriate for the type of study?	Analytic approach described in depth and justified	✓
	Are the interpretations clearly presented and adequately supported by the evidence?	Statistical analysis conducted using appropriate test Analysis, presentation and interpretation provided	✓
	Discussion and presentation		

Is adequate account taken of previous knowledge and how the findings add?	Findings presented with reference to existing literature, and how they contribute	✓
Is the manuscript well written and accessible?	Evidence of following guidelines (format, word count) Written for a health sciences audience	✓