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Introduction

The worldwide demand for donated organs and tissues has grown substantially, driven by the steady addition of new organs to transplantation repertoire. The first successful corneal transplantation is now over a century away (1906), subsequent opportunities arriving spasmodically (kidney, 1954) and then latterly at a faster pace (liver, heart, pancreas, lung, intestines, hand, face, etc). Technical innovations automatically generate increasing demand but supply remains a problem resulting in yet further health service waiting lists. Advances in donation numbers have been halting and securing more organs for transplantation presents a major health challenge. This quest has met with considerable variation across continents, countries and regions. 'League tables' of high and low performers abound in the professional and popular literature, as do explanations for relative success or failure (Johnson and Goldstein, 2004; Abadie and Gay, 2006). Spain is customarily positioned as the clear world leader in the donation league tables, with UK, Germany and Sweden bringing up the rear. To date, research has struggled to understand these disparities and the reasons behind them and major policy modifications seem unable to overcome them.

Although quite unique in its procedures and practicalities, deceased organ donation shares in the complexities experienced in the delivery of all services in modern medicine. The ultimate outcome (transplantation) requires the coordinated effort of hundreds of players (patients, donors, recipients, families, physicians and surgical teams from assorted departments and institutions), often operating with different motivations and objectives. Understanding the requisite processes and interactions has drawn on conceptual schemas extracted from clinical, management, social science and public health theories (Steiner, 2008). For all these reasons we are confronted with a prime example of a complex adaptive system in health care (Plsek and Greenhalgh, 2001). Multiple, self-adjusting, unpredictable and interacting pathways operate in the death-to-donation-to-transplantation process.

This methodological paper offers an initial framework for evaluating the effectiveness of transplant coordination regimes. Our approach is based in a strategy known as 'programme theory evaluation', a tradition that is commonplace in the study of social interventions (Chen and Rossi, 1980; Coryn *et al.*, 2010) but less widely used in bio-medical evaluation (Pawson and Sridharan, 2010; Funnell and Rogers, 2011). This approach is also known as 'theory-based' or 'theory-driven' evaluation (Atsbury and Leeuw, 2010; Donaldson, 2007; Leeuw, 2003; Rogers *et al.*, 2000; Pawson and Tilley, 1997; Weiss, 1995, 1997). Put simply, research designs begin by eliciting the ideas, the planning or the 'programme theory' that has gone into the making of an intervention and then move to a period of sustained empirical investigation whose purpose is to gauge the extent to which the theories are met in practice. In complex systems, all manner of practical flows, blockages, inconsistencies and insynchronicities will confront the programme theory. The research builds up a picture of how these contingent forces shape the effectiveness of an intervention, which can then be fed back to practitioners in order to help improve their service.

More specifically, programme theories are the sets of ideas and assumptions, which professionals and practitioners use in the planning and execution of interventions. The

programme theory spells out the coordinated sequence of activities A, B, C, etc. that are thought to be necessary in achieving the programme goal Z. The evaluative component lies in a process of electing and mapping the ideas that have gone into the making of an intervention (Leeuw, 2003; McLaughlin and Jordan, 2004) and then going on to test empirically how the ideas are put into practice and whether they are sufficient to achieve the intended outcomes. The tests of programme theories normally requires a multi-method evidence base (quantitative, qualitative, comparative, documentary, etc) and have the aim of seeking 'lateral support' for a theory rather than manufacturing all-conclusive 'facts'(Pawson, 2013).

We build on this strategy in three ways. The first part of the paper uncovers the stunning complexity of the programme logistics that are involved in donation and transplantation services. It turns out that the process is not as simple as A, B, C but has an iterative, recursive structure involving the coordination of a multiplicity of stakeholders with different and sometimes competing interests. The second part of the paper contrasts the subtleties and complexities involved in this everyday drama of donation with the 'single-lever' and 'nudge' theories that have dominated recent policy thinking in the UK about how to overcome the donation shortfall. Many contemporary policy recommendations suggest a reform of parts of the donation regime without considering their place in or effect upon the whole system. The final section is a more speculative piece indicating how the programme theory approach might be used to improve the design and implementation of donation services. Programme theories can act as: i) a 'drilling rig' allowing us to penetrate down the micro-processes on which improvement depends, and ii) a 'bridgehead' facilitating the construction of cross-national comparisons that allow us the tease out the elements of best practice.

1. Organ Donation and Transplantation as a Complex Adaptive System

A complex adaptive system is a collection of individual agents with freedom to act in ways that are not always totally predictable, and whose actions are interconnected so that the action of one part changes the context for other agents (Plsek and Greenhalgh, 2001). The dynamics of these multiple, diverse and interconnected elements imbue any attempt to change the system with significant unpredictability. In complex, open systems like the donation/transplantation process, any innovation must be understood as an adaptation to a system rather than a novel treatment aimed at a fresh outcome. To predict and test the efficacy of an 'improvement' targeted at one aspect of the system requires knowledge of the whole system.

To illustrate the point, Figure 1 shows a basic programme theory of the steps needed for a successful death-to-donation-to-transplantation regime within acute hospitals. This 'logic map' was derived in a scoping study, which involved dialogue with key stakeholders (national and local procurement organisations, donor and recipient charities, healthcare staff, members of the public, etc) in the UK and Spain, and a synthesis of core planning and service delivery documentation. Like all 'ideal-type' models it is itself a simplification (Weber, 1949). Its purpose is to highlight and accentuate the number of steps needed to

achieve the anticipated changes, the relationships among them and how these facilitate or hinder progress. Later in the paper we will add various overlaps and non-linearities, as well as providing more detail in showing how each step is a complex system in itself.

Our immediate aim is to describe, at first approximation, the intricacies of the organ donation implementation chain in order to show that improvement of the whole depends on a close understanding of the parts. The coordination of the parts is the key and, in this respect it is interesting to note that in most countries a dedicated 'transplant coordinator' has become part of best practice for overseeing the project from screening to organ retrieval. This model commences in the hospital and sets aside, for the moment, pre-existing public attitudes to donation and prior social marketing efforts to influence them.

[Figure 1 about here]

1. The donation process in hospitals has as clinical point of origin when patients enter the institution with a devastating brain injury and they are maintained on a ventilator. When patients are comatose, they require artificial ventilation and they have unresponsive dilated pupils, it is deduced that brain death is likely. If the patient is confirmed brain dead, donation after brain death (DBD) could be organised. If the patient is not brain dead yet but his/her injuries are non-survivable, donation after circulatory death (DCD) will be under consideration. Significant antecedents thus need to be in place before the donation teams appear in the process and DBD and DCD encounter a distinct set of operational (NHS Blood and Transplant, 2010), legal (Lock and Crowley-Makota, 2008) and ethical challenges (Manara *et al.*, 2012). All of these decisions are complex and many-sided and are made by different combinations of staff acting in different hospital locations. Making a diagnosis of brain death is not straightforward and perceptions and definitions continue to be contested. For instance, brain death was only legally recognised as end of human life in Japan in 1997 and DCD is unlawful in Germany. In short and from the beginning, a complex calculation ensues on what is in the best interest of the patient and best practice in preserving the organs.

2. Donors with poor prognosis of survival, by whatever route, then need to be admitted into intensive care units for assessment and organ maintenance. It is the task of professionals in intensive care units, wards and emergency rooms to acknowledge and verify the presence of a potential donor but the availability of intensive care beds is also at stake. Donor detection and referral is, therefore, the second step in our model, itself significant in determining how many families are subsequently approached by hospital staff to consider donation. The calculation is once again complex and driven by immediate contingencies and local circumstances. For instance, intensive care practitioners working in institutions with low bed capacity, as in some UK hospitals, might not admit patients with a poor prognosis in favour of patients more likely to benefit from intensive care (Fabre *et al.*, 2010).

3. Once a potential donor is identified and housed, stage three is to determine suitability for donation through a process of donor assessment. This consists of a thorough medical and social history, physical examination, serologic testing, etc. Physicians not only decide who should receive organs but have a complex calculation to make on who can donate them. The standards adopted and actual practices vary considerably across countries but donor

eligibility criteria are based essentially on age and medical history. Expanding the donor pool is a fast moving science with older individuals and those with co-morbidities and infections now being accepted as donors (Lopez-Navidad and Caballero, 2003; Caballero *et al.*, 2012a).

4. Stage four represents the pivot of the mode – the need to establish consent for organ donation. In terms of decision-making, it is the most complex component, involving as it does a balancing act of the wishes and expectations of a variety of stakeholders. We produce a separate model of the micro-processes involved later in the paper. Here we note the key dynamic. Wishes to donate may have been clearly expressed by patients but frequently this is not the case and families normally act in proxy to express the person's wishes. Families are thus confronted with the dilemma of whether to consent or to refuse to donation in an enormously tragic moment. Decision making is febrile under these circumstances – sudden death, violent death, age of the patient, cultural practices, parental involvement, kinship relationship of the decision maker are amongst the many factors conditioning the consent/refusal rate (Moraes *et al.*, 2009).

5. Next is donor maintenance, the challenge here demonstrating clearly the overlap and interdependence of the stages. The problem of perishability drives the donation process as it does with blood donation (Titmuss, 1971). Time constraints (around 72 hours from brain death to extraction) restrict both donation and consent procedures. They limit the period in which healthcare professionals have to reach and speak with relatives and also the time that families have to achieve an agreement on following the patient's wishes. Organs that cannot be stored using cryogenicisation have to be transplanted promptly after removal for them to retain their functional qualities. This period is variable (approximately 40 hours for a kidney, four hours for a heart, etc) but as a general rule, the shorter the amount of time, the better the outcomes. Other body parts like corneas, skin and other tissues, can be stored allowing for lapse between removal and transplantation. DCD is a procedure which is less predictable and has been argued to face more hazards in preserving some organs than DBD because some organs have a lower tolerance for warm ischemia than others.

6-11. The process then moves to transplantation proper (stages six to eleven in the model). Although allocation and transplantation complexities are not the focus of this paper, a further brief summary follows to demonstrate that successful donations do not always convert into successful transplantations. Organ allocation systems are sustained by a national registry for organ matching and selection criteria (who gets on to the transplant list) and allocation policies (who is prioritised to receive organs) are decided according to geographical and clinical principles. Distribution policies follow diverse demand management models (based upon need and/or outcome) which they are supposed to ensure equity of access, justice and fairness (Neuberger, 2012). The whole process – from allocation to removal to implantation into the multiple recipients – often takes less than a few hours and this is another key to reform and evaluation. Coordination of donation and retrieval must be carried out in emergency conditions and logistical planning is at an essence. In most cases, several organs are removed and this must be done in sequentially to minimise their susceptibility to warm ischemic damage. Several surgical teams for heart, lung, and abdominal organs – often from different institutions – need to be carefully coordinated. Furthermore, donor and recipient systems need to be synchronised. For some organs (heart and lungs) the recipient operation often commences prior to the arrival of the organ at the recipient institution. After organs are recovered, they need to be preserved and

protected from damage before they can be transported. Some organs stay within the same institution and others are transported nationally or internationally (European Commission, 2003) and by land or air requiring assistance from the police, ambulance services and airline companies.

To summarise, one can say that the material and human resources required, all of which have to be mobilised at short notice and executed with great speed, are evidence of the 'social production' of organ donation (Steiner, 2008). Figure 1 demonstrates that organ donation is deeply embedded in an institutional context and gives a first indication of why rates of donation and transplantation rates vary so widely across hospitals, districts, regions and nations.

2. Policies designed to improve donation rates – an ex-ante assessment

We now move to a critical consideration of two policies designed to tackle the problem of low donation rates. Once again we call on a programme theory approach and use logic maps to locate the proposed reforms within the 'whole system', thus gaining a measure of their likely reach and potential impact. To understand these policies we need to introduce a second logic model to our inquiry (See Figure 2), which might be termed the 'consent pathway'.

This is a much less tangible process than the 'organ pathway' but equally important to outcomes. The inclination of individuals to donate passes through stages reflecting increasing levels of commitment (Guadagnoly *et al.*, 1999). 1) Some potential donors (often younger individuals) will have spared not a thought to donation. 2) Some will have broadly supportive values but never move beyond tacit approval. 3) Some will have transformed inclination into explicit consent. It is this mix of volitions that faces organ donation services and formal systems of registration can only ever measure the extent and maturity of 'consent' imperfectly. What follows in the consent process and what always happens next is thus, 4) the family interview. At this point the consent pathway loops back on itself in a process whereby the potential donor's family and the organ donation coordinator 'reconstruct' the wishes of the individual. The inclination to donate is literally retested 5), often in the absence of a formally recorded preference, against the family's everyday knowledge of the person's personality, attitudes and beliefs.

[Figure 2 about here]

The junction where these two pathways collide is a crucial phase; it is a meeting point of the ambiguous legal framework, the painful situation in which the family suddenly finds itself, the unvoiced preference of the donor and the different organisational structures and transplant regimes. Personal decisions on donation may be rendered less decisive because of the paramount role of the family interview. The urgency of decision making in the hospital setting has a tendency to shift control into the hands of the immediate decision makers. Historical choices and inclinations are not ignored or overridden but mediated by relatives. The two logic models (organ and consent pathways) give a first indication of why donation and transplantation rates vary so widely. The models give a first indication that

there are no magic bullet solutions to bettering donation services and signal that the task of improving conversion rates depends on close scrutiny of every constituent micro-process.

With this premise in mind, we move on to appraise two contemporary interventions, much vaunted in their claims to increase donated deceased organs: ‘presumed consent’ and ‘mandated choice’ for organ donation. These two examples are chosen because they have become clear policy drivers in the UK in recent years. The need to reduce waiting lists through increasing the number of donors has become a priority in the NHS Organ Donation and Transplantation Directorate. In 2006, the Government set up the Organ Donation Taskforce to identify barriers to organ donation and recommend actions needed to increase organ donation and transplantation. In 2008, they made 14 recommendations proposing significant changes in existing systems (Department of Health, 2008a). They also produced a review of the potential impact of changing the legislative system over consent for organ donation in the UK (Department of Health, 2008b). In 2011, they published a final report, describing progress made towards their challenge to increase organ donation by at least 50% by 2013 (Department of Health, 2011).

Our appraisal provides a rapid ex-ante assessment using secondary data from other contexts in which the same programme theories have been applied previously.

I. Presumed consent and opting out

In 2011, the Welsh Government published a White Paper to introduce a ‘soft opt-out’ system of organ donation, meaning that unless an individual opts out explicitly, it is ‘presumed’ that their organs and tissues will be available for donation. The soft approach means that individuals will have a formal mechanism for registering objection and relatives will be involved in the decision (Welsh Government, 2011). Presumed consent policies are not the same everywhere. The key gradation has been described as ‘strong/hard’ to ‘weak/soft’, referring to the level of family consultation. Studies aggregating international data – with few exceptions – often neglect to consider this implementation gradation and tend to make comparisons based on the broad legislative requirement, namely whether there is ‘informed or ‘presumed’ consent. In practice there is always subtle operational and bureaucratic blurring of the difference. For instance, Spain registers wishes to donate but it does not consult them and it does not provide its population with a formal tool to record wishes not to donate.

Against this background, a heated debate has followed about the merits of presumed versus informed consent. Countries with high donation rates apparently share a common denominator: namely, presumed consent legislation under which all deceased persons are considered potential donors in absence of explicit opposition before death. By contrast, in the UK, one of several countries (US, Australia, Germany) under informed consent legislation, donations are not only low but in 40% of cases relatives do not consent to donation (Department of Health, 2008a). Powerful lobbyists have assembled under each banner. At the time of writing, the British Medical Association supports presumed consent and the NHS Organ Donation Taskforce opposes it. The Royal College of Surgeons, the British Transplant Society and the Royal College of Pathologists also prefers a system of presumed consent and the Royal College of Nursing removed its opposition to presumed

consent in 2008 (British Medical Association, 2009). In 2008, the Organ Donation Taskforce reviewed international evidence on donations and concluded that donation rates cannot be successfully improved with legislation change and that efforts were to be concentrated in better infrastructure and resources (Department of Health, 2008a; 2011). This UK debate extends to the international research literature with studies offering contradictory data to whether presumed consent countries produce significantly higher organ donation rates (Johnson and Goldstein, 2004; Abadie and Gay, 2006; Rhitalia, *et al.*, 2009).

Much of the confusion here, we submit, stems from ambiguity over what it means to 'consent' to organ donation before death. People may communicate their preferences explicitly or implicitly. 'Explicit' includes joining the official registry, carrying a donor card, or using other written materials to express wishes (e.g. wills, advanced directives, etc). Explicit consent is thereby considered to signal a clear donation preference to family members who will inevitably be asked about patient's donation wishes. However, cards and registers do not always carry legal status and their stipulations are not enforced in most countries. Physicians have also questioned whether they represent a real 'medical informed consent' in the sense of fully understanding the consequences of the decision (treatment that is not in their best interest, etc). Practicalities of finding donor cards when patients are in A&E and accessing donor registers are also at stake. Donor register consultation does not always occur (Van Leiden *et al.*, 2010) and effectiveness of donor databases is contingent to significant factors common to any computerised data management system: Errors associated with pulling data together from many sources (Department of Health, 2010); software errors when the database is used as an operational tool; poor data quality and accuracy of information like out-of-date address information, incomplete donor identification details -a key factor in countries like the UK with no ID cards-, etc.

Explicit wishes in verbal form may also occur but they are more difficult to trace and more likely to be disputed within some families. In short, informed consent programmes allow individuals with strong preferences for donation to state their wishes but do not guarantee that these will be fulfilled. There is a parallel and potentially greater ambiguity about the meaning of 'lack of consent'. Inaction, of course, may signal everything from intolerance to apathy to forgetfulness. It has been argued, however, that families confronting this unknown intention infer that non-registered relatives are not active supporters of donation and, accordingly, do not consent on their behalf (Bilgel, 2012). Under such an interpretation, the registers may become an unintended mechanism that acts to reduce donation numbers for those (the majority of the population) who do not formally record their wishes. We can call on programme theory to trace these indeterminacies through the system. Figure 3 shows the logic map of informed consent. Once a donor is identified, the individual's wishes to donate are explored. Two possible situations can occur: the person had registered as a donor, or more commonly, the person had not formally registered their wishes anywhere. Interestingly, donation wishes whether formally expressed or otherwise have no binding impact in the process; they do not foreclose the remaining pathways in the decision tree.

[Figure 3 about here]

In both situations the next of kin is asked to consent to organ donation on behalf of the individual. This conversation can end up in acceptance or refusal of organ donation. Again a

certain amount of indeterminacy prevails. In the UK, theoretically, families have no authority to overrule the wishes of an individual to donate in the event of their death. In practice, however, clinicians being obliged to engage in consultation with close family members, rarely ignore their objections (British Medical Association, 2012). The BMA frames this practice in their duty of care to the bereaved relatives: 'Insisting on donation in the face of their [relatives] strong and sustained opposition is likely to add to their distress as well as, potentially, generating public hostility towards organ donation. It is also questionable whether all individuals who sign up to the ODR would want their wishes followed if to do so would cause very significant additional distress to their families' (British Medical Association, 2012: 11-12). As noted earlier, consultation with the family is a fraught affair, its outcome dependent on many contingent factors of which deceased's precise donation preferences is only one.

Let us now interrogate in closer detail the programme theory underlying presumed consent, considering to what extent the underlying dynamic of Figure 3 is modified. Figure 4 represents the logic map of the presumed consent programme as it is proposed for implementation in Wales (Welsh Government, 2013). This form of presumed consent, a soft opt-out, preserves the donor register and it also uses it to give people the opportunity to register their preference not to donate. In this figure, it is evident that the only discernible change from the previous logic map lies in the central spine, where individuals not wanting to consent can guide their relatives to that preference by formally expressing this wish. Inexorably, this pathway then joins all others in the 'family consultation' box. A closer look through the microscope at these two systems thus reveals only a minor difference. Regardless of the type of legislation and of whether a deceased individual is registered as a donor (or as a non-donor), in most countries, Spain included (Matesanz and Miranda, 2002), families are allowed, one might say are expected, to have the last word. Steps in the donation process are not given but negotiated locally. Negotiations and tacit knowledge shape and reshape what actually happens in each system.

[Figure 4 about here]

II. *Mandated and Prompted Choice*

The current UK government casts a favourable eye (Hayes *et al.*, 2012) on 'nudge interventions' to prompt behavioural change in public health matters – an approach popularised by Thaler and Sunstein (2008). The preference is for non-regulatory interventions designed influence behaviour by modifying the context in which people make choices. Close attention is thus paid to the 'choice architecture' of interventions and policies. One short chapter of their book explains how donor pools could be increased through 'mandated choice' interventions. As evidence, the authors refer to an online experiment with 161 respondents and a mandated choice programme on renewal of the driving licence implemented in Illinois that met with apparent success (Thaler and Sunstein, 2008: 184-192).

Despite the broader evidence-base for the effectiveness of 'nudges' being questioned by a House of Lords enquiry (Science and Technology Select Committee, 2011), the coalition government set up a Behavioural Insights Team promoting choice re-architecture as the

Manzano & Pawson (2014- In Press- Journal of Health Organization & Management)

solution to common public health issues (i.e. obesity, smoking, etc). Accordingly, 2011 saw the introduction in England of a programme of 'prompted choice' on the online application form for renewing and applying for driving licences. During this routine activity people were nudged into thinking about organ donation. Applicants are mandated to answer one question (with three pre-determined answers) about whether they would consider joining the donor register (See Box 1). This question already existed in the paper application form but now online applicants have no option but to complete it before they can continue with their application.

[Box 1 around here]

The programme theory is that, currently, many applicants for a driving licence either miss or ignore the organ donation question (prompted seemingly by the sentence included in the paper application: 'You do not need to fill in this section'). These recalcitrants would now be forced to respond, prompting expectations of an instant rise in registration numbers. The largest source of people joining the UK Donor register is from drivers applying for a provisional driving licence (DVLA, 2006) and this younger population, moreover, are thought to prefer online registration.

At the time of writing there was no published data on whether this architectural modification has led to significant increase in the donor pool. There are questions, however, about the elbow power and even the direction of the nudge described above. The possibility remains that citizens who were reluctant to answer questions in paper form may still opt for equivocation by clicking a box now labelled 'I do not want to answer this question now'. Moreover, other experiences with mandated choice suggest mixed outcomes. An early experiment in Texas was counterproductive, with 80% of individuals refusing to designate themselves as organ donors with a concomitant reduction in organ procurement (Siminoff and Mercer, 2001). The problem is that choice architecture is a matter of people's dispositions as well as their options. As Titmuss (1971) has taught us, the 'gift relationship' is tenuous and precarious. It is possible that altruism can be stifled if it is nudged too hard.

Such a possibility raises questions about how far specific choice architecture strategies do build around expectations of persuading the readily compliant, and about the prospects for targeted groups raising their guard in response. Certainly, nudges gain some of their appeal by presenting individuals as actors who may be easy to manipulate, or easy to persuade by creating the right environmental factors. The role of emotions and affective attitudes attached to organ donation are not generally approached by default architectural interventions. Possible registrees deal with the so-called 'ick factor' (feeling disgust towards the idea of organ donation) and 'the jinx factor' (the superstitious belief that registration could lead to harm or death for the registrant), these being two of the most prominent instinctive reactions to registration (Morgan *et al.*, 2008). How the ick and jinx factors are taken into account in policy designs is important. It is also important to consider whether registration attached to potentially dangerous activities can activate these feelings.

Our main reservations about mandated choice, however, lie in our previous discussion on the complexity of the entire donation and transplantation system. To rely exclusively on interventions dealing with only one phase of the multiple processes described above ignores

the large number of other agents involved in the system, the connections amongst them, the institutional practices required to implement the system, and the cultural, legal and ethical forces that shape the entire system. Interventions directed at increasing organ donation registrations are preliminaries that impinge on our models only at stage four in Figure 1 and as side channel entering the flow diagram of figures 3/4 at the moment of 'consultation with register'. As we have already documented, the donor's wishes are never followed automatically; they enter the process as one negotiable part of the complex and ever-present family confabulation on consent. It follows that 'supply' or 'upstream' solutions will always be moderated and generally speaking it may be said that organisational behaviour it is likely to play a bigger role than individual behaviour in increasing the *operational* organ donor pool.

3. How to put complex systems to evaluation?

Having established the endless complexity of the donation and transplantation system and the perils of some of simpler ideas on its transformation, we reach the ultimate question. How should such complex programmes be evaluated (Pawson, 2013) in a way that can contribute to their improvement (Berwick, 2008)? The solutions raised in this section should be regarded as tentative; indeed they are work-in-progress, currently being pursued in a range of pilot inquiries and scoping studies.

The literature on deceased organ donation tends to approach this topic from different perspectives biomedical (outcomes) and ethnographic (meanings and emotions). Theory-based evaluation is presented here as an alternative to these method-driven approaches, making two further suggestions: i) modelling micro-processes, and ii) comparative case study designs.

1. Modelling micro processes

A key feature of the programme theory approach is that it allows inspection of the implementation process to drill down from macro to meso to micro levels (Funnell and Rogers, 2011). A macro model such as Figure 1 allows inspection of the integrity of the entire implementation chain and permits the identification of the strategic flows and blockages. It is equally possible to narrow focus to any step in the chain and use a logic model to explore the delivery of component process. As an example of how micro processes can be modelled, we take the family interview, one of the key phases of obtaining consent to deceased organ donation for transplantation, with some identifying it as the stage at which most potential donors are lost. It is our families who have the power to make the ultimate decision of whether to grant the ultimate gift of recyclable organs. It is their altruism and not ours that is the key element here. Their views on body integrity, their understanding of death, their relationship with healthcare staff are all at stake and this is the point in the process where they come to the fore.

The research literature abounds with tentative hypotheses on factors that may influence a family's inclination to agree or decline donation – donor and next-of-kin factors, request

timing, requestor characteristics, prior knowledge and opinions about organ donation, numbers making the decision, communication processes and satisfaction with the healthcare team, ethnicity, and so on (Simpkin *et al.*, 2009; Simoff *et al.*, 2011). Practical definitions of 'family' can add further ambiguity here since family composition (nuclear and extended families, etc) and patterns of proximity of residence affect how rapidly the next of kin can be located for consultation purposes. Any single member of the family in the interview room (no matter how distant) disagreeing with donation could be a potential barrier to donation. The stakes are unusually high in these interviews, relatives being decision-makers rather than opinion-bearers.

Even in this specific encounter complexity skyrockets and a strategy is needed to prioritise evaluation on the key issues. One method is to concentrate on process and we illustrate this with a tentative 'process map' as in Figure 5. Interviews with relatives of potential donors are normally carried out by dedicated transplant coordinators. What happens at this stage is basically a delicate process of family counselling and support. There are many existing models of the counselling function which suggest that clients are best accommodated by enabling them to come to terms with their 'problem' in a series of transitions (Kübler-Ross, 1969). In the 'consent interview' this process of adaptation has to occur in a highly compressed sequence. The point, once again, is that it is a procedure that can be planned, mapped, investigated and improved.

The process can be modelled (with the usual provisos about simplification) in five phases: a) gathering information about the family; b) managing the interview and its setting; c) setting up and explaining death; d) explaining the consent process e) handling queries and apprehensions. When specifically trained coordinators have full responsibility for the donation process, our initial observations suggest that a range of persuasive strategies are activated in order to manage these stages at a time when families are going through an emotional shock. It would be pernicious to call them 'tricks of the trade' but it should be noted that they are found in all interviews on sensitive topics with vulnerable subjects (Liamputtong, 2007).

[Figure 5 about here]

Detailed examination of these processes would be carried out using the normal methods of process inquiry – interviews and focus groups with transplant coordinators, close observation of the interviews, debriefing and respondent validation. The methodological point is that the programme theory provides the point of entry, allowing the researcher to use the model to elaborate which strategies work for whom in what circumstances. This will help us to map the effectiveness of various modes of interpersonal influence. Persuasion comes in many forms: At stage a) the donation team gather information about family composition and dynamics, the emotional impact of the type of death (accidental, sudden, expected) and their implicit or explicit views on donation; all these factors will influence the strategies to employ. At stage b) techniques to manage the setting relate with choosing interview room and suggesting which family members should attend the interview and what staff will perform it (transplant coordinator alone, with clinician, etc). The third phase is the official start of the interview. Death is communicated and emotions are comforted. Only when irreversibility is understood, the communicators should proceed to the fourth stage. Consent to donation is explained and according to relatives' response, persuasive options

follow. Gómez and de Santiago (2008: 113-114) describing the interview model used in Alicante (Spain) explain how they offer arguments pro-donation by invoking feelings of altruism (appealing to social, group and individual needs), utilitarian arguments ('unfortunately, he/she does not need the organs anymore') and those of gratification and glorification of donor values ("I bet he/she was a generous person who helped neighbours and friends"). In the last stage, queries and apprehensions are handled. Answering fears about body integrity and funeral practicalities and correction of myths or wrongly held beliefs which can lead for instance to joint interview with spiritual leaders. In some countries funeral expenses are partially or totally funded for donors and this pragmatic argument will also be presented to relatives.

An understanding of what works for whom and how many of these stratagems and in what circumstances are put in place elucidates contextual factors that will guide researchers through possible explanations. Whilst we lack reliable data to make sound comparisons on the effectiveness of the consent interview it is clear that there is variation here, with for instance Caballero *et al.*(2012b) reporting a 100 % (N=40) success rate in consent interviews in a Spanish hospital during a period of 20 months in 2011-2012. Without assuming that such levels of performance are sustainable or transferrable, they do indicate the need for precise explanations about what might fire and misfire in a consultation. The point is (again) that without the orientation provided by the logic maps previously illustrated, the search for 'success factors' will remain unfocussed and arbitrary.-

II. *Comparative Case Studies*

Our second suggestion for coming to a better understanding of the inner workings and outworkings of complex systems is to engage in a programme of comparative case studies. Swanson's (1971) maxim that 'thinking without comparison is unthinkable' probably applies to all research but leaves us far short of the optimal design for designing a study to understand the contrasting fortunes of different organ donation regimes.

A useful starting point takes us right back to John Stuart Mill's (1843) 'method of difference' in which he recommended examining systems with markedly different outcomes and then tracing through their inputs to find the crucial variable that distinguished between them. It is quite possible to begin here and we will pursue this illustration by returning to the 'league tables' and using an example a potential comparison between the Spanish and the UK regimes. These offer a simple orientation that accommodates Mill's idea of investigating at points of 'maximum difference'. But how can we uncover the key factors that may account for outcome heterogeneity? As we have already seen, not only are there a multiplicity of sub-processes in respect of which the two regimes might differ but, crucially, the success of the process depends on their multiplicative action. In other words we are unlikely to find a crucial 'variable' in terms of which the systems differ; rather the explanatory mechanism is likely to lie in the interconnection and co-ordination of sub-processes with each system.

To accommodate this crucial contingency a method known as 'comparative process tracing' has evolved in the comparative and historical social sciences (George and Bennett, 2005) and what follows is an attempt to adapt the idea to the study of healthcare organisations. The starting point once again is the programme theory. Any intervention, programme or service has an implementation chain, which can be rendered as a logic model describing the

stepping stones required to convert the inputs within a system into outputs. Figure 6 (upper section) depicts in an entirely abstract fashion an input-outcome conversion process that will apply to any system. No intervention achieves its aim in one fell swoop and in general it is possible to map the multifarious activities that convert inputs into outputs and then further down the chain onto immediate, intermediate and final outcomes.

[Figure 6 about here]

We have already produced such a model of the donation to transplanting pathway and this abstract map may act as a baseline for empirical research in the manner depicted in the further stages of Figure 6. We know that in any real system that the programme theories will always be achieved imperfectly. Such systems can never be reproduced exactly. Any transplantation regime will face uncertainty, ambivalence or resistance, it will generate unintended consequences, other priorities and programmes will intervene. The purpose of the empirical analysis is thus to inspect the fidelity of the hypothesised implementation chain in order to uncover its 'flows', 'blockages' and 'leakages'. Under the guidance of abstract template it is possible to trace the process through in each case study, comparing like-point with like-point and thus charting with some precision the stages at which the execution differs (a scenario depicted in the abstract in the lower sections of Figure 5). The idea to construct explanations of why conversion from, say, point D to E differs between the systems and, in so doing, to ascertain transferable lessons on system improvement.

This is the design that is under construction in our present work and we possess only candidate theories on the crucial contexts and mechanisms that differentiate between systems. We illustrate the process with a preliminary example that sits right at the beginning of the process (steps 1 and 2 in Figure 1): the need to improve the detection of potential donors. The programme theory is that organ donation is low because few eligible patients are approached and asked. A key outcome measure used in international comparisons is 'conversion rate' (the number of actual donors as a percentage of the potential donor pool) and therefore, identifying that 'potential donor pool' is the key issue.

In Spain transplant coordinators -who are physicians with special interest in donation and transplantation- screen through intensive care medical histories for possible donors. Their UK equivalents -who are nurses with special interest in donation- tend to rely on referrals from emergency staff not always knowledgeable about the increasingly flexible criteria for potential donors (Pont Castellana *et al.*, 2008), and who could potentially be perceived as having a conflict of interest when deciding to withdraw treatment (McMaster and Vadeyar, 2000). Power issues affecting nurse-physician relationships and end-of-life strategies in emergency rooms (Bailey *et al.*, 2011) enter the UK donation scene. With little availability of intensive care beds, a plausible hypothesis is that in the UK, patients with hopeless prognosis are not prioritised for admission. Moreover, withdrawal of treatments that are no longer beneficial may occur sooner than in countries with greater critical care capacity (Manara *et al.*, 2012). What can be seen from this vignette is that 'stage effectiveness' depends on 'system effectiveness'. Donor identification is facilitated by the co-presence of a range of structures, procedure, and historical practices. And this brings us to a final consideration on donation and transplantation policy - namely to beware of one-size-fits-all solutions for the service.

In 2010, a European Union directive aimed at achieving uniform quality and safety standards and improving waiting times for transplants gave to Spain (Watson, 2010) the role of improving the training of transplant coordinators. In the same year, the World Health Organization recommended reproduction of the Spanish model of organ donation worldwide assuming that self sufficiency in the supply of organs will follow and that the universal trend of organ trade and trafficking will therefore be reduced (WHO, 2011). Such initiatives are entirely consonant with the current institutional drive for international policy transfer (Dolowitz and Marsh, 2000). In rapidly changing policy environments governments often look for ready-made policy solutions, presented as panaceas.

But is such direct transfer possible in complex adaptive systems? Is a transplantation regime transplantable? What exactly is supposed to be transferable? Key factors identified as the active ingredients of the so-called Spanish model are: a) independent transplant coordination teams; b) hospital reimbursement policies, which compensates hospitals for organ procurement costs; and c) a multi-layered network at the national, regional, and hospital level, which coordinates and manages activities (Matesanz and Domínguez-Gil, 2007). As we have shown, it is far from clear why these factors are singled out, and, more significantly, we have demonstrated that it is not the ingredients *per se* that bring about improvement. What is important is how the macro, meso, and micro ingredients are combined and blended, and whether the existing structures and staff relationships allow for that integration. Even within the Spanish system one would expect the requisite configurations to vary between regions and certainly between hospitals with or without neuro-surgery departments (Matesanz *et al.*, 2012) or transplant units (Velasco *et al.*, 2010). Hospitals with transplant units keep for themselves the organs that can be transplanted in their institutions unless there is a national emergency, while hospitals which only generate organs are confronted with increased logistic difficulties at no tangible benefit for the institution. Indeed, a recent study published in the Lancet (Rodríguez-Arias *et al.*, 2010) exposed some of the less publicised challenges of the Spanish procurement system.

Coming to cross national comparisons, one can say that these contextual constraints are even more pronounced. The real purpose of comparative case studies, therefore, is to produce explanations for differences in inputs, outcomes and outputs. The aim to discover 'what works for whom in what circumstances and in what respects and why' (Pawson and Tilley, 1997). The same innovation can stifle or improve, depending on context, and it thus important to have some understanding of system interdependencies (Batalden and Davidoff, 2007).

Conclusion

The importance and urgency of all service reform is often marked with the use of metaphors about life and death situations. In the case of organ donation this is literally the case – body parts from brain dead patients with beating hearts are removed in the hope of prolonging the life of another human being. Hundreds of people are involved in this single transaction. Inevitably, their interpretations and practices vary widely. Unequivocally, the consequence is substantial diversity in transplantation outcomes. The beating heart of the donation process

is the organisation. We have attempted to show how death and life depends on the accumulation of series of embedded, institutional sub-processes.

Evaluations need to be concerned with this whole system rather than with its discrete parts or sectors. A change to any element will bring about an anticipated effect only if it is absorbed and supported by the remainder of the system. We have argued that this daunting predicament can be confronted by the incorporation of a theory of system change as an initial step in policy development and evaluation. The great advantage is that that this strategy poses the self-same question – dear policy innovator, will your newfangled idea be absorbed, supported and promoted within the well-worn systems and structures into which it is pitched?

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<http://wales.gov.uk/topics/health/nhswales/majorhealth/organ/?lang=en>

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Figure 1

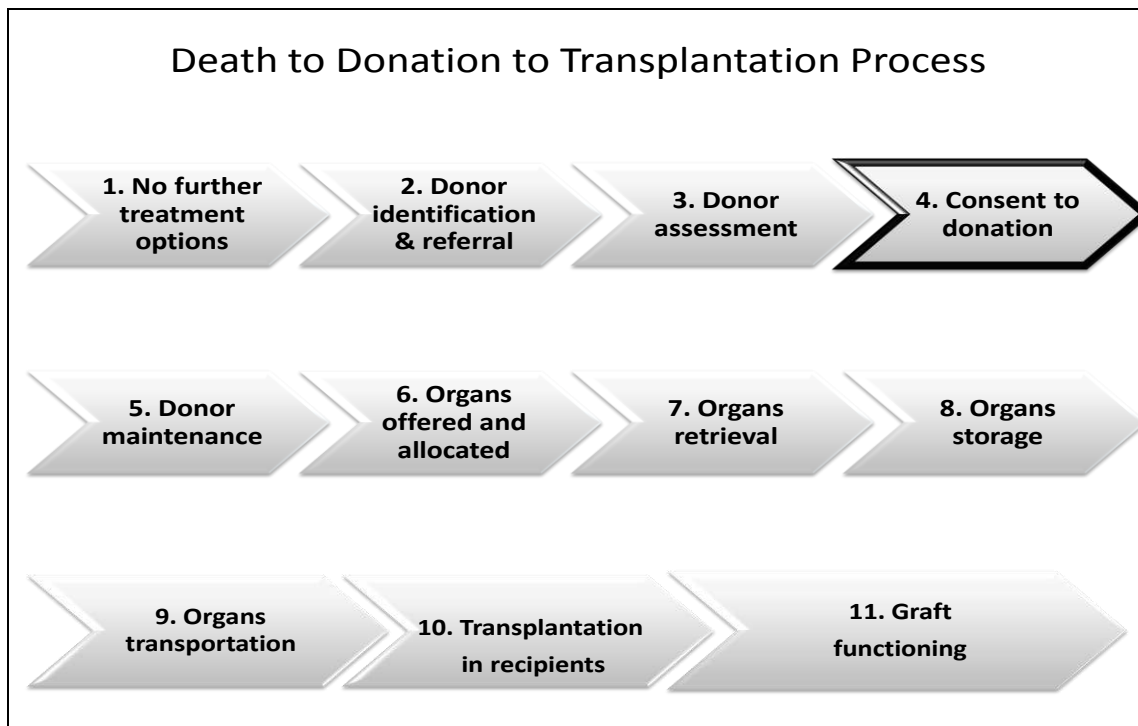


Figure 2

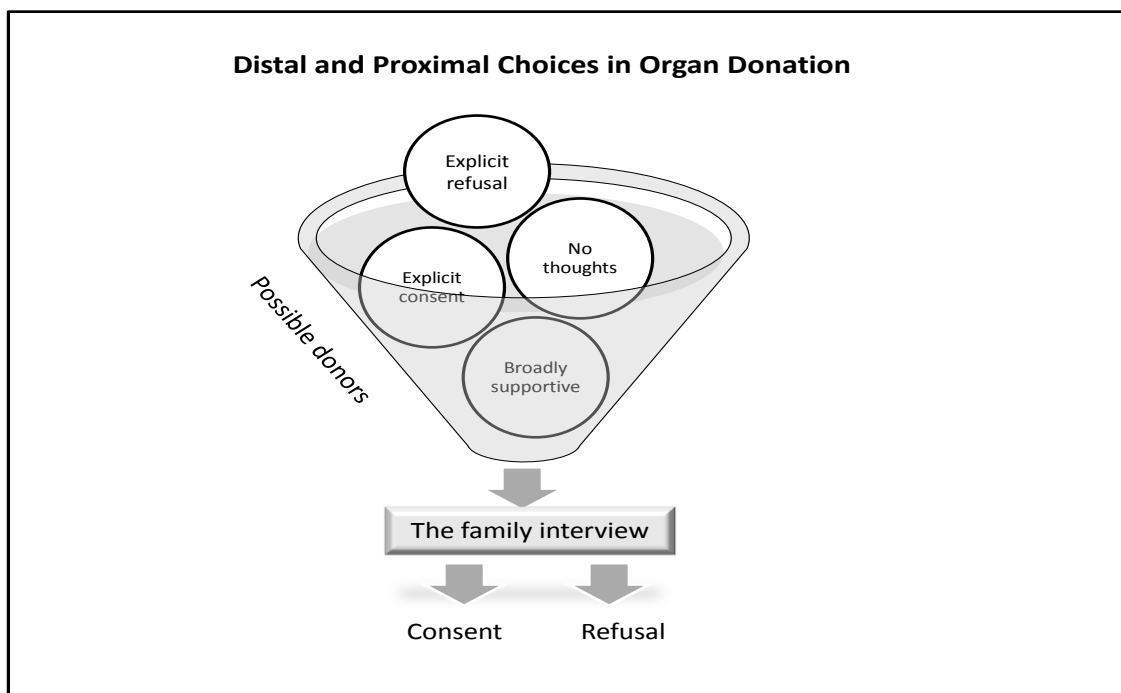


Figure 3

Logic Map of Informed Consent

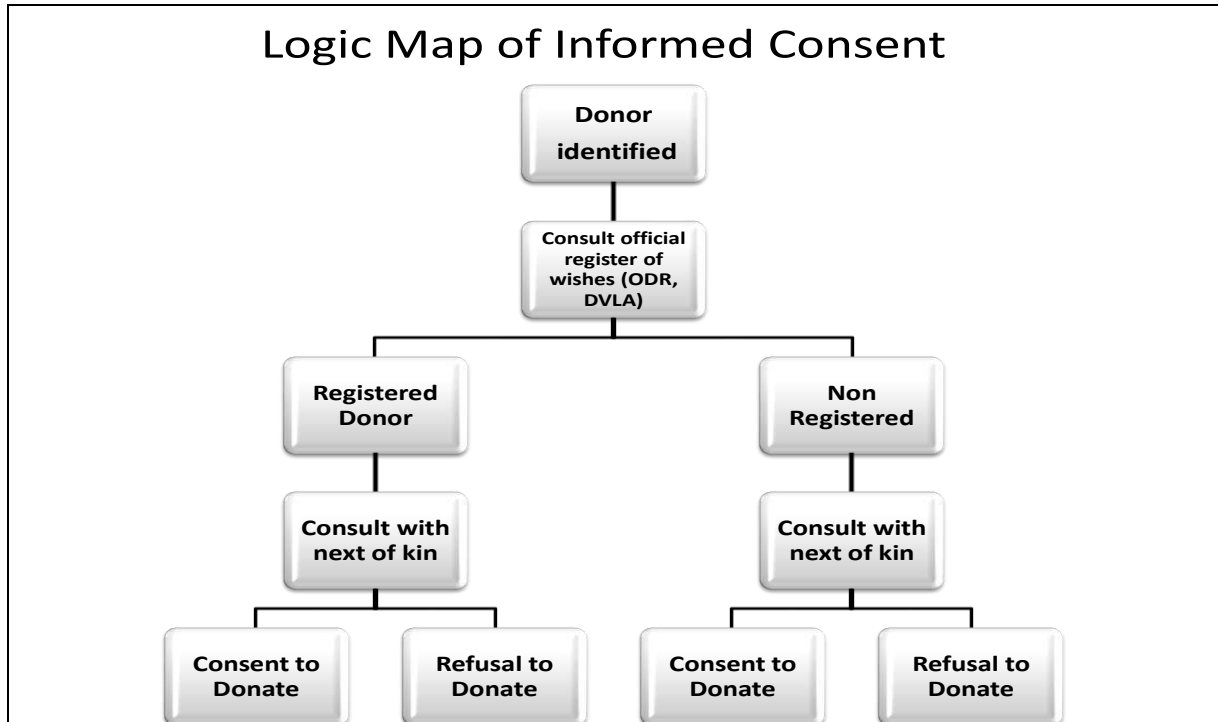


Figure 4

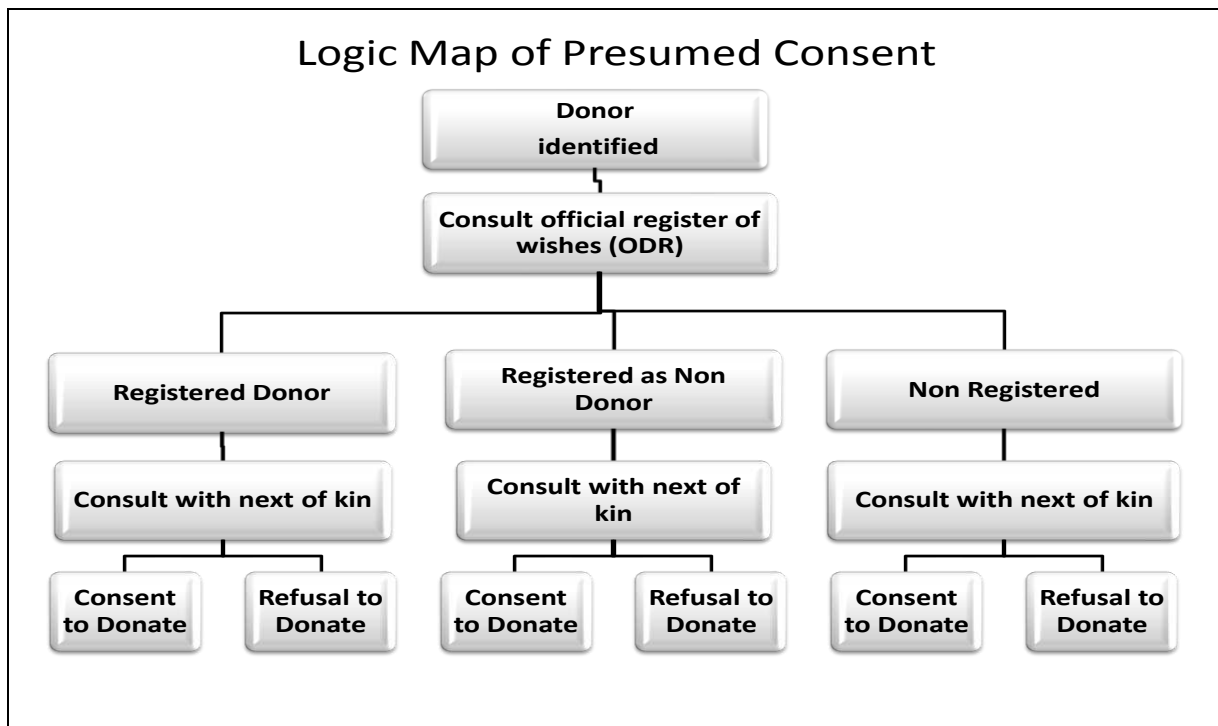


Figure 5

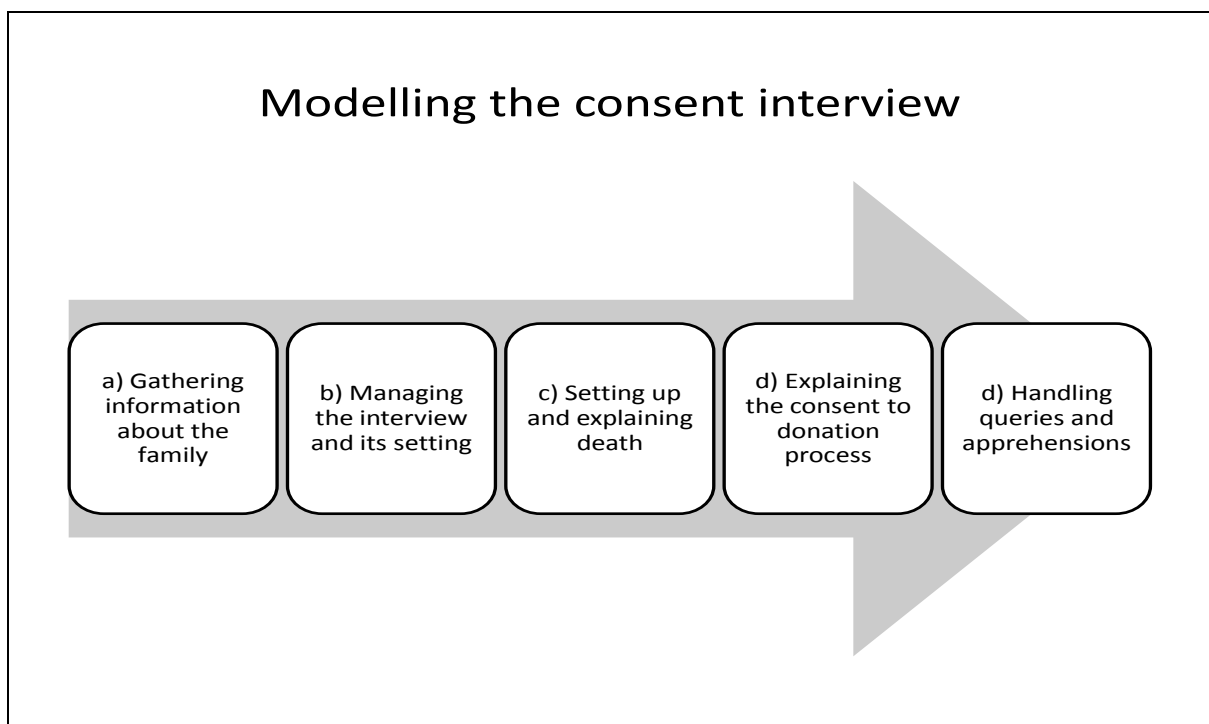
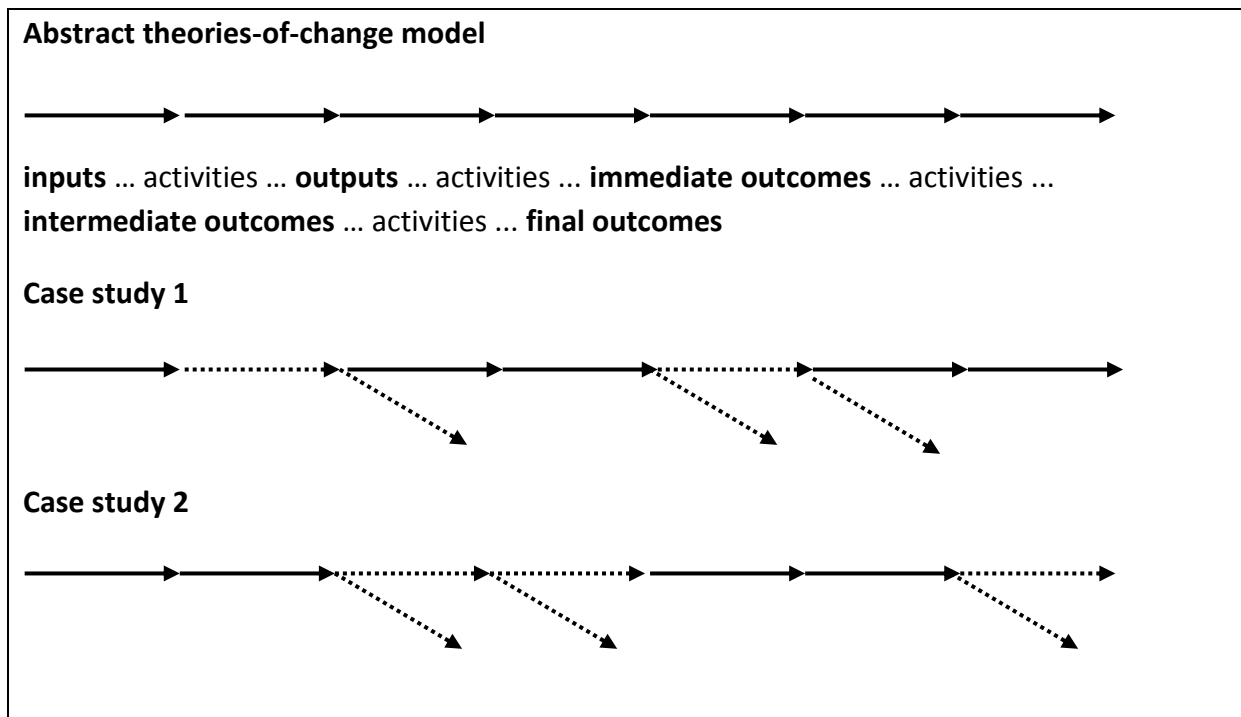


Figure 6: Comparative Process Tracing



Box 1

Box 1: The English driving licence prompted choice programme

Driving licence online applicants have to tick one of three options below to answer a question on organ donation before they can complete their application:

- Yes, I would like to register
- I do not wish to answer this question now; or
- I am already registered on the NHS Organ Donor Register.