**DO COUNTRIES WITH AN OPT-OUT ORGAN DONATION SYSTEM HAVE BETTER ORGAN DONOR RATES AND/OR TRANSPLANTATION ACTIVITY? AN EMPIRICAL ANALYSIS OF OECD COUNTRIES**

**INTRODUCTION.** The Department of Health and Social Care has launched a consultation as part of the planned introduction of a presumed consent (also termed opt-out) system in England to mirror the change made in Wales. However, debate continues as to whether a switch from opt-in to opt-out alone is sufficient to increased organ donor rates, with empirical evidence to that effect is lacking. The aim of this study was to analyse countries with opt-in versus opt-out organ donation systems, factoring in important country-specific confounding variables, to ascertain if any significant difference in organ donation/transplantation rates is evident.

**METHODS.** This panel study utilised secondary data analysis to compared organ donor and transplant rates among the 35 countries registered with the Organisation for Economic Co-operation and Development (OECD). Organ donation/transplantation rates from latest available year (2016) were extracted from the Global Observatory for Donation and Transplantation (GODT), with any missing data sought from the International Registry in Organ Donation and Transplantation (IRODaT). Other variables analysed included; population, Gross Domestic Product, Road Traffic Accidents, legal system, religious affiliation, education, hospital beds, debt (household and Government, tax on personal income and health spending. Sources for this data included; OECD website, World Health Organisation, Pew Research Centre and the UN Department of Economic and Social Affairs. Multiple linear regression analysis was undertaken using STATA 15 statistical software.

**RESULTS.** Out of our 35 OECD-registered countries, minimal data was available for Luxembourg and was therefore excluded from further analysis. From our remaining 34 countries, 16 were classified as opt-out (or presumed consent) countries if the national organ donation infrastructure included a mechanism for registering opt-out wishes, with the remaining 18 classed as opt-in countries. Opt-out countries exclusively practised civil law systems compared with opt-in countries (100.0% versus 61.1% respectively, p=0.004), with 38.9% of opt-in countries having a common law system. The was no statistically significant difference between opt-out versus opt-in countries in the following social and economic variables; Gross Domestic Product, Road Traffic Accidents, religious affiliation, % achieving tertiary education, hospital beds, household debt, Government debt, tax on personal income or health spending. Comparing opt-out to opt-in countries, we observed no significant difference in deceased-donor kidney rates in per million populations (29.2 versus 23.6 respectively, p=0.373) but opt-out countries had significantly less living kidney donor rates (4.6 versus 16.3 respectively, p<0.001). Overall there was no difference kidney transplantation rates between opt-out versus opt-in countries (33.8 versus 39.9 respectively, p=0.248). When overall solid organ transplantation activity was analysed, we observed no significant different in total transplantation rates between opt-out versus opt-in countries (60.0 versus 61.9 respectively, p=0.523). In a multivariate linear regression model, adjusted for country-specific variables, countries with opt-out organ donation systems were independently predictive of increased deceased donor kidney transplantation rates (ß = 24.2 [95% CI 1.1 - 47.2], p=0.042) but decreased living donor kidney transplantation rates (ß = -8.6 [95% CI -0.8 - -16.5], p=0.034). However, no significant difference was observed in overall kidney transplantation or total solid organ transplantation activity stratified by whether countries had an opt-out or opt-in organ donation system.

**DISCUSSION.** Countries with opt-out registration systems have better deceased-donor kidney transplantation activity but worse living donor kidney transplantation activity, independent of country-specific social, economic or infrastructural factors. However, overall kidney (and solid organ) transplantation is no different. Our data suggests a change in organ registration system across England may not automatically lead to increased kidney transplantation activity. With living kidney donation rates already on the decline, the proposed introduction of presumed consent across the rest of the UK must be balanced with additional resource to promote living kidney donation. In addition, strategies to improve consent may be more beneficial than changes in organ registration systems to improve overall kidney transplantation activity.