Institution: University of Stirling

Unit of Assessment: 3. Allied Health Professions, Dentistry, Nursing and Pharmacy

Title of case study: Providing the evidence base to support the move to opt-out organ donation legislation in Scotland

Period when the underpinning research was undertaken: 2010-2019

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	**Role(s)**	**Period(s) employed by submitting HEI:**
Ronan O’Carroll	Professor of Psychology	1996-99, 2003-2020

Period when the claimed impact occurred: 2010-2020

Is this case study continued from a case study submitted in 2014? No

1. Summary of the impact

There is a world-wide shortage of organ donors. One donor can save the lives of up to 9 people. In Scotland, every year approximately 500 people are on the waiting list for an organ transplant and many die while waiting or are removed from the list due to deteriorating health. While 90% of the adult population support organ donation in principle, only 50% have opted-in to the Organ Donation Scotland donor register. Arguments in favour of “opt-in” versus “opt-out” consent organ donation systems have been based on limited and controversial evidence. Scotland currently operates an opt-in organ donor system, which will change to an opt-out system on 26th March 2021. Our research provided key evidence that informed the decision to change from opt-in to opt-out under the Human Tissue (Authorisation) (Scotland) Act 2019, which was passed by the Scottish Parliament on the 11th of June 2019.

2. Underpinning research

Focus on the individual

One obvious solution to the organ donation problem is for more people to agree to donate their organs after death, rather than having them cremated or buried. However, only half of the population in Scotland have signed up to be organ donors after death. Many initiatives to encourage more people to become organ donors focus on trying to provide persuasive factual information/evidence about the need for organ donation. Over the last 12 years, our research has consistently demonstrated that ***feelings/emotions*** such as discomfort at contemplating one’s own death, medical mistrust, fear of life-support machines being switched off prematurely etc. rather than facts/evidence are key deterrents to registration as an organ donor. Funded by the Scottish Government and working in partnership with NHS Blood & Transplant (NHSBT) UK, we conducted a very large randomised controlled trial with 14,500 members of the general public where we attempted to increase organ donation rates by focusing on feelings rather than facts. We targeted the feeling of regret, as many other studies have found that anticipating regret acts to significantly increase the desired health behaviour, e.g. cervical screening uptake. Participants randomised to the intervention arm were asked to consider possible future regret if they did not register as an organ donor. We used new verified registrations on the UK organ donor register as our primary outcome and paradoxically, found that relative to the control conditions, this anticipated regret intervention *decreased* organ donor registrations (**R1**). While feelings/emotions are important barriers to organ donation, attempting to manipulate anticipated regret did not increase donation rates.

Focus on the family

A further possible target for intervention is to focus on the family rather than the individual. This is because the role of the next-of-kin is crucial and controversial. They have the power in a “soft opt-out system” (which will be used in Scotland and the rest of the UK) to overrule the wishes of the deceased potential organ donor. The family refusal rate in the UK is around 32% and is amongst the highest in Europe. We demonstrated that concerns about later regret for not agreeing to donation, disgust and the perceived benefits of donation were key determinants influencing the next-of-kin decision. Family members were much more likely to be willing to permit the donation of their loved one’s organs when the patient had actively registered to be an organ donor (**R2**).

Focus on legislation

Rather than interventions that focus on targeting the individual or family, an alternative strategy adopted by many countries (e.g. Wales and England) has been to change to opt-out organ donation legislation. This system presumes consent to organ donation, "deemed consent" unless the individual actively opts-out. Automatically being on the organ donor register becomes the "default" position. However, there is significant concern that many people may react against this default legislative change as it can be perceived as automatic "state control" of one's organs – removing the individual's decision to choose to give. In the Netherlands, 30,000 people opted-out of the register the day after the opt-out law was introduced and 22% of the Scottish population have indicated that they intend to opt-out when the law changes. We have attempted to gain a better understanding of why so many people are motivated to opt-out by interviewing those who plan to do so. Key factors to emerge include heightened concern over the issue of presumed consent and government control, loss of autonomy, together with fears of criticism and potential stigma if one decides to opt-out (**R3**). We then tested the impact of a "myth-correcting" intervention (as used on the current UK NHSBT organ donation website) for those who plan to opt-out in Scotland. This involved asking participants to answer questions about common myths and fears surrounding organ donation (e.g. "the doctors might turn off the life support machine before I am dead") and we then provided corrective information. We found that this myth-correcting intervention reliably increased intention to donate – **but** only in those supportive of organ donation – it had the *opposite* effect in our key target group, those who plan to opt-out. Paradoxically the myth-correcting intervention seemed to evoke reactance and strengthen the resolve of those who plan to opt-out (**R4**). As a result, we have now turned our attention to this key issue of reactance and systematically evaluated the type of text/narrative that could be used in public health campaigns to support a move to opt-out. In a randomised controlled trial with 1,350 members of the general public, we found that using high threat text (use of forceful adverbs and imperatives) coupled with a gain frame (focus on number of lives saved by transplant) significantly increased intentions to donate under opt-out, whereas a high threat/loss frame (focus on number of lives lost awaiting a transplant) reliably reduced intentions (**R5**). This research identified optimal communication styles to reduce reactance and decrease the number of people who opt-out when the law is implemented.

Opt-in versus Opt-out – systematic review of the international evidence

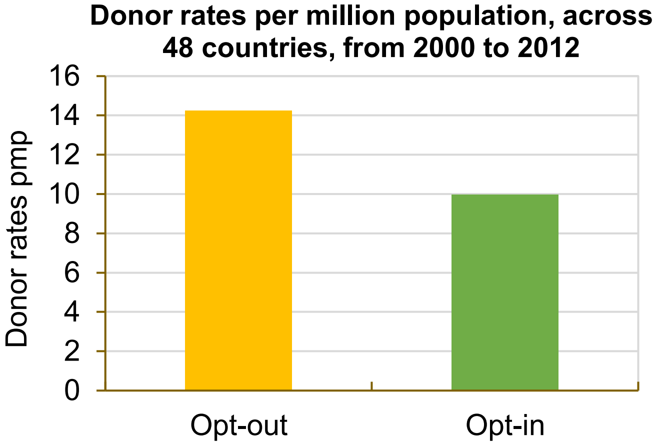


Figure 1 [source: Table 5 in R6]: The impact of opt-out consent on organ donation rates (per million population; in 48 countries) 2000-2012. Countries with an opt-out system have a significantly higher rate of deceased donations.

In 2008, Gordon Brown, the then Prime Minister, publicly signalled, for the first time, support for an opt-out organ donation system as a way of improving the poor rates of organ donation in the UK. However, at the same time, the 2008 UK Organ Donation Taskforce concluded that "*no convincing evidence*" was available to suggest that implementing an opt-out system would act to increase rates of donation and transplantation. The move to an opt-out system, at first glance, seems a very simple and logical solution, using the power of defaults ("nudge" approaches) to change behaviour. However, the evidence base supporting this strategy is conflicting and controversial e.g. in 1998 Brazil had to reverse their move to opt-out following public outcries about this move to "state ownership of organs" and Germany recently voted against adopting opt-out organ donation legislation. In an attempt to bring clarity to this key issue, we conducted the definitive systematic review of the international evidence on opt-in versus opt-out legislation using longitudinal data from 48 countries over a 13-year period. We used multi-level modelling controlling for all important confounders, including GDP, number of hospital beds, road traffic accident fatality rates etc. We found that internationally, a change to an opt-out policy resulted in significantly more deceased organ donations (**R6**; Figure 1). This work has been cited extensively as key evidence supporting the move to opt-out legislation in Scotland and internationally.

3. References to the research. UoS authors in bold text.

R1. O'Carroll RE, Shepherd L, Hayes PC & Ferguson E (2016) Anticipated Regret and Organ Donor Registration: a randomised controlled trial. *Health Psychology,* 35(11):1169-1177. DOI: 10.1037/hea0000363.

R2. Shepherd, L., & O'Carroll, R. (2013). When do Next-of-Kin Opt-In? Anticipated Regret, Affective Attitudes and Donating Deceased Family Member's Organs. *Journal of Health Psychology*. 10.1177/1359105313493814.

R3. Miller, J., Currie, S., McGregor, L. M., & O'Carroll, R. E. (2020). "It"s like being conscripted, one volunteer is better than 10 pressed men': A qualitative study into the views of people who plan to opt-out of organ donation. *British Journal of Health Psychology*, *9*(4):e025159. DOI: 10.1111/bjhp.12406.

R4. Miller J, Currie S & O'Carroll RE (2018). 'What if I'm not dead?' – Myth-busting and organ donation. *British Journal of Health Psychology,*4,1316-1318. DOI: 10.1111/bjhp.12344.

R5. Miller J, McGregor L, Currie S & O'Carroll RE (2020) Investigating the effects of threatening language, message framing and reactance in opt-out organ donation campaigns. Presentation at the European Health Psychology Conference 26th August 2020 https://ehps.net/ehps2020online/ and *Annals of Behavioral Medicine* (in press).

R6. Shepherd L, O'Carroll RE, Ferguson E (2014). An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study. BMC Medicine 12(1):131. DOI: 10.1186/s12916-014-0131-4.

Grants

G1 Chief Scientist Office Grant. PI: **O'Carroll**. Partners: Ferguson, **Shepherd**. A randomised controlled trial to test if a simple Anticipated Regret manipulation leads to a significant increase in organ donor registration (CZH/4/686). £162,650.

G2 NHS Blood & Transplant Epidemiology Unit Award. PI: Fergusson. Partners: **O'Carroll**, Lawrence, Noyes. Evidence in support of individualized risk assessment. 2019-20. £70,000.

G3 British Academy Award. PI: **O'Carroll**. Partners: **Livingstone**. Implicit attitudes as barriers to registration as an organ donor. 2011-14. £7,483.

4. Details of the impact

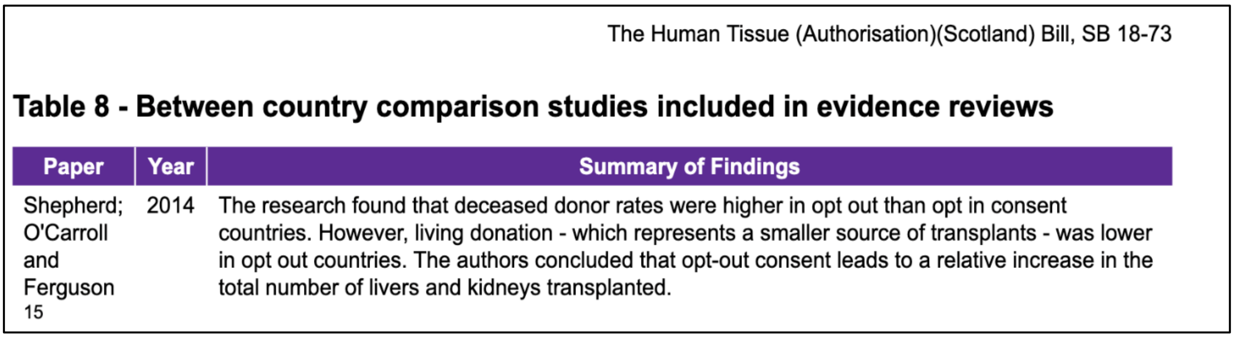
Our work on the change to opt-out organ donation is directly linked to the decision to introduce an opt-out system of organ donation in Scotland, the implementation of which was delayed because of Covid-19 to March 2021. O'Carroll was invited to present evidence to the Scottish Government Policy Team to discuss a move to an opt-out system (**S1**). He was then asked to advise the Scottish Government on a scoping review of the international evidence (**S2**). The Government scoping review (**S2**) provided the essential evidence for the legislation to move to opt-out organ donation in Scotland. Only three people are acknowledged in this review for their support, O'Carroll is one of these: "Thanks are due to several people for their input and advice … Ronan O'Carroll, Stirling University, for providing support in scoping out the review" (**S2**). Key evidence in the Scottish Government's review was our systematic review (**R6**) of the international evidence of 48 countries over 13 years where we found significantly higher donation rates in opt-out countries. This study was the most recent, largest and most comprehensive systematic review of the international literature. A further study, on factors influencing next-of-kin decision-making (**R2**), was also cited. Our papers (**R2** & **R6**) are the most cited (10 times) research in the Scottish Government review e.g.:

> "Shepherd et al (Shepherd; O'Carroll and Ferguson, 2014) [**R6**] conducted a statistical analysis comparing opt in and out countries in terms of both deceased and living donation. The evidence suggests that deceased donor rates (per million population) were higher in opt out than opt in consent countries However, they found that living donation, which generally represents a smaller source of transplants, was lower in opt out countries." (**S2,** p.11).

> "Shepherd et al found that family members were much more likely to be willing to permit the donation of their loved one's organs when the patient had registered to be a donor (Shepherd & O'Carroll, 2014) [**R6**]." (**S2,** p.24).

This review directly informed the Scottish Parliament (SPICe) Briefing paper (**S3**), which is written for and used by Members of Parliament and their personal staff to inform the legislation process. This stated:

> "The Scottish Government's rapid review also looked at published research since 2012. The following table [Figure 2] summarises the findings of the most relevant and robust research found in each review. This is limited to studies which examined actual donation rates as opposed to proxy indicators such as willingness to donate." (**S3,** p.24)



The Human Tissue (Authorisation)(Scotland) Bill, SB 18-73

Table 8 - Between country comparison studies included in evidence reviews

Paper	Year	Summary of Findings
Shepherd; O'Carroll and Ferguson [15]	2014	The research found that deceased donor rates were higher in opt out than opt in consent countries. However, living donation - which represents a smaller source of transplants - was lower in opt out countries. The authors concluded that opt-out consent leads to a relative increase in the total number of livers and kidneys transplanted.

Figure 2. Summary of Stirling evidence presented in SPICe Briefing (**S3**, p.25).

A previous Scottish Government SPICe Briefing (**S4**), only cites five academic sources: one of these is our systematic review (**R6**). The Briefing's section (**S9**, pp.11-14) on international comparisons of opt-out systems and donor rates is directly and only informed by our research. This Briefing, while written to support an earlier iteration of legislative reform ((The Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill, that did not become law)) was then cited in and supported the Government scoping review (**S2**) that underpinned the Human Tissue (Authorisation) (Scotland) Bill.

Our systematic review therefore provided the most definitive evidence that moving to an opt-out organ donation system will make more organs available, and ultimately save more lives. There is thus clear evidence that this UoS research has had a major impact on the change to legislation in Scotland – the Human Tissue (Authorisation) (Scotland) Act 2019, NHS Policy and Guidelines (**S5**).

A Scottish Government Research Officer employed to evaluate the move to an opt-out system, confirmed that the UoS research was crucial and informed the move to an opt-out system:

> "[T]he Stirling [O'Carroll] paper [**R2**]. …points to certain/various factors, affective factors that might actually influence those decisions of behalf of loved ones so, … it definitely forms part of our understanding and the kind of contextual behavioural factors… it's an important piece. … [W]hat is useful about the Stirling research as well as a lot of the research we've used it that gives a broad, multi-faceted picture of what the state of play is currently.*"* **(S6)**

Impact on NHS Policy and Guidelines

The National Institute for Health and Care Excellence (NICE) is the key national body for health service research policy, impact, translating research evidence into NHS recommended policy and practice. As a direct result of the societal impact of UoS research, O'Carroll was invited and served on the UK NICE organ transplantation clinical guideline development group (2010, 2014, 2016). As the sole psychologist on the clinical guideline development group, O'Carroll played a key role in proposing NICE research priorities for the NHS e.g.:

> "2.1 Reasons for refusal for consent - Why do families refuse to give permission for organ donation? "High-quality research using mixed methodology is needed to identify the reasons behind family refusal to see if there are factors that are changeable (for example, poor understanding of the process, medical mistrust, 'knee-jerk' response that is later regretted)." (**S7,** p.84, **S8**).

International impact

Our systematic review of opt-in/opt-out (**R6**) has now been cited 169 times and has an Altmetric score of 145. Our "myth-busting" paper (**R4**) has an Altmetric score of 106, placing both in the top 5% of research outputs scored. The systematic review has been used extensively in key debates internationally regarding the evidence base for a move to an opt-out organ donor legislative system, e.g. policy documents in the United States, European Union, and Northern Ireland (**S9**). The Netherlands recently moved to an opt-out system and our work was cited in the Parliamentary paper supporting this move:

> "The most comprehensive and recent comparison between 48 countries with data over a 13-year period shows that countries with an opt-out system have more post-mortem organ donors than countries with an opt-in system. In this study, adjustments were made for religion, number of IC beds, GNP, and number of road casualties. Furthermore, the recent study concludes that opt-out systems can be related to an increase in the willingness to donate and an increase in the number of organ donations." (**S10**).

5. Sources to corroborate the impact

S1 **Email invitation to give evidence to Scottish Government 14th Feb 2017.**

S2 **Scottish Government review of the evidence for a move to opt-out legislation in Scotland.** Niven, J., & Chalmers, N. (2018). Opt-Out Organ Donation: a rapid evidence review; Scottish Government report. ISBN: 9781788519229. http://stir.ac.uk/37t (see page references in Details of Impact section above).

S3 **Robson, K., (2018) SPICe Briefing paper - The Human Tissue (Authorisation)(Scotland) Bill, 18-73.** http://stir.ac.uk/37u

S4 **Rennick, L., (2015) SPICe Briefing Transplantation (Authorisation of Removal of Organs Etc) (Scotland) Bill, 15/75.** https://www.parliament.scot/ResearchBriefingsAndFactsheets/S4/SB_15-75_Transplantation_Authorisation_of_Removal_of_Organs_Etc_Scotland_Bill.pdf

S5 **The Human Tissue (Authorisation) (Scotland) Bill**. This Scottish Government Bill was introduced by the Cabinet Secretary for Health and Sport, Shona Robison MSP, on 8 June 2018. The Bill passed Stage 3 on 11 June 2019. Received Royal Assent on 18 July 2019. http://stir.ac.uk/37w

S6 **Interview with Scottish Government Research Officer.**

S7 **Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation – full guideline** http://stir.ac.uk/37v Section 3.2, p.4**.**

S8 **British Medical Journal summary of NICE guideline recommendations.** Chamberlain, K., Baker, M. R., Kandaswamy, P., Shaw, E. J., McVeigh, G., & Siddiqui, F. (2012). Donor identification and consent for deceased organ donation: summary of NICE guidance. *BMJ*, *344*(jan12 4), e341–e341. http://doi.org/10.1136/bmj.e341.

S9 **Altmetric documentation of international policy documents.**

S10 Translated from the original Dutch: Parliamentary paper (Netherlands) Bill to amend the Organ Donation Act in connection with the inclusion of an active donor registration system, Senate of the States General, 3rd February 2017, Chamber File 33506. https://zoek.officielebekendmakingen.nl/kst-33506-G.html (in Dutch).