Title A General Practice Intervention Targeting
Registration on the NHS Organ Donor Register

Name: Dr. Catrin Pedder Penn-Jones

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A General Practice Intervention Targeting
Registration on the NHS Organ Donor Register

Catrin Pedder Penn-Jones

A thesis submitted to the University of Bedfordshire, in fulfilment of
the requirements for the degree of Doctor of Philosophy.

University of Bedfordshire
Institute for Health Research
March 2020
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Abstract

**Background:** There is a shortage of organs for transplant in the UK. Family consent is a critical part of the organ donation pathway, and prior knowledge of a person’s wishes makes this decision easier for families. The most effective way to express organ donation wishes is through registration as an organ donor. General practice is an underutilised setting for organ donation interventions, and is the only NHS setting which can put people directly on the organ donor register. Therefore, interventions could be developed in this setting to maximise the opportunities for UK residents to register their request to donate their organs after death. This thesis aims to explore this by developing and evaluating the feasibility of a general practice intervention designed to increase organ donor register sign-up in the UK.

**Methods:** A literature review, systematic review, and theoretical review were conducted to establish a basis for the intervention. Intervention Mapping was then used to develop it based on these empirical and theoretical findings. Based on the IIFF model of organ donation registration, the intervention consisted of three parts; staff training, asking patients in consultations if they wished to join the NHS Organ Donor Register (prompted choice) and the provision of leaflets and posters in the waiting room. A single practice feasibility study was conducted to assess five dimensions; recruitment, data collection materials, resources, acceptability, and intervention promise. Intervention mapping was revisited to refine the intervention based on the single practice study findings.
**Results:** Staff conducted prompted choice on 12.4% of face to face consultations they had with patients over three months, with 214 patients joining the NHS ODR. Some staff found prompted choice both feasible and acceptable, with opinions dependent on staff professional role. Responses to the training sessions were positive; however, although leaflets and posters were found to be feasible and acceptable, the majority of patients did not notice them. Significant challenges to implementation were found with SystmONE the practice software, the NHS Ethics process (particularly the confidentiality advisory group) and recruitment of practices. These resulted in the ultimate abandonment of a planned multi-practice feasibility randomised controlled trial.

**Conclusion/Discussion:** These findings were positive and indicated that general practice could be an acceptable location to provide the facility to join the NHS ODR in the UK verbally. However, due to implementation issues, consideration is required as to how best to test the intervention further for feasibility. Recommendations include conducting a larger feasibility randomised controlled trial with more resources (people and financial), to help aid recruitment and the implementation of the required SystmONE elements.

**Contribution to Knowledge:** This is the first academically tested intervention allowing people to sign-up to the NHS ODR verbally, and one of the first organ donation interventions in UK general practice. It is also the second intervention internationally to use Intervention Mapping for organ donation behaviour, and this thesis adds to the evidence base in each of these areas.
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List of Publications

Journal Articles


Conference Presentations


Papadopoulos, C., Jones, C. P., Randhawa, G., & Asghar, Z. ‘The Role of Primary Care in Increasing Organ Donation’. *5th ELPAT Congress: Developing Dialogue - Pioneering Practice*. Auditorium Maximum of the Jagiellonian University, 26-29 April, Krakow, Poland.


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List of Acronyms

ATQS – Assessment Tool for Quantitative studies
BAME – Black Asian and Minority Ethnic
BCW – Behaviour Change Wheel
BPS – British Psychological Society
BTS – British Transplant Society
CAG – Confidentiality Advisory Group
CCG – Clinical Commissioning Group
DNAZ – Donor Network of Arizona
DMV – Driving Motor Vehicle Offices
DVLA – Driver and Vehicle Licensing Agency
GDPR – General Data Protection Regulation
GP – General Practice or General Practitioner
HRA – Health Research Authority
IIFF Model – Information, Immediate Sign-up, Focused Engagement and Favorable Activation Model
IG – Information Governance
IHREC – Institute for Health Research Ethics Committee
IM – Intervention Mapping
MRC – Medical Research Council
NHS – National Health Service
NHSBT – National Health Service Blood and Transplant
NHSBT PDM – National Health Service Blood and Transplant Partnerships and Development Manager

NHS ODR – National Health Service Organ Donor Register

NHS REC – National Health Service Research Ethics Committee

NICE – National Institute of Clinical Excellence

PBC – Perceived Behavioural Control

PIS – Participant Information Sheet

PLT – Protected Learning Time

PPG – Patient Participation Group

QOF – Quality Outcomes Framework

RCT – Randomised Controlled Trial

SOC – Stages of Change

SES – Socioeconomic Status

SNOD – Specialist Nurse in Organ Donation

SPIRT – Standard Protocol Items: Recommendations for Interventional Trials

TPB – Theory of Planned Behaviour

TRA – Theory of Reasoned Action

TTM – Transtheoretical Model

UK – United Kingdom

USA – United States of America
1 Chapter 1: Introduction

This research is funded jointly by the National Health Service Blood and Transplant (NHSBT) and the University of Bedfordshire, to investigate an intervention hosted in general practice (GP) to increase membership of the National Health Service Organ Donor Register (NHS ODR). I initially applied for this studentship due to the experiences of a close friend of mine who has Cystic Fibrosis. We discussed her disease at length, and it is almost inevitable that she will need a lung transplant. Therefore, when the opportunity arose to research the area of organ donation, my motivation went beyond only doing a PhD but to have a positive impact on the lives of those who will one day face transplantation, like my friend. During my masters study in Health Psychology organ donation was not included in the curriculum. Public health and psychological interventions tend to centre more around diet, physical activity, exercise, stress, and smoking. It is surprising to me that both policymakers and researchers in this area seem to neglect organ donation, given that it can save lives and significantly improve life quality. This thesis combines my background in Health Psychology with the topic of organ donation to design, refine, and test for feasibility an intervention in a relatively unexplored topic in the area. I hope it can contribute to this sparsely researched field, potentially encourage more health psychologists to venture towards the issue of organ donation, and develop psychological interventions to help save lives.

1.1 Rationale

In the United Kingdom (UK), there is a discrepancy between the number of people awaiting transplant and the number of organ donors (NHS Blood and Transplant, 2019d). To address
this action is required to increase the number of people donating their organs after death (NHS Blood and Transplant, 2019d). General practice interventions have been shown to be promising in recruiting to organ donor registries in the United States of America (USA) and UK (Jones, Papadopoulos and Randhawa, 2017). However, barriers to implementation and the acceptability of these have been expressed (Pradeep, 2015). Further, the feasibility of intervening, regarding organ donation, in this setting has yet to be examined in a UK context. Therefore this research aims to examine if general practice is a feasible and acceptable place to run an NHS ODR intervention for both patients and general practice staff.

1.2 Aim

To develop and evaluate the feasibility of a general practice intervention targeting organ donor registration.

1.3 Objectives

Objective 1: To collect, synthesise, and review literature that will inform an intervention targeting organ donation registration rates in UK general practice.

Objective 2: To design, develop, and refine a general practice intervention targeting NHS ODR sign-up.
Objective 3: To assess the feasibility and acceptability of an NHS ODR sign-up intervention implemented in UK general practice.

1.4 Thesis Overview

This thesis is split into nine chapters which fulfil the above objectives (Figure 1). Chapters two-four meet objective one by undertaking a literature review, systematic review and theoretical review. Chapters two-eight fulfil objective two of this thesis by developing and designing an intervention and pretesting this. Chapters six and seven fulfil objective three of this thesis by undertaking a single practice feasibility study to test the intervention for feasibility and acceptability. Chapter one outlines the rationale, aims, and objectives of the thesis. Chapter two presents the literature review exploring organ donation in the UK, previous organ donation interventions, and potential settings for organ donation intervention. Chapter three contains a systematic review of organ donation interventions in primary care and highlights the dearth of interventions conducted in this setting internationally. Chapter four explores the theoretical foundations for the intervention. In Chapter five, the intervention is designed, in chapters six and seven tested for feasibility and acceptability, and in chapter eight, it is refined. Finally, chapter nine discusses the research conducted in this thesis, and provides some recommendations for future research to be undertaken based on its findings.
Objective 1: To collect, synthesise and review literature that will inform an intervention targeting organ donation registration rates in UK general practice.

- Chapter 2 - Organ Donation - A Review
- Chapter 3 - Organ Donation Interventions in Primary Care - A Systematic Review
- Chapter 4 - Organ Donation - A Theoretical Review

Objective 2: To design, develop and refine a general practice intervention targeting NHS ODR sign-up.

- Chapter 2 - Organ Donation - A Review
- Chapter 3 - Organ Donation Interventions in Primary Care - A Systematic Review
- Chapter 4 - Organ Donation - A Theoretical Review
- Chapter 5 - Intervention Development
- Chapter 6 - Single Practice Feasibility Study - Methodology and Methods
- Chapter 7 - Single Practice Feasibility Study - Results
- Chapter 8 - Intervention Refinement

Objective 3: To assess the feasibility and acceptability of an NHS ODR sign-up intervention implemented in UK general practice.

- Chapter 6 - Single Practice Feasibility Study - Methodology and Methods
- Chapter 7 - Single Practice Feasibility Study - Results

Figure 1: Overall thesis outline and how the objectives are fulfilled by each chapter.
Chapter 2: Organ Donation - A Review

This chapter provides an overview of organ donation in the United Kingdom (UK) and the literature on interventions to promote it. It aims to define the location for the intervention and inform which techniques should be considered during intervention development (Chapter 6). In section 2.1 the landscape of organ donation in the UK is discussed including the following sections: the importance of family consent, organ donor registries – specifically the National Health Service Organ Donor Register (NHS ODR), the move to an opt-out system in England, and the rationale for developing more organ donation interventions in the UK. Building on this, section 2.2 reviews the literature on organ donation interventions, by first examining systematic reviews and meta-analyses, and moving on to examining interventions conducted in the UK. This section will inform the techniques used in the intervention developed in this thesis. Finally, section 2.3 explores where an intervention should be conducted. To do this, the NHS ODR is examined to determine which demographic groups are most in need of intervention. In particular, how they registered, to examine gaps which can be used to maximise registrations by existing methods. Finally, the National Health Service (NHS), as a setting for organ donation intervention will be discussed, ultimately justifying general practice as the setting for the intervention in this thesis.
2.1 Organ Donation in the United Kingdom

2.1.1 An Introduction to Organ Donation

Organ donation is a lifesaving process by which organs or tissue are removed from a donor and transplanted into a recipient in need (NHS Blood and Transplant, 2019a). The process of transplantation was first made feasible in 1902, with medical developments allowing blood vessels to be successfully surgically connected (National Health Service, 2015). It was not until 1965 that the first successful transplant was carried out in the UK (NHS Blood and Transplant, 2019a). Since then, thousands of patients have benefitted from transplantation, and approximately 300 patients receive a heart, and more than 3,000 receive a kidney transplant each year (NHS Blood and Transplant, 2019a). The National Institute of Clinical Excellence (NICE) first published guidelines in December 2011 regarding organ donation for transplantation. These focus on organ donation identification and consent for deceased donation in the UK (National Institute for Clinical Excellence, 2016a). Revised in December 2016, these guidelines provide a pathway for healthcare providers detailing how the organ donation process should be conducted (National Institute for Clinical Excellence, 2016b).

In the UK, organ donation services are run by NHS Blood and Transplant (NHSBT) (NHS Blood and Transplant, 2019e). NHSBT is an executive non-departmental public body, sponsored by the Department of Health and Social Care. The first stage is ‘early identification of potential organ donors,’ including the identification of eligible patients through brainstem death or circulatory death testing. Following this a Specialist Nurse in Organ Donation (SNOD), employed by NHSBT, will be approached to discuss organ donation with either the patient if they have capacity or the patient's family (National Institute for Clinical Excellence, 2016b).
In most cases, the patient is unable to give consent to donation; therefore, organs will only be donated in the UK with the express permission of families (NHS Blood and Transplant, 2013a).

NHSBT produce annual activity reports detailing UK organ donation and transplantation activity (NHS Blood and Transplant, 2018a). Between April 2018 and March 2019, 3,951 transplants were carried out from 1,600 donors (NHS Blood and Transplant, 2019d). However, there were 6,077 patients on the active transplant waiting list during this period (NHS Blood and Transplant, 2019d). This pattern, where the number of patients awaiting transplant is higher than those donating, has been the case for several years (NHS Blood and Transplant, 2018a). Two instrumental strategies were developed to target this gap; the NHSBT strategic plan and the Taking Organ Transplantation to 2020 strategy. The NHSBT strategic plan for 2017-2022 aims to reduce this gap by increasing family consent rates, deceased donor rates, and as a result the number of transplants (NHS Blood and Transplant, 2017b).

The Taking Organ Transplantation to 2020 strategy, published in 2013, aims to match the best performing countries worldwide regarding organ donation and transplantation, for example, Spain (NHS Blood and Transplant, 2013b). In May 2017 NHSBT produced a mid-point review of the Taking Organ Transplantation to 2020 strategy (NHS Blood and Transplant, 2017c). This report showed that progress had been made towards improving donation rates in several areas along the NICE Pathway (National Institute for Clinical Excellence, 2016b; NHS Blood and Transplant, 2017c). The first of these is the increase in the number of families consenting. Compared to 2013/14, in 2016/17 a 6% increase in consent
rate was found, with 63% of families asked providing consent for their loved ones organs to be donated (NHS Blood and Transplant, 2017c). A facilitator of these decisions was prior knowledge of their loved one’s wishes, with families providing consent for donation on 93.5% of occasions when wishes were known, compared to only 51.2% of times when wishes were unknown (April 2018 - March 2019) (NHS Blood and Transplant, 2019d). Knowledge of a person’s wish to donate has been investigated thoroughly in the literature, and will be explored in the next section.

2.1.2 The Importance of Family Consent and Knowledge of Wishes

Family consent, although a necessary as part of the organ donation pathway, is a significant barrier to donation in the UK (Hulme et al., 2016). Knowledge of loved ones wishes has been found to overcome this barrier in a number of studies (de Groot et al., 2012; Walker, Broderick and Sque, 2013; Ralph et al., 2014; Chandler et al., 2017). Walker et al. (2013) conducted a systematic review of 20 international studies. The authors found in two-thirds of studies, that knowledge of wishes was a statistically significant factor in family donation decision making. This finding is mirrored in findings by Chandler et al. (2017) who conducted a scoping review of international literature on the family consent process. From 168 articles (2000 - 2015), they found that if the deceased's wishes to donate were known, families were more likely to give consent (Chandler et al., 2017). Ralph et al. (2014) synthesised the qualitative literature concerning family perspectives on deceased organ donation and found similar results. The theme ‘honouring the donor’s wishes' was found repeatedly, and the research demonstrated that in cases where wishes were known, families were more confident in their decision making. Not knowing wishes, on the other hand, caused families
to experience hesitation and indecision when approached for consent (Ralph et al., 2014). Finally, an integrative review by de Groot et al. (2012) of 70 studies found that in families that declined donation when their loved ones wishes were to donate, their grief process was negatively affected. Additionally, in some instances, families regretted this decision (de Groot et al., 2012). These results highlight the importance of communicating a wish to be a donor to family members, who will ultimately be making the decision. As well as discussing donation with loved ones verbally, more formal ways of documenting wishes are available - organ donation registries.

2.1.3 Organ Donor Registries

Organ donor registries aim to record donation decisions, usually that a person wishes to donate their organs after their death (Rosenblum, Li, et al., 2012). Registries to record a decision not to donate ones organ after death are also present in some countries where an opt-out system is in place, for example in Wales (NHS Blood and Transplant, 2018a) (Rosenblum, Li, et al., 2012). Rosenblum et al. (2012) examined international variation in donor registries and reviewed these in 27 nations. Most registries are operated at a government or national level, with Canada and the USA examples of state-run registries. The authors state that there is a wide variation in registry characteristics; for example, the UK is unusual in that it does not have a minimum age requirement (along with only five other countries). A key finding of this review is that although opt-in registries are often used as part of public campaigns to promote organ donation, typically less than 40% of populations are registered. A further paper by Callinson and Levin (2016) examined data on registry implementation from 1988-2006 in the USA, and found that registry adoption was
linked to an 8.1-9.5% increase in actual donation rates. Although positive, this increase is also modest.

These modest rates of registration are compelling when paired with the literature on the impact registries can have on donation decisions made by families. Two papers by de Groot et al. (2015 & 2016) interviewed Dutch families who had previously made a donation decision. The first of these focused on families who had consented for their loved ones organs to be donated (de Groot et al., 2015). Families expressed that registration by their family member was a strong predictor of them consenting to donation (de Groot et al., 2015). In the second paper, however, families who did not consent to donation and whose loved ones had not registered, did not agree to donation even when they had discussed donation through informal means (de Groot et al., 2016). This latter finding suggests that formal registration could potentially be a stronger predictor of positive donation decisions than family discussion alone.

At the time of writing, England adopts a ‘hard opt-in’ system meaning family permission to donate organs is not legally required if their loved one is on the NHS ODR (NHS Blood and Transplant, 2013a). However, when examining the activity reports, it is clear that families are consulted and allowed to refuse consent, even when their loved one was registered (NHS Blood and Transplant, 2018a). Registration, therefore, provides two functions, to demonstrate a person’s intention to donate, and as a guide for the family to understand those intentions at a time of distress. The next section will discuss the NHS ODR in more detail to explore these findings further, and aims to demonstrate why targeting registration as a donor is a suitable avenue to explore for the intervention in this thesis.


2.1.4 The National Health Service Organ Donor Register

In the UK, the NHS ODR is run by NHSBT (NHS Blood and Transplant, 2018a). The NHS ODR was established in 1994 and consists of a computer-based database of those who wish to donate their organs after death (NHS Blood and Transplant, 2018a). Before the development of the NHS ODR, if a person wanted to demonstrate their intention to donate their organs, their only option available was to carry a donor card (NHS Blood and Transplant, 2019a). Authors have commented that although expressing a decision in any way is positive; donor cards have limitations. For example, cards may not always be available at the time of clinician and family donation decision making (Sung et al., 2008).

Unlike donor cards, when a patient is placed on the organ donation pathway (National Institute for Clinical Excellence, 2016b) the NHS ODR will be checked by a SNOD or by clinicians (NHS Blood and Transplant, 2013a). This checking ensures that families are always informed if their loved one is on the NHS ODR (NHS Blood and Transplant, 2013a). As previously discussed, between April 2018 and March 2019 46% of organ donors were registered on the NHS ODR (NHS Blood and Transplant, 2019d), and when patients were on the NHS ODR family consent for donation was 93.0%. The consent rate when wishes were known by any method (including NHS ODR registration) was 93.6% (NHS Blood and Transplant, 2019d). Only a 0.6% increase in donation rate was found for those families who knew wishes through either discussion or NHS ODR registration compared to NHS ODR registration alone (NHS Blood and Transplant, 2019d). These results show the strong impact registration can have on family decision making over discussion alone, specifically in a UK context.
Academic studies focused on the role of the NHS ODR support the importance of registration on family consent decisions. For example, Sque et al. (2018) investigated influencers of family consent using qualitative interviews with UK donor families (Sque et al., 2018). Their findings echo those above that a key influence on families’ decisions was knowledge of wishes through registration on the NHS ODR. However, a quantitative analysis by Hulme et al. (2016) found that awareness of wishes through both registration and family discussion had the most significant effect on donation likelihood as opposed to NHS ODR alone (Hulme et al., 2016). This finding suggests that registration may not be enough to encourage donation for UK families and that interventions focusing on NHS ODR sign-up should also incorporate the promotion of family discussion where possible (Hulme et al., 2016).

In summary, registries can help guide family donation decision making. They demonstrate to families the wishes of their loved one and as the above results show this helps guide their decision whether to consent to donation. These findings provide support for the current intervention to focus on NHS ODR registration as it is a definite positive expression of wishes.

2.1.5 An Opt-Out System in England

This research commenced in October 2016. The landscape of donation, however, has changed significantly in the period since the start of this research. It is prudent, therefore, to
discuss these changes and how this body of work fits in the new system of organ donation to be implemented in the UK in Spring 2020, an opt-out policy of consent.

As part of NHSBT strategy, a change in organ donation law has been proposed. At the start of this research, an ‘opt-in’ or ‘express consent’ system was in place in England, Scotland and Northern Ireland (NHS Blood and Transplant, 2019c). In this system, members of the public have to actively express consent to donate their organs through registration on the NHS ODR or by discussing wishes with their family (NHS Blood and Transplant, 2019c). In Wales, however, an ‘opt-out’ or ‘deemed consent’ system has been in place since 2015 (NHS Blood and Transplant, 2019a, 2019c). This system assumes that the population wishes to donate their organs after death unless they have expressly opted out through the ‘opt-out register’ (NHS Blood and Transplant, 2019c). In 2018 a public consultation was held on the possibility of moving to a ‘deemed consent’ system in England (NHS Blood and Transplant, 2019c). Responses to this consultation were predominantly positive, and in 2019 MPs voted to introduce ‘deemed consent’ into law in England as of Spring 2020 (NHS Blood and Transplant, 2019c). The opt-out legislative change has increased the number of Welsh people donating their organs, with a consent rate of 80.5% compared to a consent rate of 66.2% in England (NHS Blood and Transplant, 2018c). However, it is important to clarify that although these increases are positive, the system adopted in Wales and proposed to be adopted in England is ‘soft opt-out’ (British Medical Association, 2019b). ‘Soft opt-out’ systems require family consent for approval of donation, whereas ‘hard opt-out’ systems do not (Dallimore et al., 2019). Although these results appear promising for Wales and the ‘opt-out’ system, it is important to reflect on whether causality can be determined in this case. Is the increase in organ donation rates due to the change in legislation? Alternatively, could
this increase in rates be due to other factors associated with implementing the system, rather than the opt-out system itself?

The introduction and success of presumed consent systems has been debated at length by healthcare professionals and members of the public (Rithalia et al., 2009; Bird and Harris, 2010; Potts et al., 2010; Randhawa et al., 2010; Rieu, 2010; Saunders, 2010, 2012; Bramhall, 2011; Prabhu, 2018; Sharif, 2018). In 1996 a review of 10 years of presumed consent legislation in Belgium was published (Michielsen, 1996). One of the first papers of its kind, Michielsen described the process of implementing presumed consent in 1986 (Michielsen, 1996). A key finding was that although presumed consent legislation was in place, and family consent was not legally required, healthcare professionals very often consulted the family regardless (Michielsen, 1996). This finding is echoed in a commentary by Claudio Csillag on the abolition of opt-out in Brazil (Csillag, 1998). Hard opt-out legislation was only in place for a short period; however, doctors were unwilling to remove organs without family consent (Csillag, 1998). Like in Brazil, Orentlicher (2009) discusses the rise and fall of opt-out consent in the USA. Opt-out was first introduced in the late 1960’s in some states and by 2006 legislation had changed back to an opt-in system. This change is attributed to its soft opt-out nature, that the legislation did not address the reasons why families did not consent. As a result, opt-out did not increase donation rates in the states which adopted it (Orentlicher, 2009). Similarly, Dominguez and Rojas (2013) discussed the impact of opt-out systems in Chile and found that donation rates decreased after its introduction. They believe this to be due to fears and mistrust of healthcare systems in the country, and emphasised the importance of the family in consent to organ donation (Dominguez and Rojas, 2013).
Previous research has considered that some positive reviews of opt-out are influenced by the high rates of organ donation in Spain, widely considered to have the best organ donation system (Fabre, 2014; Rudge, 2018). Spain has the highest donation rate in the world, an 85% family consent rate (Fabre, 2014). The ‘Spanish Model’ is revered worldwide and is often cited as being due in part to an opt-out system (Fabre, 2014). However, this is incorrect, as the legislation in Spain is mostly irrelevant when examining the reasons for Spain’s success (Miranda, Vilardell and Grinyó, 2003; Fabre, 2014). There are no opt-in or opt-out registries in Spain, and the majority of the public are unaware of the legislation (Miranda, Vilardell and Grinyó, 2003). Its success is due to other factors such as the high number of beds in intensive care units (Rudge, 2018) and the transplant co-ordinator program (Miranda, Vilardell and Grinyó, 2003). The Spanish case, in particular, highlights the need to be cautious when attributing increases in donation rates to opt-out systems.

Several authors have examined organ donation and transplantation rates between opt-in and opt-out systems in multiple countries. Abadie and Gay (2006) found that opt-out systems have higher numbers of organ donors than opt-in systems (Abadie and Gay, 2006). However only a 25-30% increase was found in their review from 22 countries over a ten year period, which the author’s state is not enough to close the donation – transplantation gap in most countries (Abadie and Gay, 2006). Bendorf et al. (2013) extended the literature base by examining living and deceased kidney donation rates between 53 countries. Opt-out systems had a significant positive correlation with deceased kidney donation; however, the reverse was found for living donation, with a significant negative correlation found (Bendorf
et al., 2013). This research, in particular, indicates that although opt-out, may increase some specific areas of donation it can harm other forms of donation.

Critical research on this topic comes from two papers which controlled statistically for the effect of Spain in their analyses (Neto, da Silva and Campelo, 2012; Arshad, Anderson and Sharif, 2019). Neto, da Silva and Campelo (2012) found a positive impact of opt-out systems in comparison to opt-in systems (Neto, da Silva and Campelo, 2012). More recently, however, Arshad, Anderson and Sharif (2019) conducted a comparison of donation rates between opt-in and opt-out countries, and their results do not support this. They found that opt-out countries had significantly less living donors than opt-in countries, and importantly, no significant difference in deceased donation rates between the two systems was found. They recommend that other interventions, such as improving opt-in registration rates, are required to increase donation rates, in place of transitioning to an opt-out system (Arshad, Anderson and Sharif, 2019).

In a UK context, the results from Wales appear to indicate that opt-out has improved rates, with a presentation at the British Transplant Society (BTS) and NHSBT Congress in 2019 stating that when comparing donation rates in Wales to England, the increase in donation after legislation was introduced has now reached statistical significance (Madden, 2019). However, the preliminary results showed that in the initial period of opt-out, there was only an increase of 3 donors in the 21 months post its adoption (Parsons, 2018). This finding led authors to publish commentaries on the success or lack of success of the legislation, with a variation of views demonstrated. For example, Stephens (2018) and Albertsen (2018) stated personal views that opt-out had been successful in Wales (Albertsen, 2018; Stephens, 2018).
whereas Parsons (2018) viewed the legislation more negatively with the sizeable anticipated increase in donation not materialising (Parsons, 2018). Shaw (2018) also considered the opt-out legislation in Wales negatively emphasising that due to the public information campaign to inform people of opt-out, donation rates increased even before the legislation was introduced (Shaw, 2018). This finding suggests that the opt-out legislation itself could be less critical to increasing donation rates than the accompanying increase in donation awareness associated with it (Shaw, 2018).

Shaw (2018) also found that 25% of the Welsh population were not aware of the legislation change, however, highlighting the potential for organs to be donated from those who were unwilling to be donors (Shaw, 2018). This lack of awareness indicates that introducing opt-out does not negate the need for other organ donation interventions, particularly those targeting the population and their awareness of donation. Most articles that discuss opt-out systems agree that it is challenging, if not impossible, to attribute any increase in donation to the legislation alone; that the introduction of legislation usually occurs alongside other interventions or organisational changes (Moore, Thomas and Jones, 2018). Moore, Thomas and Jones (2018) also suggest that for opt-out to be introduced, public opinion will already be more favourable towards donation, meaning opt-out could be a reaction to public attitudes which could increase donation rates. Finally, also presented at the BTS and NHSBT congress was a commentary from Bethan Moss, a SNOD, discussing how they reacted to the introduction of opt-out (Moss, 2019). This presentation strongly supports the assertion that opt-out alone is not responsible for increases in donation. Moss (2019) discussed how the SNODs were not experiencing any higher success rates until they discussed how to improve their communication style with families of patients (Moss, 2019). SNODs changed from their
traditional approach of asking families what their loved ones wishes were, to an approach which stated they assumed their loved one consented to donation through their absence on the opt-out register. Rudge (2018) supports this and suggests that changes in approach to families could be influential in opt-out systems, more so than the legislation itself (Rudge, 2018).

These results and discussions regarding the success of opt-out are essential to consider when moving forward to increase organ donation rates in the UK. The key finding is that opt-out may not necessarily be effective alone, but alongside other changes and interventions, if it is effective at all. More important is that the role of the family in the organ donation consent process remains the same in soft opt-out systems, the type which will be implemented in England in Spring 2020, and which is already in place in Wales. Families will always be consulted regarding donating their loved ones organs, and although not legally required, it is likely that healthcare professionals will not override their wishes (Rosenblum, Horvat, et al., 2012). Indeed Rosenblum et al. (2012) found that in only 8 out of 54 nations would family wishes be overridden if the deceased had previously consented to donation, regardless of legislation and official or legal position (Rosenblum, Horvat, et al., 2012). They conclude that based on previous work and their review, family consent could have a more significant impact on donation rates than changes in legislation (Rosenblum, Horvat, et al., 2012). Changing legislative system is also accompanied by promotional programs aimed to inform the public, and by extension will encourage discussion of organ donation and expressing preferences. Either through registries or expressing wishes verbally to each other. Indeed it could even be prudent to develop and introduce other interventions
like that discussed in this thesis, to capitalise on the increased public awareness that accompanies a transition of this type.

2.2 Organ Donation Interventions: A Literature Review

The next section explores previous interventions targeting organ donation to determine appropriate techniques to use, and settings in which to conduct the intervention developed and tested in this thesis. It also aims to examine gaps in the literature that the intervention in this thesis may fill.

2.2.1 Systematic Reviews & Meta-Analyses of Interventions Targeting Organ Donor Registration

The first area to be examined in this section will be systematic reviews and meta-analyses. These will provide a basis for the intervention in this thesis - particularly with regard to the setting and population it could be conducted in, the elements the intervention could contain, and areas to consider for the methodology.

Systematic reviews and meta-analyses are viewed as a robust form of literature which should be prioritised over individual studies in a literature review. A collective summary of research papers can provide stronger evidence to indicate the success or non-success of interventions than single study papers alone (Aromataris and Pearson, 2014; Lockwood and Oh, 2017). A literature search was conducted in Autumn 2016 – Spring 2017, and again in April 2019 to identify systematic reviews, reviews or meta-analyses of interventions targeting registration as an organ donor using the following search terms: AB ("organ
donation" OR "organ donor" ) AND AB ( intervention* OR program* ) AND AB ( "donor register*" OR "organ donor* register*" OR regist* ) AND AB ( review OR systematic review OR synthesis OR meta ) in all databases available in the University of Bedfordshire library catalogue. Twenty-nine relevant papers were found in total (without duplicates); five systematic reviews of interventions and one protocol. One review was not included as it targeted healthcare professionals, the identification of possible organ donors in hospitals and the family consent process, as opposed to organ donor registration (Figure 2).

Figure 2: PRISMA Flow Diagram documenting the literature search for systematic reviews and meta-analyses of organ donation interventions.
The four reviews discussed below focus on the following types of intervention or target audiences: communication campaigns, ethnic minority interventions, adolescent interventions, and community-based interventions. The first of these is conducted by Feeley and Moon (2009) who analysed 23 organ donation campaigns across 16 studies, mostly in the USA with one study in Sweden. A single primary outcome combined family discussion, organ donor registration and attitudes towards donation. A meta-analysis found that overall public education campaigns had an effect of 5% over control groups. No statistically significant effects were found for potential moderators of this effect (ethnicity, campaign exposure and mode of delivery). However, the authors state that other moderators could be responsible for this 5% effect. Although this paper provides positive evidence for public campaigns to promote organ donation, it does not specify which methods should be used to do this. The meta-analysis also combines several different outcomes into an overall effect, which for the present research does not allow us to differentiate between campaigns which successfully target organ donor registration (the target behaviour), and attitudinal changes or family discussion (Feeley and Moon, 2009). The second review, on the other hand, provides more explicit guidance on intervention techniques which can be used to increase organ donation registration.

A review of educational-based interventions was conducted by Li, et al. (2013). They propose that as adolescents are often presented with opportunities to register as an organ donor when they apply for a driving license, educational interventions could be beneficial at increasing registration at this time point. Fifteen articles were included in this review, predominantly from the USA and Europe. Two studies used a theoretical framework to underpin the intervention, and five studies were of high methodological quality. In all ten
studies that examined knowledge, five studies that examined attitude and six studies that examined family discussion, an increase was found in these outcomes post-intervention. For intention to register, however, intervention success was variable, and no studies measured actual registration or donation as outcomes. The authors note that although these results are promising, most studies did not specify the educational program used in the intervention making the translation of these findings to future interventions challenging. They make further recommendations to move away from intention to register as an outcome measure due to social desirability bias and also recommend interventions should highlight the supply-demand problem that exists for organs worldwide (Li et al., 2013).

Like the previous review, Deedat, Kentan & Morgan (2013) conducted a systematic review of interventions which aimed to increase knowledge, registration as an organ donor or intention to register in a specific population - ethnic minorities. They found 18 studies, 17 from the USA and one from the UK, and concluded that interventions using mass media alone did not increase intention to register as an organ donor. Educational and interpersonal interventions combined with mass media, or educational and interpersonal interventions alone were more effective at increasing knowledge, intention to register and registration amongst these groups. Key findings suggested by the authors are the importance of readiness to register as a donor and access to sign-up opportunities. The authors suggest that registration as an outcome measure has limitations in groups less ‘ready’ to register (such as ethnic minorities), as they do not measure any improvements to readiness caused by interventions. They also highlight the importance of access to sign-up opportunities in those more ready to register or those termed ‘passive positives’. Passive positives are those who have positive attitudes towards organ donation, wish to donate but
have not yet signed up. This group are easily ‘nudged’ or ‘prompted’ towards registration, and this also can be facilitated by providing access to a sign-up opportunity. A lack of assessment of intervention acceptability and a lack of consultation with target groups during intervention development was noted by the authors, and they recommend intervention researchers investigate this further. (Deedat, Kenten and Morgan, 2013).

The final review, which also references ‘passive positives’ was conducted by Golding and Cropley (2017). They investigated community-based interventions, specifically targeting registration as an organ donor and found 24 studies in total. The majority of these studies were conducted in the USA, four in Europe and one within the UK. The authors focused on psychological interventions and found only eight studies were methodologically strong. They found nineteen studies increased registration rates but not all of these reached statistical significance. Effective elements of these interventions included developing brief interventions, combatting myths surrounding organ donation, and as in the previous studies, providing an immediate sign-up opportunity. A key finding is the success of interventions in the Driving Motor Vehicle Offices (DMV) in the USA targeting ‘passive positives’. All five studies that took place in DMV offices and targeted these significantly increased registration rates; however, 3 of these studies scored ‘weak’ in the quality assessment. The authors indicate that as this location provides an opportunity to access large proportions of the population, further investigations should be conducted in this setting. They note, however, that as this location is not frequented by all, some people may be excluded from these interventions or opportunities to register. (Golding and Cropley, 2017).
A predominant theme of these reviews is the targeting of ‘passive positives’ whom only require minimal intervention to sign up to a register, discussed by both Deedat, Kenten and Morgan (2013) and Golding and Cropley (2017). This group could be simpler to target as they experience higher levels of ‘readiness’ to register (Deedat, Kenten and Morgan, 2013; Golding and Cropley, 2017). Golding and Cropley (2017) also discuss the potential of the DMV in the USA to host organ donation interventions; that they have access to a large proportion of the population. Based on these findings, a setting in the UK which has access to a large proportion of the UK population, as well as access to the NHS ODR, should be investigated further as a location to host the intervention. Attributes of successful interventions were also derived from these reviews; using nudge or prompting to target passive positives (Golding and Cropley, 2017), improving access to NHS ODR registration opportunities (Golding and Cropley, 2017), providing an immediate sign-up opportunity for those experiencing the intervention (Deedat, Kenten and Morgan, 2013; Golding and Cropley, 2017), using interpersonal elements (Deedat, Kenten and Morgan, 2013), addressing organ donation myths (Li et al., 2013; Golding and Cropley, 2017), providing information on the need for organs in the UK (Li et al., 2013), and that it should be brief (Golding and Cropley, 2017).

Finally, some methodological considerations should be taken forward in the design of this research. Intervention techniques and components should be explicitly specified in published literature, to allow other researchers to clearly understand the intervention (Li et al., 2013; Douville, Godin and Vézina-Im, 2014). To include the target population in the development process (Deedat, Kenten and Morgan, 2013). To assess the intervention for
acceptability (Deedat, Kenten and Morgan, 2013), and finally use actual registration as an outcome, not intention to register (Li et al., 2013).

2.2.2 Organ Donor Registration Interventions in the United Kingdom

A key finding from the systematic reviews is the dearth of research conducted in the UK. This could be due to an actual lack of research conducted into NHS ODR registration in general, or that the research conducted in the UK does not fit with the inclusion and exclusion criteria of the review papers. Therefore, as the intervention designed in this thesis is conducted in the UK, the next section aims to search for UK based interventions targeting sign up on the NHS ODR, that were not included in the systematic reviews above. The following search was conducted in Autumn 2016 – Spring 2017, and again in April 2019 and found 167 journal articles not including duplicates; AB (UK OR U.K.OR "united kingdom" OR "great britain" OR britain OR scotland OR wales OR england OR "northern ireland") AND AB ("NHS Organ donor register" OR "donor register" OR NHS ODR OR regi*) AND AB "organ don*", in all databases available in the University of Bedfordshire library catalogue (Figure 3).
Figure 3: PRISMA Flow Diagram documenting the literature search for UK organ donation interventions.
Ten relevant studies were found; two examined the use of peer outreach educators to target NHS ODR sign-up in ethnic minority populations (Buffin et al., 2015; Pradeep, 2015), six studies examined reciprocity priming, emotional salience and anticipated regret using experimental methods in controlled conditions (O’Carroll, Foster, et al., 2011; O’Carroll et al., 2016, 2017; Doherty et al., 2017; Miller, Currie and O’Carroll, 2018; O’Carroll, Quigley and Miller, 2018) and the final two studies examined ‘nudge’ strategies to increase NHS ODR sign-up (Moseley and Stoker, 2010; Sallis, Harper and Sanders, 2018).

Peer educators were explored to target NHS ODR registration in Asian populations. A PhD thesis by Pradeep (2015) detailed two intervention strategies targeting NHS ODR registration; using leaflets and posters to prompt patients to discuss organ donation with their GP, and using peer educators at community events. Issues in implementation were found with the former study; subsequently, no patients signed up in the intervention period. The second strategy used, however, proved to be successful, with 2,874 new registrations in 24 months collected at 289 events by South Asian health professionals trained as peer educators. Strengths of the intervention include its theoretical basis (the Health Belief Model) (Rosenstock, 1974) and stakeholder involvement (Pradeep, 2015). These findings support the findings concerning the importance of gatekeepers, and including theoretical underpinnings in interventions as found in the systematic reviews.

Buffin et al. (2015) also found peer educators to be a successful way for people to sign-up to the NHS ODR, with 8.8% of Asian attendees at 34 events signing up. The majority of those had previously considered it, and the two main barriers to sign up were ‘not knowing enough about it’ and ‘not understanding how to sign-up’. The authors followed up 54
people who stated they would sign-up at a later date after the intervention. However, none had signed up (Buffin et al., 2015). Providing further support for the previous findings from systematic reviews that an immediate sign-up opportunity is important, and that people may not register after an event. It also supports the concept of readiness to sign-up; perhaps those who signed up at events could be ‘passive positives’ if the majority of them had already considered donation.

Six studies were conducted by Professor Ronan O’Carroll and other researchers. Unlike the previous studies, these focused on experimentally testing the techniques used in messages to encourage NHS ODR registration, predominantly using questionnaires as an intervention technique. The first study by O’Carroll et al. (2016) examined the role of anticipated regret in encouraging sign-up to the NHS ODR. Anticipated regret aims encourage focus on the regret a person may feel in the future by not participating in a specific health behaviour – in this case, signing up as an organ donor. A previous pilot of this study (O’Carroll et al., 2011) found that the inclusion of questions concerning the anticipated regret of not donating one’s organs encouraged participants to sign-up to the NHS ODR in significantly higher numbers than in control groups. However, a subsequent study on 9,139 randomly selected participants in the Scottish population did not support this. Of the total sample, 5.40% registered on the NHS ODR after receiving a questionnaire and participants exposed to the anticipated regret questionnaire were significantly less likely to register than in the control arm. The authors believe that this result was due to the inclusion of ‘affective questions’, and that participants were subject to negative contextual cueing. Due to the negative nature of some of the affective questions participants negative views on organ donation
were primed, and subsequently impacted their likelihood of signing up to the NHS ODR (O’Carroll et al., 2016).

A second study explored the impact of these affective questions on NHS ODR registration (Doherty et al., 2017). Participants who did not receive affective attitude questions were significantly more likely to register a positive intention to join the NHS ODR, and were marginally more likely to accept a donor card than those who received them. No significant effect on these outcomes was found between participants who only had negative affective items displayed and the group that completed both positive and negative (Doherty et al., 2017). These results suggest that affective questions or messages in interventions to increase NHS ODR sign-up should be used with caution. They also potentially support the previous finding by Golding and Cropley (2017) that brief interventions may be more effective, i.e. that the shorter questionnaires were more effective.

The third study by O’Carroll et al. (2017) focused on reciprocity priming instead of anticipated regret. This study used a face to face or online intervention to encourage sign up to the NHS ODR and used a technique called reciprocity priming. This concept is based on reciprocal altruism and primes participants to think on the question “if you needed an organ, would you take one?”. Significantly higher intention to donate was found in the reciprocity priming groups compared to control. Additionally, no significant effect was found on seeking further organ donation information between groups, but participants who experience a face to face intervention were more likely to seek information than those who experienced intervention online (O’Carroll et al., 2017). A second study by this group found participants exposed to reciprocity priming had significantly higher intention to donate than
those in the control, and like the previous study, no significant difference was found between groups on rates of clicking for a link to register (O’Carroll, Quigley and Miller, 2018). The results support that reciprocity priming can positively influence intentions to register as an organ donor; however, intention may not be an adequate measure of NHS ODR registration. The use of proxies (information seeking) in this study goes some way in countering this problem. However, actual NHS ODR registration could be used as an outcome measure in this thesis to counter this limitation.

The final study by this group examines the impact of emotional contextual cueing and myth-busting on the likelihood of registration on the NHS ODR (Miller, Currie and O’Carroll, 2018). In this study, in line with the new developments in opt-out policy in England, the researchers asked participants whether they intended to opt-in, do nothing and act with the deemed consent legislation, opt-out of donating their organs or if they were unsure. For participants who stated they would opt-in or use deemed consent, both an emotional barriers questionnaire and myth-busting questionnaire significantly increased their intention to donate. However, for those who selected opt-out or not sure, the emotional barriers questionnaire significantly decreased intention, and the myth-busting questionnaire had no effect on intention. These findings provide additional support to the notion of different categories of potential registrants; particularly passive positives in the UK. They could also provide evidence that those who are less sure about registration or oppose it, react differently to interventions compared to those who have positive views on donation (Miller, Currie and O’Carroll, 2018) - indicating that interventions could be tailored to target these different groups.
The strength of the studies described above is in the rigorous and randomised experimental methodology used. However, there are concerns with how applicable this research could be to a large national intervention, particularly regarding the implementation of sending questionnaires. The practical constraints and transferability of this research need to be taken into account when selecting intervention methods and settings in this thesis; however, the results found in these studies can help guide the messaging techniques used. Additionally, the ‘core’ intervention component in these studies is the use of a questionnaire to encourage sign-up. Sign-up rates overall were modest using this method, and other methods should be considered alongside this in this thesis.

The final two studies test applied interventions; a comparison of a booklet versus face to face discussion intervention (Moseley and Stoker, 2010) and an online intervention targeting users of the Driver and Vehicle Licensing Agency (DVLA) website who are paying their road tax (Sallis, Harper and Sanders, 2018). Moseley, Smith and Stoker (2010) examined two techniques for behaviour change; ‘nudge’ and ‘think’. Nudge is a top-down strategy used by policymakers, which presents information in a certain way in order to encourage behaviour change. It is based on the theory that humans only process a small amount of material around them when making decisions. The think approach assumes that humans are deliberators who need to discuss and contemplate, prior to making decisions about their behaviour. The authors found a higher percentage of participants intending to register in the nudge group than in the think group; however, both nudge and control had a similar % of participants intending to register. These findings indicate that there may be a negative effect of un-facilitated discussion (think group) on organ donation, which could be explained based on the previous studies investigating affective attitudes; that discussion
could have centred around the affective elements of donation. However, it is unclear exactly what was discussed in those groups. It is important to note that this study also supports the assertion by Li et al. (2013) that brief interventions may be more effective at encouraging NHS ODR registration (providing booklets compared to group discussion), perhaps due to being less likely to encourage affective assessments of organ donation.

The final study was conducted with 1,085,322 participants. Sallis, Harper and Sanders (2018) examined the effect of different types of messages presented to visitors to the DVLA road tax website over four weeks. The investigators wished to examine the effect of 7 theoretically based sentences alongside a link to register; social norms based messages (alone, with an image or with the NHSBT logo), loss-framed, gain-framed, reciprocity and cognitive dissonance. They found that participants presented with the reciprocity message were 1.38 times more likely to click through to the NHSBT website than control, and they were also significantly more likely than control to join the NHS ODR. Loss-framed messages were also significantly more likely to cause participants to click through to the website; however, they were not significantly more likely than control to sign-up. This study was a rigorous large scale field experiment which used randomisation of participants and had a large sample. The findings, therefore, are robust, that reciprocity messages are important to include in brief NHS ODR interventions, supporting the previous work by O’Carroll et al. (2017) and O’Carroll, Quigley and Miller (2018).

Of importance is that 29,772 people registered to be an organ donor in this study which is a large number; however, this only equates to 2.7% of participants. Considering it is stated by NHSBT that 90% of the population wish to be organ donors, this number seems low (NHS
Blood and Transplant, 2018a). It begs the question therefore that although reciprocity messages should be used where possible in our intervention, is there a better way to increase sign-ups to the NHS ODR, than presenting people with a passive link to the register after completing another unrelated activity. A final finding of note is the number of people who clicked through to the NHSBT website (n=44875, 4.1%) versus the number who signed up (n=29772, 2.7%). This drop off of 15,103 people or 1.4% of people could provide evidence for a gap between intention to donate organs and actual registration. This intention-behaviour gap should be explored further in subsequent sections of this thesis, to determine whether an intervention can adequately target this gap or part of it.

In summary, in a UK context, there are a limited number of interventions published and fewer published in high-quality peer-review journals. The largest intervention was conducted by Sallis, Harper and Sanders. (2018) and provides robust evidence that prompting sign up works to a modest extent. Also important is the way in which messages are framed or delivered can impact sign-up and this should be considered in intervention design (O’Carroll et al., 2011; Doherty et al., 2016; O’Carroll et al., 2016, 2017; Miller, Currie and O’Carroll, 2018; O’Carroll, Quigley and Miller, 2018; Sallis, Harper and Sanders, 2018). However, due to the dearth of research on interventions in the UK encouraging actual NHS ODR sign-up, special consideration was taken into which settings the intervention in this thesis should be located. It is important to consider the current ways people can sign-up on the NHS ODR, as simply introducing a novel way to sign-up could be enough to increase NHS ODR registration rates. Once more intervention research is published on simple interventions focusing on access to the NHS ODR, then it would be prudent to explore types of messages to facilitate this. However, until this body of literature exists, it seems wise to
develop an intervention which is simple, brief, provides an immediate sign-up opportunity and most importantly increases access to signing up to the NHS ODR. The next section will discuss this in more detail, explore current ways to sign up to the NHS ODR, as well as possible settings to host the intervention in this thesis.

2.3 Settings for a National Health Service Organ Donor Register Intervention in the United Kingdom

This section first aims to examine the demographics of the NHS ODR and identify which groups are underrepresented; this will help target the intervention in this thesis to these groups. Secondly, how people currently sign-up to the NHS ODR will be examined to identify any untapped opportunities for improving sign-up and where underrepresented groups could be best targeted.

2.3.1 The National Health Service Organ Donor Register - Who is Registering?

Overall rates of sign-up to the NHS ODR were discussed previously in this chapter, with more organ donors needed to meet the demand of the transplant list. The NHSBT activity reports that provide this information also provide a detailed breakdown of who signs up to the NHS ODR by organ registration preference, gender, age, socioeconomic status and ethnicity (NHS Blood and Transplant, 2018a). By March 2019, of those who had ethnicity recorded, 92.6% were White, 3.3% Asian, 1% Black, 0.3% Chinese, 2% Mixed Ethnicity and 0.7% other ethnic groups. Compared to the general population, there is a poor representation of Black, Asian and Minority Ethnic (BAME) groups on the NHS ODR (NHS Blood and Transplant, 2018b). However, only 34% of registrants had ethnicity recorded,
meaning the exact ethnic profile of the register cannot be established. More females than males are signed up to the NHS ODR, 53% and 46% respectively and predominantly more people from younger age groups register on the NHS ODR (ages 16 – 30) (Figure 4) (NHS Blood and Transplant, 2019d).

Figure 4: Age and gender at registration of all members of the NHS ODR as of 31st March 2019 (NHS Blood and Transplant, 2019b).

Also, compared to the UK population, fewer people from lower socioeconomic groups are registered (Figure 5) (NHS Blood and Transplant, 2018a).
Finally, organ donation preference of those registered reveals 79% requested to donate all their organs and tissues. Of those who did not want to donate one or more of their organs, 75% stated they did not wish to donate their corneas equating to 10.6% of all registrations on the NHS ODR. People were most likely to donate their kidney with 0.8% of all registrants refusing, followed by liver 1.5%, lungs 2.4%, pancreas 2.6% and heart 2.6% (NHS Blood and Transplant, 2018a).

These descriptives are essential for developing the intervention in this thesis, as the setting and techniques used should ideally target those underrepresented on the NHS ODR; males, older people aged 40+, cornea registrants and lower socioeconomic status registrants. However, the NHSBT Activity Reports do not explore the interaction of these demographics with each other.
2.3.2 The National Health Service Organ Donor Register - How do People Register?

Based on the findings from the literature review, an existing setting which has connectivity to the NHS ODR should be examined in which to improve access to sign-up opportunities, mainly to target passive positives. Further, the intervention should also provide access to the underrepresented groups described previously where possible. The NHSBT Activity reports provide brief information on sources of sign-up to the NHS ODR. Three of these are via tick box; through the DVLA, Boots Advantage Card and GP Practices. Four other sources of sign-up are specified; website, paper form, telephone, and ‘other' sign up methods (NHS Blood and Transplant, 2018a) (Figure 6).

Figure 6: NHS ODR registrations categorised by source of registration (NHS Blood and Transplant, 2019b)
The data provided by the NHSBT activity reports only show how people signed up recently to the NHS ODR (2016-2017 and 2017-2018) not how all members of the register have signed up. A journal article in preparation by Jones, Papadopoulos, and Randhawa (Appendix 1) fills this gap and analyses sources of sign-up to the NHS ODR using inferential statistics. Only registration age, current age, and gender reached the threshold required to be of note with sources of sign-up. These results help to examine which methods could target the underrepresented groups discussed above; men, cornea donors, infants and children, and those over 40. Unfortunately, however, ethnicity could not be included in this analysis.

2.3.2.1 The Driver and Vehicle Licensing Agency

The most popular sign-up method between April 2018 - March 2019 was via the DVLA – 47% (Figure 6) (NHS Blood and Transplant 2018a). People are presented with a tick box to join the NHS ODR when registering for or renewing their driving license. A link is also presented to the NHS ODR registration website page after completing road tax payments online (NHS Blood and Transplant, 2019b). Jones, Papadopoulos and Randhawa (Appendix 1) found the highest adjusted residuals for DVLA sign-up for the age group 15-19, which is unsurprising, given that in the UK adolescents can register for a driving license from the age of 15 years and nine months (Gov.uk, 2019). Another high adjusted residual was found for older age groups spanning age 65-89, which is also unsurprising, as those over 70 are required by law to renew their driving license and continue to renew it every three years (Department for Transport, 2019). This setting cannot target children due to the minimum age restriction on driving in the UK, however. Additionally, registration via the DVLA targets males significantly
more than females; this can be assumed due to the higher numbers of men who register for driving licenses than women (Department for Transport, 2018). Although promising for targeting these underrepresented groups, it is challenging to observe gaps where an intervention could be placed in the DVLA. Website links to the NHS ODR have been added to post-DVLA online tasks, and researchers and NHSBT are already targeting this location (Sallis, Harper and Sanders, 2018). Therefore other settings could be explored where there are more substantial opportunities for improving access which have not yet been utilised.

2.3.2.2 Boots Advantage Card

A tick box is also afforded to people who sign up for a Boots Advantage Card, a loyalty scheme provided by the store Boots in the UK and people can obtain a card via paper form or online (Boots, 2019). This method accounted for 2% of registrations between April 2018 and March 2019, significantly more women than men signed up than expected, and in the age groups 20-64 and 80-90+ (NHS Blood and Transplant, 2019d) (Appendix 1). As with DVLA sign-up, Boots Advantage cards are typically only used by adults who purchase items at Boots, not children. Although there appears to be no age limit for gaining a card, this method does not target children according to the previous analyses (Appendix 1). Of note is that when comparing registration age groups to the current age groups on the register, the current age groups who signed up via Boots Advantage Card are 30-34 and 40-74 year olds. Demonstrating that less young people are currently signing up via Boots Advantage Card, potentially explained by a lessening popularity of these and a shift in shopping habits. Due to the closed corporate nature of Boots data on the success of their advantage card are not publicly available.
2.3.2.3 Website, Paper and Other Methods

The second most commonly used method to sign up is via the online NHSBT website, which registered 34% of the registrations between April 2018 and March 2019. Paper registration forms are also provided by NHSBT, which made up 1% of registrations, and all other methods account for <0% of registrations (NHS Blood and Transplant, 2019d). Unlike the DVLA, Boots Advantage Card and GP Practices, these are passive methods of sign-up which predominantly people seek out as opposed to being presented with. However, like Sallis, Harper and Sanders (2018), these can be integrated within interventions and used as a tool to present an opportunity. It is unclear, however, from NHSBT activity reports whether this occurs and if so, how many people sign-up from interventions using these methods.

Website based interventions are likely to continue to exclude older age groups and have been previously targeted by interventions combined with the DVLA (Sallis, Harper and Sanders, 2018). Further, the DVLA and website sign-ups appear to continue to be used by younger groups, when comparing registration age distribution and current age distribution (Appendix 1). If these sign-up methods are still being used by some of the target groups, then perhaps investigation into the other sign-up methods and why they are being used less could help guide the setting for this intervention.

2.3.2.4 General Practice

The tick box method of sign-up found via the DVLA and Boots Advantage Cards is also delivered in UK GP Practices via their new patient registration form. The GMS1 Form (Appendix 2) is presented to patients who wish to join a GP Practice, and on the first page of
this form, an opportunity to register on the NHS ODR is presented (National Health Service, 2017). Between April 2018 – March 2019, 16% of registrations were received by this method; however NHSBT note there is currently a backlog of these registrations being added to the NHS ODR (NHS Blood and Transplant, 2019d). No significant difference between gender was found by Jones, Papadopoulous, and Randhawa (Appendix 1), and the age groups 0-14 and 20-39 were statistically significantly more likely than expected to sign-up via the GP. However, when examining current age, the people who signed up via this method are now aged 35-54, as well as aged 0-14 (Appendix 1). Like with Boots Advantage Card, this demonstrates that fewer young people are currently signing up in this manner. However, this method is still used to sign-up children on the NHS ODR (Appendix 1).

Importantly a gap for opening access could be present in this setting. The authors highlight that these age groups are not in line with the age groups who use GP practices, predominantly older people (Appendix 1). It is speculated that this is due to the opportunity to sign-up on the NHS ODR only being provided to new patients registering with a practice.

In summary, few gaps for intervention are present via the DVLA. This setting has been explored recently by researchers (Sallis, Harper and Sanders, 2018), indicating that it may be maximised for registration rates - particularly as it is the best performing method of sign up to the NHS ODR. Online registration methods are also a high performer for NHS ODR sign-up and do not demonstrate any demographic gaps. Boots Advantage Card sign-up, on the other hand, could have a gap for intervention, particularly in younger age groups. However the data is not publicly available on sign-up rates to these cards; therefore it cannot be established whether the lack of sign-up rates in younger people illustrates a gap, or that younger people are not signing up for the cards at all. Additionally, access to Boots
Advantage Card sign-up settings is through a corporate organisation, and will, therefore, have barriers to access. The most promising gap for intervention is present in general practice as fewer older people than expected sign-up using this method, which indicates that the setting may not be utilised to its full extent based on the high volume of older people who use general practice settings (Appendix 1). Additionally, these findings show that there is a gap in NHS ODR interventions in the NHS as a whole, with GPs the only setting in which to register patients directly. It is crucial, therefore, to understand how the NHS is structured and explore whether GPs or other NHS settings would be most suitable for intervention.

2.3.3 Intervening in the National Health Service

The NHS in England consists of primary care and secondary care. Primary care is defined as the first point of contact for patients in the NHS and includes general practice, dentists, opticians, and pharmacies (NHS England, 2019c). When describing primary care in the UK, NHS England predominantly refers to primary care as GP Practices, defining them as the ‘bedrock of the NHS (NHS England, 2019b). Secondary care in the NHS is defined as that which one may be referred to from primary care, including hospitals (Contact for Families with Disabled Children, 2019). Approximately 309 million appointments were conducted in general practice between August 2018 and July 2019 (NHS Digital, 2019a), whereas fewer interactions with patients were conducted in hospitals. There were 119.4 million outpatient appointments in 2017-2018 (statistics to be updated for 2018-2019 by NHS Digital on 21st October (NHS England, 2018)), 24.8 million attendances in A&E (NHS England, 2019a), and 17.1 million admissions into hospital (NHS Digital, 2019b). These findings suggest that
primary care has greater access to patients for an NHS ODR intervention than secondary care.

In order to decide whether secondary or primary care should be targeted as the setting for intervention, a search was conducted for systematic reviews of organ donation interventions in healthcare settings, using the following search terms: AB ( "organ donation" OR "organ donor" ) AND AB ( intervention* OR program* ) AND (doctor* OR nurse* OR clinician* OR "healthcare prof*) AND AB ( "donor register*" OR "organ donor* register*" OR regist* ) AND AB ( review OR systematic review OR synthesis OR meta ). Only two systematic reviews were found investigating organ donation interventions and both targeted health professionals (Douville, Godin and Vézina-Im, 2014; Witjes et al., 2019) (Figure 7).
Witjes et al. (2019) exclusively targeted interventions in secondary care. Douville, Godin and Vézina-Im (2014) did not explicitly target secondary care settings; however, they focused on interventions aiming to improve the organ donation process or increase donation rates—specifically changing healthcare professional practice. No systematic review of organ donation interventions in primary care was found. Although these systematic reviews go some way in supporting that interventions can be conducted in secondary care, none of these examined targeting NHS ODR registration. The lack of investigation in registration interventions in all healthcare settings demonstrates a considerable gap in the literature.
which the present thesis can fill. However, it does not guide whether primary or secondary care should be used as a setting.

In contrast, the type of interactions with the NHS within each type of care could successfully guide this decision, due to the ethical concerns associated with organ donation interventions. Appointments in secondary care typically concern more serious issues than those in general practice, particularly as a proportion of visits will be in emergencies (NHS England, 2019a) or admittance into hospital, where a patient is likely to be suffering to some degree (NHS Digital, 2019b). However, outpatient appointments could be seen as less serious and a setting where an intervention targeting registration on the NHS ODR could occur. When comparing this to the number of appointments in general practice, approximately 309 million, it could be concluded that there is a better opportunity to target NHS ODR registration in GP practices - as there are a larger number of ‘less serious’ interactions with the health service. Some serious discussions do occur in general practice, however, and have important implications for bringing up the topic of organ donation with patients. Organ donation is a sensitive topic to discuss as it centres around the topic of death which could potentially cause distress to patients. This distress could be particularly acute in health settings where patients are vulnerable and visiting for health-related issues (Richards, 2002). Therefore interventions should aim to prevent harm and distress in these vulnerable populations, which could be simpler to do in general practice where patients are visiting for less serious health issues. These ethical issues will be discussed further in chapter five, intervention development, but for this reason, primary care will be explored as the setting for the present intervention to help limit the potential for patient distress resulting from NHS ODR interventions.
2.3.4 Intervening in General Practice

At present, the opportunity to sign-up is only awarded to a specific small group of people in general practice, new patients. It could be relatively simple to target a new group of people in this setting ‘existing patients’ to produce a new access opportunity. A new registration opportunity could be challenging to integrate within the DVLA and Boots who are already offering everyone who is applying for a card or renews a driving license an opportunity. Indeed the fact the DVLA account for 50% of existing sign-ups could also indicate they are maximising the access opportunities they provide, which is also supported by their engagement in research to expand the reach of these (Sallis, Harper and Sanders, 2018). GP Practices, on the other hand, only have the third-highest percentage of all sign-up methods to the register. On average, a GP has 979 face to face consultations every week (Baird et al., 2016). In 2016 there were 8,341 permanent full-time GPs in England and Scotland (General Medical Council, 2018); they are afforded 40 days of annual leave per year and will work for 44 weeks during the year (British Medical Association, 2019a). It can, therefore, be calculated that each permanent full-time GP has 43,076 face to face consultations per year approximately, resulting in approximately 359,296,916 face to face consultations with general practitioners and patients occurring each year. Taking into account that more face to face consultations with patients will occur in GP practices, by part-time GPs, locum GPs, nurses, healthcare assistants and other clinicians; there is a large footfall of patients not being targeted by an opportunity to sign-up to the NHS ODR. Particularly when examining that in total, only 5,930,859 NHS ODR registrations have been recorded via the GP (Appendix 1). These statistics support the assertion that there are more untapped
opportunities in this setting to pursue than at the DVLA or Boots, primarily with existing GP practice patients.

Using primary care and specifically general practice as a setting to target organ donation registration has been suggested by authors based in the UK. Neuberger and Keogh (2013) wrote an editorial on this topic, stating that general practice offers the opportunity to discuss organ donation with a qualified healthcare professional not only with patients but for families who often attend appointments together (Neuberger and Keogh, 2013). They suggest that GP practice staff can help raise awareness of donation, can emphasise the benefits to donor families that come from donation and dispel common myths around the donation process. Strategies to do this include providing increased opportunities to register on the NHS ODR, providing media in waiting rooms, verbally discussing donation in consultations, and including an organ donation indicator on the Quality Outcomes Framework (QOF). Hourigan also recommends general practice as a location for organ donation intervention, going further than Neuberger and Keogh by suggesting that general practice can provide a complete census of people’s views using their computer system which already has NHS ODR capabilities (Hourigan, 2005). Pradeep et al. (2018), based on her PhD thesis, also published a commentary piece on the promise of primary care specifically for targeting ethnic minority populations. She states that although there is much research investigating the role of GPs in health promotion, there is very little exploring their role in promoting organ donation. An important point is that GPs have a vital role in community health and have access to ethnic minority communities. However, based on her PhD research, she found that GPs do not appreciate the role they could play in promoting organ donation to BAME communities (Pradeep et al., 2018). These commentaries are
useful in guiding where researchers and policymakers should dedicate their efforts. However, considering the first of these was published nearly 15 years ago, little progress in the UK has occurred in investigating GP practices and their role in organ donation promotion.

A series of UK based survey studies have examined the attitudes of healthcare professionals to organ donation. McGregor, Hayes and O’Carroll (2008) examined GP attitudes towards living donation compared to the general public. They found that GPs are significantly more likely to want to donate their organs when they die than the public (85.2% v 33.6%) and significantly more likely to carry a donor card or be on the NHS ODR (66.5% v 19.5%) (McGregor, Hayes and O’Carroll, 2008). Vamvakopoulos, Melpmeni and Cockwell (2007) found similar results, that out of 3,252 medical students and 669 doctors working in the UK, two-thirds had a donor card or had registered to donate their organs (Vamvakopoulos, Melpmeni and Cockwell, 2007). McGlade, McCleahan and Pierscionek (2014) surveyed nursing students in all four UK countries and found that 46.8% were registered as donors less than the previous two studies (McGlade, McClenahan and Pierscionek, 2014).

These results on their own could indicate that healthcare professionals hold more favourable attitudes to donation compared to the general public, as demonstrated by their registration status. However, Vamvakopoulos, Melpmeni and Cockwell (2007) and McGlade, McCleahan and Pierscionek (2014) also found that healthcare professionals held misconceptions similar to the public. For example, perceived organ misuse was found to be the most significant barrier against donation (Vamvakopoulos, Melpmeni and Cockwell, 2007) and registration caused fears of death to be felt.
A further study by Sque, Payne and Vlachonikolis (2000) also found that nurses in the UK hold similar ambivalent views and fear as the general public (Sque, Payne and Vlachonikolis, 2000). These results indicate that although UK medical professionals hold more favourable views than the public, they also hold similar concerns and barriers to donation. This finding could potentially be due to the limited attention given in medical school curricula to organ donation and transplantation training (Anker et al., 2015), highlighting a further need to intervene with healthcare professionals in general practice. Finally, a study in Ireland aimed to investigate what GPs currently do to promote donation. Ward, Watson, and Holian (2012) found that of the 125 GPs surveyed, 62% did not provide organ donor cards for patients, and only 28.2% had organ donation information on display. Promisingly 81.3% of respondents felt comfortable discussing donation with their patients; however, only 4.8% had done this (Ward, Watson and Holian, 2012).

These findings help support the assertion that UK general practice is an underutilised location for organ donation intervention, particularly given that it is the only healthcare setting with the ability to register patients on the NHS ODR directly. Additionally examining the settings where interventions were carried out in the previous literature review, only 1 study was conducted in GP Practices in the UK (Pradeep, 2015) and no systematic review on the topic was found. Settings which hosted interventions in the UK were the DVLA, community locations such as churches or community centres, schools, universities, and hospitals. As the findings above indicate, there is an untapped NHS ODR access opportunity in general practice, and it would be prudent to explore this further in a systematic review.
2.4 Summary

There are a lack of donor organs in the UK. To help improve organ donation consent rates, targeting the family consent process is vital, particularly by ensuring families are aware of their loved ones wishes to donate. In the UK the NHS ODR is an opt-in organ donation registry that is searched when a person is placed on the organ donation pathway. A person’s status on the NHS ODR is then relayed to the family, and knowing their loved one registered as a donor is an active facilitator of a positive decision to consent. In opt-out systems, healthcare professionals have been found to consult families for their wishes, even when not legally necessary. Therefore it is important to develop NHS ODR interventions when opt-out is introduced in England in Spring 2020.

A review of systematic reviews, meta-analyses, and UK intervention studies found that it is possible to target the NHS ODR and improve rates of registration. Public education campaigns were shown to increase attitudes, knowledge, intention to register and actual registration by 5% over controls. However, the results do not distinguish between each of these outcomes. There is little research into UK interventions targeting health professionals to increase sign-up; they predominantly focus on training health professionals who are involved in the donor identification and procurement process. Also, there is very little evidence of healthcare professional interventions in primary care or investigating healthcare professionals who may facilitate registry sign-up. Most of the interventions reviewed did not have a strong theoretical underpinning. It is important, therefore, to ensure interventions are underpinned by theory to help improve their success rate. A common element of interventions was that intention to register was examined, not actual registration, and it is
recommended that future studies examine actual registration on the NHS ODR.

Interpersonal and educational interventions were more effective for ethnic minority populations; again, however, registration was not always used as a measure of intervention success.

A distinction between ‘types’ of potential donor was found with a scale of ‘readiness to register’ proposed in numerous studies. The term passive positives, in particular, indicates a group of people who are more likely to join the NHS ODR when presented an access opportunity to do this. It is sensible therefore to target this group as they are more likely to register on the NHS ODR rather than those less ready to register, who will require a more intensive intervention to transition them to being ready to. The methodological quality of studies varied with no feasibility studies found for organ donation interventions. It is important, going forward, to test settings and interventions for feasibility prior to testing for efficacy or effectiveness, as results could be due to implementation related factors as opposed to the actual intervention. The success of DMV interventions in the USA was noted, however, in the UK there is not an equivalent location where members of the public are asked in person if they would like to join the NHS ODR. Before intervening with staff members, or tailoring messaging, the present intervention could consider simply providing a new access opportunity for registration based on being verbally asked. There is a lack of good quality intervention field research in the UK, and the high-quality research is conducted either via paper mail-outs, in-person lab setting conversations or online, and aims to experimentally test theoretical forms of message to encourage sign-up. Although useful, there is a gap for field-based studies in the UK targeting NHS ODR sign-up by simply providing a new access opportunity - predominantly to passive positives.
Examining the statistics concerning settings and sign-up to the NHS ODR, a gap is present in sign-up rates that could be explored for the intervention – the NHS. Presently, only GP practices can add patients directly to the NHS ODR, whereas hospitals cannot. Although outpatient clinics could be a setting for intervention, fewer outpatient hospital appointments are held throughout the UK than GP appointments - therefore, GP practices can target more patients than hospitals. Also, the lack of existing infrastructure to add patients to the NHS ODR directly from hospitals increases the complexity of secondary care as a setting for intervention. This infrastructure is particularly important given the focus of this thesis on increasing access to NHS ODR sign-up opportunities, as opposed to education or attitude targeting interventions that do not present a sign-up opportunity. Finally, organ donation is a sensitive topic to present patients with as it concerns death. It is vital to protect patients as much as possible from potential distress as a result of organ donation interventions, and due to the nature of appointments in secondary care, distress is more likely to be a risk of intervening in this setting compared to primary care. In conclusion, this thesis will aim to design and test an intervention in general practice which aims to improve access to NHS ODR sign-up while limiting potential distress for patients of this topic.
3 Chapter 3: Organ Donation Interventions in Primary Care - A Systematic Review

As the previous chapter demonstrates, there is a gap in the literature for a systematic review of organ donation interventions conducted in GP Practices. Due to the dearth of research found for GP practice organ donation studies in the UK, this systematic review was conducted to examine interventions conducted in a primary care setting internationally. A scoping search was conducted to examine if organ donation interventions in primary care had been explored previously via systematic review. The following search strings were used:

- TI organ donation AND intervention AND primary care
- TI organ donation AND TI ("primary care" OR GP OR doctor)
- TI organ donation register AND (systematic review OR meta-analysis OR review OR meta)
- TI organ donation AND TI (systematic review OR meta-analysis OR review OR meta)
- TI (organ donor OR organ donation) AND TI ("primary care" OR GP OR doctor)
- AB organ donation register.
- Databases: All databases available in the University of Bedfordshire Library Catalogue

As a result of this search, no previous systematic review investigating organ donation interventions in primary care could be found. The present review was conducted in 2016 – 2017 and was published in the journal Transplantation Reviews in October 2017. This
systematic review, alongside the previous chapter, fulfils part of objective one of this thesis ‘To collect, synthesise, and review literature that will inform an intervention designed to increase organ donation registration rates in UK general practice.’

3.1 Systematic Review Methodology

In 2009 the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines (PRISMA) were developed, to improve the reporting of systematic reviews (Moher et al., 2009). The PRISMA checklist and PRISMA diagram (Figure 8) were used to ensure transparent reporting of this systematic review (Appendix 3) (Moher et al., 2009). These guidelines are only used for reporting not to inform the conduct of systematic reviews. The Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0, was used to inform how to conduct a systematic review (The Cochrane Collaboration, 2011). This handbook provides detailed guidance on conducting systematic reviews that will be published by the Cochrane Collaboration and focuses on reviews specifically of healthcare interventions (The Cochrane Collaboration, 2011). Cochrane Reviews are known internationally to be of a high methodological standard (Jadad et al., 1998), and although this review is not a Cochrane Review, rigour can be obtained by working to the standard of these.

3.2 Background and Rationale

The Cochrane Handbook states that reviews should be preceded by a background section which highlights the already established body of knowledge (The Cochrane Collaboration, 2011). The previous chapter fulfils this 'background' section. In summary, the 'condition'
being addressed by this review is deceased organ donation, and the ‘intervention’ is any technique used in primary care targeting this.

3.3 **Objective**

To synthesise evidence from previous organ donation interventions conducted in a primary care setting.

3.4 **Method**

3.4.1 **Protocol**

A protocol for the systematic review was produced in October – November 2016 and can be found in appendix 4. The full review was submitted for publication in April 2017 and accepted in Transplantation Reviews in August 2017 (Jones, Papadopoulos and Randhawa, 2017).

3.4.2 **Eligibility Criteria**

Typically PICO is used in Cochrane Reviews, and for this review, PICO is as follows;

- **Participants** – Any intervention participant using or working in a primary care setting
- **Interventions** – Organ donation interventions in primary care
- **Comparisons** – All comparators will be accepted, including no comparators
- **Outcomes** – Primary outcomes; actual behaviour - including register sign-up and conversations with family, Intention to donate, intention to sign up to a register and
intention to discuss with family. Secondary Outcomes - knowledge improvement, attitude change, and barrier and facilitator improvement or identification.

The Cochrane Handbook also recommends that reviewers seek out rigorous methods, particularly randomised controlled trials (RCTs), and specify the populations their review targets (The Cochrane Collaboration, 2011). The handbook also discusses that a trade-off is made during systematic review design; restricting types of study to only rigorous RCT methods to ensure the high quality of a review, or allowing less rigorous methods to be included in circumstances where less studies are likely to be found. Due to the lack of research found previously on organ donation interventions, the latter position was chosen to include all types of study design and all types of intervention participants (i.e., all types of staff and all patients). The decision was made to include grey and unpublished literature in this review for the same reason.

Included studies were primary studies of deceased organ donation interventions in a primary care setting written in the English language. All types of study design, target participants, and interventions targeting organ donation were included. Several outcomes were included in the searches (see above). Excluded studies included interventions not conducted in primary care, not targeting organ donation and those targeting living organ donation.
Information Sources, Search Strategy and Study Selection

Electronic literature searches were conducted between 27th November 2016 and 19th July 2017 using the following electronic databases: PsycINFO, CINAHL, Medline, Scopus, Web of Science and Global Health. Medline was included as it is the database recommended for search by the Cochrane Handbook (The Cochrane Collaboration, 2011). PsycINFO was chosen due to its focus on behavioural science (EBSCO, 2019), CINAHL for its focus on nursing and allied health professionals (EBSCO Nursing Resources, 2019) and Global Health for its focus on international public health (Ovid, 2019). Web of Science and Scopus were also searched due to the breadth of topics they cover (Clarivate Analytics, 2019; Scopus, 2019). The search string used was (((Organ OR transplant)) AND intervention*) AND (GP OR "general pract*" OR "family medicine" OR physician* OR "primary care"). This search string was chosen to ensure both international studies and UK based studies were found, due to the varying terminology used worldwide for primary care, e.g. ‘family medicine.’ An additional search was conducted on Ethos for UK theses using the search string; organ donation AND primary care.

The reference lists of all papers that passed the inclusion and exclusion criteria were hand searched. Experts in the field were also contacted for studies suitable for inclusion. Articles were screened by their title, abstract (if applicable) and the full-text articles were reviewed of those that met the inclusion, and exclusion criteria following abstract screening, or for those which eligibility could not be determined. Full texts were also screened by a second reviewer for eligibility, and a third reviewer was available for review should disagreements arise; this, however, did not occur. The PRISMA Flow Diagram can be viewed in figure eight.
### 3.4.4 Data Collection Process

Data was extracted into an excel spreadsheet containing the following columns; title, author, date of publication, language, aims, hypotheses, design, sample details (size, method), intervention design, timescale, intervention theory, intervention target group (patients/staff), intervention target gender, intervention target participant age, intervention target participant ethnicity, intervention target participant socioeconomic status (SES), attrition, outcome, outcome measures, analysis method, outcome results, other results, limitations and other comments (The Cochrane Collaboration, 2011). Endnote Desktop for Windows version X7 was used to store search records and remove duplicates.

![PRISMA Flow diagram for the systematic review.](image)

*Figure 8: PRISMA Flow diagram for the systematic review.*
3.4.5 Quality Assessment

The Cochrane recommended ‘Assessment Tool for Quantitative Studies’ (ATQS) published by the ‘Effective Public Health Practice Project’ was used to assess the quality of included studies (Thomas et al., 2004; Effective Public Health Practice Project, 2010; Armijo-Olivo et al., 2012). ATQS scores studies along the following criteria; selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity, and analyses. These scores are combined and enable studies to be categorised into strong – with no weak ratings for any criterion, moderate – with one weak rating for one criterion and weak – with two or more weak ratings across the criteria.

3.4.6 Analysis

A meta-analysis was not conducted due to the variability in outcome measures and how those were reported. For example, some studies used independently verified register sign-up, whereas others used self-reported sign-up measures or intention to register. Narrative synthesis was used to analyse the studies, and the type of intervention conducted guided this.

3.5 Results

3.5.1 Study Selection

The search identified 3,185 studies before duplicate removal, which was reduced to 1,407 after this was conducted (Figure 8). During title and abstract screening, 1,395 were excluded, and twelve articles progressed to the full-text review stage. Two articles were excluded at this stage, as neither were conducted in a primary care setting but in various
other settings across Europe (Siegel et al., 2008; Manyalich et al., 2013). Included studies were four peer-reviewed journal articles (Bidigare and Ellis, 2000; Salim et al., 2015; Thornton et al., 2016; Natt et al., 2017), two conference presentations provided in correspondence with the authors and not publicly available (Degenholtz et al., no date; Razdan et al., no date), two theses (Faudree, 2010; Pradeep, 2015), one student presentation (Rocque, 2017) and one unpublished study (Asghar and NHS Blood and Transplant, no date). During eligibility screening, 100% agreement was found between the first and second reviewer for the full-text articles.

3.5.2 Study Characteristics

All studies were conducted in general practice, and the details of included studies can be viewed in table one. Two were conducted in the UK (Asghar and NHS Blood and Transplant, no date; Pradeep, 2015), seven in the USA (Degenholtz et al., no date; Razdan et al., no date; Bidigare and Ellis, 2000; Faudree, 2010; Salim et al., 2015; Thornton et al., 2016; Rocque, 2017), one in Canada (Natt et al., 2017) and all were conducted between the year 2000-2017. Two were RCTs (Degenholtz et al., no date; Thornton et al., 2016), one was a non-randomised controlled trial (Bidigare and Ellis, 2000), one was an interrupted time series (Salim et al., 2015) and six studies used a one-group cohort design (Asghar and NHS Blood and Transplant, no date; Razdan et al., no date; Faudree, 2010; Pradeep, 2015; Natt et al., 2017; Rocque, 2017). Five interventions combined staff training and targeted patients (Asghar and NHS Blood and Transplant, no date; Degenholtz et al., no date; Razdan et al., no date; Faudree, 2010; Pradeep, 2015) and five intervened only with patients (Bidigare and Ellis, 2000; Salim et al., 2015; Thornton et al., 2016; Natt et al., 2017; Rocque, 2017). Nine
studies used actual registration as an organ donor as their primary outcome (Asghar and NHS Blood and Transplant, no date; Degenholtz et al., no date; Razdan et al., no date; Bidigare and Ellis, 2000; Faudree, 2010; Pradeep, 2015; Salim et al., 2015; Thornton et al., 2016; Natt et al., 2017) and one study used intention to register (Rocque, 2017).
Table 1: Characteristics of the studies included in the systematic review (Jones, Papadopoulos and Randhawa, 2017).

<table>
<thead>
<tr>
<th>Author (Date)</th>
<th>Location</th>
<th>Design</th>
<th>Intervention Description</th>
<th>Primary Outcome(s)</th>
<th>Sample N (Clinics, Staff trained and/or patients)</th>
<th>Sample Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pradeep (2015)</td>
<td>North-West England, UK</td>
<td>One Group Cohort</td>
<td>GPs and staff were trained in organ donation. Posters, and brochures available in multiple languages were displayed in practices.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>5 GP Practices.</td>
<td>South Asian population - 94.66%, 93.67%, 92.19%, 90.96% and 74% in each clinic.</td>
</tr>
<tr>
<td>Faudree (2010)</td>
<td>Fort Stewart, Georgia, USA.</td>
<td>One Group Cohort</td>
<td>Military primary care staff were trained in organ donation (physicians and doctors). At patient annual health check, they asked if they wanted more information regarding donation (brochure) and if they wanted to be a donor.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>One military primary care clinic N=197.</td>
<td>85% Caucasian, 15% Hispanic.</td>
</tr>
<tr>
<td>Thornton et al. (2016)</td>
<td>Cuyahoga County, Ohio, USA.</td>
<td>Randomised Control Trial</td>
<td>5-minute video viewed by participants on iPads. Prompted to choose an organ donation question to discuss with physicians in their appointment.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>18 primary care clinics. N=915 patients randomised.</td>
<td></td>
</tr>
<tr>
<td>Bidigare et al. (2000)</td>
<td>St John Providence, Michigan, USA.</td>
<td>Controlled Trial (non-randomised)</td>
<td>Pamphlet containing commonly asked questions and a sticker for sign up given. A brief discussion with the physician also conducted.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>N=300 patients. 2 attending physicians and one visiting physician.</td>
<td>Not Specified</td>
</tr>
<tr>
<td>Salim et al. (2014)</td>
<td>Southern California, USA.</td>
<td>Interrupted Time Series</td>
<td>Kiosks set up in clinics, either staffed (6 weeks) or unstaffed (1 week). Kiosk included a poster, brochure, registration materials, and a box to place completed sign up forms.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>Three community clinics and one hospital clinic Serving 59,181 patients in unstaffed period and 9,805 patients in staffed period.</td>
<td>Clinics in Hispanic neighbourhoods. Serving a high proportion of low income and low education.</td>
</tr>
<tr>
<td>Natt et al. (2017)</td>
<td>Ontario, Canada</td>
<td>One Group Cohort</td>
<td>Three cycles of intervention were conducted. Pamphlet testing for feasibility in cycle 1, N9. Cycle 2 included pamphlet and registration form given to patients in the waiting room, N30. Cycle 3 included edited pamphlet to include graphic, rather than statistics, alongside registration form, N60.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>One primary care clinic. N69.</td>
<td>Not reported.</td>
</tr>
<tr>
<td>Degenholtz et al. (n.d.)</td>
<td>Pennsylvania and West Virginia, USA.</td>
<td>Randomised Control Trial</td>
<td>Training of physicians and office staff. Arm 1 – in-person training. Arm 2 – web-based training.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>121 clinics, N=20,000 patient encounters.</td>
<td>Patients 57.7% female aged 18-64, 95% white. Staff 87.6% female.</td>
</tr>
<tr>
<td>Razdan et al. (n.d.)</td>
<td>West Virginia, USA.</td>
<td>One Group Cohort</td>
<td>Training physicians and office staff. 50-minute in-person presentation. Rearrangement of clinic workflow to include patients being given organ donation sign up forms at clinic check-in.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>One clinic, N=733 patients</td>
<td>Not Specified</td>
</tr>
<tr>
<td>Rocque (2017)</td>
<td>Vermont, USA</td>
<td>One Group Cohort</td>
<td>Patients awaiting annual health check were given information sheets and a brochure in primary care clinic. These addressed myths and misconceptions about organ and tissue donation.</td>
<td>Intention to donate organs.</td>
<td>One primary care clinic. N6.</td>
<td>Not reported.</td>
</tr>
<tr>
<td>Asghar et al. (n.d.)</td>
<td>Enfield, UK.</td>
<td>One Group Cohort</td>
<td>Practice Nurses, Healthcare Assistants, and Practice Managers asked patients during consultation if they would like to join the organ donor register. Face to face training was provided before intervention commenced.</td>
<td>Organ Donation Registry Sign-up.</td>
<td>One General Practice clinic in the UK, N=430.</td>
<td>62.2% White.</td>
</tr>
</tbody>
</table>
3.5.3 **Quality Assessment**

Most studies were classified as weak (Table 2) (Asghar and NHS Blood and Transplant, no date; Razdan et al., no date; Bidigare and Ellis, 2000; Faudree, 2010; Pradeep, 2015; Salim et al., 2015; Rocque, 2017), with one classified as moderate (Natt et al., 2017), one classified as strong (Thornton et al., 2016) and one study classified as moderate for its assessment of physician and staff attitudes, but strong for its primary outcome – organ donor registration (Degenholtz et al., no date). Thornton et al. (2016) and Degenholtz et al. (n.d) conducted RCTs, which contained well-matched groups, valid and reliable measures of organ donation and reported clearly on participant details. The study by Natt et al. (2017) did not report on potential confounders, which resulted in a moderate rating. Five studies rated weak did not report confounders or record attrition of participants during the intervention (Asghar and NHS Blood and Transplant, no date; Razdan et al., no date; Bidigare and Ellis, 2000; Faudree, 2010; Pradeep, 2015; Salim et al., 2015).

3.5.4 **Effects of the Interventions**

Out of the nine studies which used actual registration as an organ donor as their primary outcome, eight noted an increase in organ donation registration (Asghar and NHS Blood and Transplant, no date; Degenholtz et al., no date; Razdan et al., no date; Bidigare and Ellis, 2000; Faudree, 2010; Salim et al., 2015; Thornton et al., 2016; Natt et al., 2017). Rocque (2017) found no increase in intention to register post-intervention. The size of this effect varied according to the intervention techniques used, and a summary of the results can be seen in table three.
Table 2: Quality assessment of the systematic review papers using the Assessment Tool for Quantitative Studies (Thomas et al., 2004; Armijo-Olivo et al., 2012; Effective Public Health Practice Project, 2010).

<table>
<thead>
<tr>
<th>Author</th>
<th>Selection Bias</th>
<th>Study Design</th>
<th>Confounders</th>
<th>Blinding</th>
<th>Data Collection Methods</th>
<th>Withdrawals and Dropouts</th>
<th>Global Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pradeep</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Weak</td>
<td>Weak</td>
<td>WEAK</td>
</tr>
<tr>
<td>Faudree</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Weak</td>
<td>Moderate</td>
<td>Weak</td>
<td>Weak</td>
<td>WEAK</td>
</tr>
<tr>
<td>Thornton et al.</td>
<td>Moderate</td>
<td>Strong</td>
<td>Strong</td>
<td>Moderate</td>
<td>Strong</td>
<td>Strong</td>
<td>STRONG</td>
</tr>
<tr>
<td>Bidigare et al.</td>
<td>Weak</td>
<td>Weak</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Weak</td>
<td>WEAK</td>
<td>WEAK</td>
</tr>
<tr>
<td>Salim et al.</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Weak</td>
<td>Moderate</td>
<td>Strong</td>
<td>Weak</td>
<td>WEAK</td>
</tr>
<tr>
<td>Natt et al.</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Weak</td>
<td>Moderate</td>
<td>Strong</td>
<td>Moderate</td>
<td>MODERATE</td>
</tr>
<tr>
<td>Degenholtz et al.</td>
<td>Moderate</td>
<td>Strong</td>
<td>Strong</td>
<td>Moderate</td>
<td>Strong</td>
<td>Strong</td>
<td>STRONG/MODERATE</td>
</tr>
<tr>
<td>Razdan et al.</td>
<td>Weak</td>
<td>Moderate</td>
<td>Strong</td>
<td>Moderate</td>
<td>Weak</td>
<td>WEAK</td>
<td>WEAK</td>
</tr>
<tr>
<td>Rocque</td>
<td>Weak</td>
<td>Moderate</td>
<td>Weak</td>
<td>Moderate</td>
<td>Weak</td>
<td>Weak</td>
<td>WEAK</td>
</tr>
<tr>
<td>Asghar et al.</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Weak</td>
<td>Moderate</td>
<td>Strong</td>
<td>Weak</td>
<td>WEAK</td>
</tr>
</tbody>
</table>
Table 3: Results of the studies included in the systematic review (Jones, Papadopoulos and Randhawa, 2017).

<table>
<thead>
<tr>
<th>Author (Date)</th>
<th>Intervention Description</th>
<th>Primary Outcome</th>
<th>Sample</th>
<th>Results Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pradeep (2015)</td>
<td>GPs and staff were trained in organ donation. Posters, and brochures available in multiple languages were displayed in practices.</td>
<td>Actual registration</td>
<td>5 GP Practices</td>
<td>No new registrations to the UK NHS Organ Donor Register.</td>
</tr>
<tr>
<td>Faudree (2010)</td>
<td>Military primary care staff were trained in organ donation (physicians and doctors). At patient annual health check, they asked if they wanted more information regarding donation (brochure) and if they wanted to be a donor.</td>
<td>Actual registration</td>
<td>N94</td>
<td>21% registered post-intervention.</td>
</tr>
<tr>
<td>Thornton et al. (2016)</td>
<td>5-minute video viewed by participants on iPads. Prompted to choose an organ donation question to discuss with physicians in their appointment.</td>
<td>Actual registration</td>
<td>Intervention Arm N456, Control arm N459</td>
<td>Intervention arm resulted in a higher sign-up than the control arm (22% versus 15%).</td>
</tr>
<tr>
<td>Bidigare et al. (2000)</td>
<td>Pamphlet containing commonly asked questions and a sticker for sign up given. A brief discussion with the physician also conducted.</td>
<td>Actual registration</td>
<td>N176</td>
<td>40% of patients decided to become organ donors post-intervention.</td>
</tr>
<tr>
<td>Salim et al. (2014)</td>
<td>Kiosks set up in clinics, either staffed (6 weeks) or unstaffed (1 week). Kiosk included a poster, brochure, registration materials, and a box to place completed sign up forms.</td>
<td>Actual registration</td>
<td>Staffed patient encounters N 9,805 Unstaffed patient encounters N 59,181</td>
<td>Significantly more people registered during staffed kiosk period than unstaffed (102 people versus two people).</td>
</tr>
<tr>
<td>Natt et al. (2017)</td>
<td>Three cycles of intervention were conducted. Pamphlet testing for feasibility in cycle 1, N9. Cycle 2 included pamphlet and registration form given to patients in the waiting room, N30. Cycle 3 included edited pamphlet to include graphic, rather than statistics, alongside registration form, N30.</td>
<td>Actual registration</td>
<td>N69</td>
<td>Increase in registration to become a donor by 18.3% compared to the participant’s registration status before intervention.</td>
</tr>
<tr>
<td>Degenholtz et al. (n.d.)</td>
<td>Training of physicians and office staff. Arm 1 – in-person training. Arm 2 – web-based training, Control Arm – no training.</td>
<td>Actual registration</td>
<td>Patient encounters N20,000</td>
<td>7.1% signed up to register in web training condition, 8.6% signed up in in-person training, and no new registrations were found in the control condition.</td>
</tr>
<tr>
<td>Razdan et al. (n.d.)</td>
<td>Training physicians and office staff. 50-minute in-person presentation. Rearrangement of clinic workflow to include patients being given organ donation sign up forms at clinic check-in.</td>
<td>Actual registration</td>
<td>N444</td>
<td>6.5% of patients signed up to the organ donor register.</td>
</tr>
<tr>
<td>Rocque (2017)</td>
<td>Patients awaiting annual health check were given information sheets and a brochure in primary care clinic. These addressed myths and misconceptions about organ and tissue donation.</td>
<td>Intention to register</td>
<td>N6</td>
<td>On a Likert scale, 1 – very unlikely to register and 5 – very likely to register. Average intention to register score 2.5.</td>
</tr>
<tr>
<td>Asghar et al. (n.d.)</td>
<td>Practice Nurses, Healthcare Assistants, and Practice Managers asked patients during consultation if they would like to join the organ donor register. Face to face training was provided before intervention commenced.</td>
<td>Actual registration</td>
<td>N703</td>
<td>39% of patients joined the NHS Organ Donor Register.</td>
</tr>
</tbody>
</table>
### 3.5.5 Active versus Passive Patient Interventions

Two categories of intervention were found—active interventions involving discussion, prompting, engagement or encouragement to register, and passive involving the display of printed materials which required the patient to approach these. Some studies used both techniques in their interventions, and passive were used as a control group in some studies.

The two studies that found no intervention effect were by Pradeep (2015) and Rocque (2017). Pradeep (2015), in her PhD thesis, conducted a passive study on whether leaflet and poster presentation and primary care health professional training would encourage registration. No patients signed the NHS ODR from this intervention. Challenges to the implementation of this intervention were reported, in particular, that an active intervention was initially planned, but GP practice staff refused to conduct it; they would only participate in a passive intervention due to resource limitations. Rocque (2017) used an active intervention, providing patients with an information sheet and paper survey during an annual health check-up. Only 6 participants took part in this intervention with an average intention to register score of 2.5 (where one is Very Unlikely, and five is Very Likely). The author also examined qualitative outcomes with barriers found, which included needing more time to think about their decision and the perception that their organs would not be usable.

Natt et al. (2017) tested an intervention which also included leaflets, and these were used in an active manner. Information sheets and pamphlets were presented to participants alongside a registration form. Patients acted as their control with their organ donation
registration status disclosed before the intervention. The authors report that an 18.3% increase in registration rate was found by those who returned the registration form and were not previously registered as organ donors. Both this study and the previous study by Rocque (2017), however, have a small sample size.

A study using a larger sample size was conducted by Thornton et al. (2016). An active intervention was used where patients viewed a 5-minute long video encouraging registration as an organ donor. They were also asked to choose a question about organ donation to ask their physician. An RCT was used and found a larger number of patients signed up to be an organ donor in the intervention arm compared to the control arm of usual care (N=100/456, 22% versus N=71/459, 15% respectively; adjusted odds ratio (OR), 1.50 (95 % CI, 1.10–2.13). The intervention was also found to increase organ donation knowledge, with 16% higher scores in the intervention group than control.

A UK based active intervention was conducted by Asghar et al. (n.d.), in one GP practice with staff trained to ask patients if they would like to join the NHS ODR. After four months, 39% of patients who were asked joined the NHS ODR and a high registration rate for underrepresented groups was found; 16% BAME and 55% over 50. Challenges with the recruitment of GP practices occurred; only 6 out of 49 practices approached expressed an interest in participation. Barriers included a lack of resources, particularly the time the intervention would take up during consultations.

A brochure was given to patients by their physicians, who were attending a military primary care clinic by Faudree (2010). They were also asked to disclose their registration intentions
during their appointment after receiving the brochure: post-intervention, 42 out of the 94 patients not already registered as donors opted to donate their organs. Salim et al. (2014) used staffed and unstaffed kiosks placed in the waiting rooms of primary care clinics. The staffed or ‘active’ kiosks were found to recruit significantly more people to the register than the unstaffed or ‘passive kiosks’ (Unstaffed: 0.03 per 1,000 [95% CI: 0.0–0.1]. Staffed: 10 per 1,000 [95% CI: 8–13]; p < .0001).

In contrast to these findings, however, Bidigare and Ellis (2000) found no significant difference in sign-up rates between patients who received an active intervention (printed materials and a discussion) compared to those who received a passive intervention (printed material alone). However, the authors report that they were unable to control for contamination between the two arms, with patients able to discuss organ donation in the control arm if they wished. The final study by Degenholtz et al. (n.d.) conducted a three-arm RCT to explore physician and staff training on registration and used passive materials as a control arm. No new registrations were found in the control arm, which used only posters and pamphlets to promote organ donation registration.

3.5.6 Primary Care Staff Training

Only five studies examined using training of primary care staff to target registration, often in combination with other intervention methods. Pradeep (2015) used training alongside printed materials in five UK practices, and as previously stated, no new registrations occurred as a result of this intervention. The second UK based study by Asghar et al. (n.d.) however found training combined with asking patients directly if they would like to register,
resulted in a large number of registrations to the NHS ODR. Results by Razdan et al. (n.d.) and Degenholtz et al. (n.d.) also support the impact of training in combination with providing an immediate sign-up opportunity to patients. Razdan et al. (n.d.) preceded the RCT by Degenholtz et al. (n.d.) and focused solely on training primary care staff and redesigning the workflow of practices. As a result, patients were presented with information and sign-up forms at check-in, and this resulted in 6.5% of unregistered patients to sign-up. Degenholtz et al. (n.d.) extended this study to 121 clinics and targeted over 20,000 patients. The authors tested three trial arms based on training; in-person, web-based, and a control arm with passive posters and leaflets only. The in-person training was more successful than the web-based training, 536/13,239 registrations (8.6%) and 225/7950 (7.1%) respectively. No new registrations were recorded for the control arm, and both web and in-person training resulted in significantly higher rates of registration than control. Knowledge and attitudes of staff pre and post-training were also examined, with training significantly improving knowledge (web average knowledge score 10.35/15, in-person 10.21/15, total 8.54/15, p<0.001). In-person training had the greatest impact on attitudes to organ donation with significantly higher positive attitudes found than in control (4.28/5, p<0.001) and web training (4.4/5, p=0.01). A significant positive effect was also found for web training compared to control for staff attitudes towards organ donation (p=0.04).

3.6 Discussion

3.6.1 Summary

This systematic review is the first examining organ donation interventions in primary care, to the best of the author’s knowledge. All studies found were conducted in general practice
in either the UK or USA. Eight out of the ten studies included in this review found an increase in sign-up rates to organ donation registries in this setting. However, the interventions used different techniques including staff training, active methods, and passive methods; which make attributing success to a particular method challenging. A consistent finding throughout all studies, however, is the success of active interventions versus passive interventions. Active interventions, where patients were approached, were found to be successful in recruiting to organ donation registries. However, passive interventions, where patients had to approach materials, had lower registration rates. The studies which examined education interventions also found positive intervention effects for practices that took part in training versus control practices. These findings support those found in the previous literature review, particularly concerning the higher sign-up rates of active interventions, and indicate that primary care could be a promising setting in which to conduct an active intervention in for this thesis.

3.6.2 Implications for Practice

Use of passive posters, brochures, pamphlets, and leaflets is commonplace in UK general practice (Ward and Hawthorne, 1994; Maskell, McDonald and Paudyal, 2018). The results of this review, however, indicate that specifically for organ donation, this method of health promotion may not be as effective as other methods. Recommendations from this review for the current intervention are not to use passive methods alone, but combine these with active methods of intervention to encourage registration. This is supported by previous research investigating how leaflets and posters are used in general practice; with findings showing that fidelity of leaflet display is low, concern over patient perceptions of the poster
content, and a lack of engagement with them by patients as critical barriers to their success (Freeman et al., 2009; McClinchy et al., 2011; Gignon et al., 2012). Active methods can target these barriers as concerns by patients can be alleviated by discussion with a trained staff member or that fidelity, e.g. placement or lack of exposure, can be overcome by reaching out to patients who may not have seen the materials.

3.6.3 Implications for Research

This review also guides the research methods and methodology that can be used in this thesis. Only two high-quality RCTs were found assessing interventions targeting organ donation in primary care. More high-quality research is required for both the intervention techniques used and for the setting itself. Furthermore, no study reported testing interventions and general practice settings for feasibility and acceptability before conducting efficacy or effectiveness testing. If conducted, this could have prevented some of the implementation issues found in the UK studies by Pradeep (2015) and Asghar et al. (n.d). Razdan et al. (n.d) however integrated a workflow redesign into their training intervention in collaboration with practices. This redesign was well-received, and the intervention successfully increased sign up to the registries. These results indicate that a collaborative approach to intervention design and implementation with GP practices may help overcome some of the barriers expressed.

3.6.4 Limitations

It is important also to discuss the limitations of this review. Only a small number of studies were found, with only four published in peer-reviewed journals and eight studies scoring
‘weak’ in the quality assessment. This lack of high-quality evidence means that the findings from this review should be used with caution and may not be replicable in future. Also important to consider is the number of unpublished studies found. If organ donation interventions in primary care are typically not published, then it is possible that this review missed some. For example, the research for which this review is conducted is funded by NHSBT, which provides access to the results from studies conducted by them (Asghar et al. n.d). It is indeed possible that the equivalent organ donation organisations internationally have conducted interventions in this setting that the reviewers were unable to access. This does not, however, negate the need for more peer-reviewed high-quality studies to be conducted in this area.

Another critical limitation is that most interventions often did not directly compare passive methods to active methods (Illic and Rowe, 2013). Studies in other public health areas have found that combining both active and passive methods provides superior results compared with active alone (Cheung, Chow and Parfitt, 2008; Olander and Eves, 2011). Therefore, for the current intervention, passive methods could be considered alongside active methods and should not be disregarded altogether. Additionally, no study reported on how participants interacted with the passive methods used in their interventions. Therefore, the results found could be due to poor intervention fidelity, such as inaccurate poster placement where many people do not view them, rather than the posters themselves not effectively targeting organ donation (Freeman et al., 2009; McClinchy et al., 2011; Gignon et al., 2012).
3.7 Summary and Conclusions

Several key findings from this systematic review can be taken forward to develop and test the current intervention in this thesis. Mainly, that only four peer-review journal articles were found which discussed the testing of interventions targeting organ donation in primary care. This demonstrates a clear gap in the literature for more rigorous research to be conducted and subsequently published in peer-reviewed journals. Additionally, due to the limited evidence base, particularly in the UK, more straightforward or ‘brief’ interventions, as recommended by Golding and Cropley (2017), could be introduced first in general practice before more detailed analysis of the effectiveness of specific technique is conducted. For example, it is logical to focus on brief interventions which improve access to NHS ODR sign up in general practice before testing which specific phrases used by staff to encourage sign-up are most effective. The second finding is that active interventions are superior to passive interventions, and active techniques should be prioritised over passive during intervention development in the subsequent chapters. The final finding is that in the two studies conducted in UK general practice, both experienced implementation issues. This could be a possible explanation for why so few studies are conducted in general practice regarding organ donation, simply because it is a challenging setting in which to introduce a new intervention. Despite these challenges, however, the overall results indicate that general practice is a promising setting to host an intervention.
Chapter 4: Organ Donation Registration - A Theoretical review

The previous chapters provide recommendations on intervention and methodological techniques that could be used to develop the intervention. The next stage in informing the intervention is to examine the theoretical literature that could be used as a basis during development. A theoretical underpinning helps to ensure that the intervention will work in the way in which it is expected, in this case, encourage organ donation registration (Craig et al., 2013). This chapter aims to contribute to objective one (to collect, synthesise, and review literature that will inform an intervention targeting organ donation registration rates in UK general practice) and objective two of this thesis (to design, develop, and refine a general practice intervention targeting NHS ODR sign-up), by reviewing the theoretical literature on organ donation registration in an attempt to select the theory to be used as a guide for the current intervention.

4.1 Theories of Organ Donation Registration

4.1.1 Theoretical Review Papers

As in the previous chapter, review papers of theories were searched for which provided a summary of theoretical papers on a topic area. If a review of deceased organ donation theories was not found, this was planned to be undertaken. A search was conducted for review papers of theoretical models or frameworks explaining deceased organ donation behaviour, using the search string AB ( theor* OR framework OR model ) AND AB "organ don*" AND AB review, in Autumn 2016 - Spring 2017 and again in April 2019, in all databases available in the University of Bedfordshire library catalogue. One hundred and
forty-four articles were found after duplicates were removed and only two peer-reviewed articles aimed to conduct a complete review of deceased organ donation theory; Radecki and Jaccard (1997) and Falomir-Pichastor, Berent and Pereira (2013) (Figure 9).

Figure 9: PRISMA Flow Diagram documenting the literature search for reviews of organ donation theory.
The first review conducted by Radecki and Jaccard (1997) focuses on the psychosocial elements involved in deceased organ donation (Radecki and Jaccard, 1997). The authors split the review into two areas; individual decisions concerning organ donation, and family consent decision making. A conceptual framework was used to categorise the literature, and this was based on the Theory of Reasoned Action (TRA) (Ajzen and Fishbein, 1977) and the Theory of Planned Behaviour (TPB) (Ajzen, 1991). The principle of these models is the relationship between attitudes and conducting a behaviour. TRA proposes that attitudes predict behaviour through a person’s intention to conduct it (Figure 10). This model also includes the component subjective norms, or how a persons’ social groups influence the performance of said behaviour (Ajzen and Fishbein, 1977). Subjective norms, like attitudes, are also said to predict a person’s intention to conduct a behaviour.

![Figure 10: The Theory of Reasoned Action (TRA) (Ajzen and Fishbein, 1977).](image)

TPB (Ajzen, 1991) extends TRA by including a variable called perceived behavioural control (PBC). PBC refers to the amount of control a person believes they have over conducting a behaviour, and predicts both intention and behaviour directly (Ajzen, 1991) (Figure 11).
Radecki and Jaccard’s (1997) model can be viewed in Figure twelve. This model adapts both the TRA and TPB to include types of beliefs that predict attitudes towards becoming an organ donor; religious, cultural, knowledge, altruistic, and normative. Unlike TRA and TPB, however, the authors propose that normative beliefs influence attitudes as opposed to subjective norms predicting intention directly. They also include the factor of ‘medical contraindications’ as a moderator of the relationship between willingness to donate and organ recovery (Radecki and Jaccard, 1997).
Figure 12: Radecki and Jaccard’s model of individual decisions towards deceased donation (Radecki and Jaccard, 1997).

The second two models proposed by Radecki and Jaccard (1997) explore the next of kin consent process. The first model (Figure 13) displays the family consent process when the deceased's wishes are known. Normative beliefs, i.e. the wishes of the potential organ donor, are typically the main predictor of consent decisions towards organ donation, as well as death coping mechanisms and decision coping. However, in the second model, if the deceased's wishes are not known, a larger number of predictors become influential in the decision-making process (Figure 14) (Radecki and Jaccard, 1997).
Figure 13: Radecki and Jaccard’s model of family consent decisions when the deceased’s wishes are known (Radecki and Jaccard, 1997).

Figure 14: Radecki and Jaccard’s model of family consent decisions when the deceased’s wishes are unknown (Radecki and Jaccard, 1997).
These models support the findings from the literature review in chapter two that knowledge of wishes is vital in decision making for families. Figure 14 shows the additional predictors of family attitudes towards donation which influence decision making when wishes are not known (religious beliefs, cultural beliefs, knowledge beliefs, altruistic beliefs, normative beliefs, attributional beliefs, perceived emotional support and beliefs about the medical profession). The latter predictors are not included in the previous model of organ donation decisions and are specific to family decision making when wishes are unknown (Radecki and Jaccard, 1997). Comparing these models, it is clear that when wishes are known, the complexity of the decision making for families is reduced.

Falomir-Pichastor, Berent and Pereira (2013) updated this review and produced a model of organ donation decision making which combined both individual decision making and family consent processes, also based on the attitude–intention–behaviour relationship discussed previously (Figure 15) (Falomir-Pichastor, Berent and Pereira, 2013). This model includes many variables as predictors of attitudes towards organ donation, and the authors separate these into distal factors, proximal factors, and next-of-kin factors.
The authors provide a very comprehensive review of the literature on each factor and also review the literature on strategies to promote organ donation, which can also be seen within the model (Figure 15) (Falomir-Pichastor, Berent and Pereira, 2013). For the development of an intervention, it is these strategies that are most helpful in guiding the techniques to be used. The principles which the author’s state should be used to develop interventions include: correcting myths, fear reduction, countering death-related anxiety, improving self-efficacy, fostering empathy, developing a pro-donation social context, and finally creating a positive relationship between health professionals and donors or their families. Practical strategies are provided on how to act on these principles.
The first is change in legislation, broken up into changing consent legislation and the provision of incentives (both financial and non-financial). Consent legislation change has previously been discussed in this thesis, and England will be adopting an opt-out system of consent from spring 2020. Incentives for donations, both financial and non-financial are out of the scope of this thesis and present significant ethical and operational challenges. The second strategy suggested is ‘hospital procedure enhancement’ which focuses primarily on secondary care procedures, for example, donor identification and health care professional communication with families. Again, due to the selected setting of general practice and NHS ODR registration for this intervention, these recommendations are not applicable. However, although not mentioned by the authors, procedure enhancement in general practice to improve access to NHS ODR sign-up opportunities is a possible strategy to employ.

The final strategy proposed is communication campaigns. It is recommended to take into account the following factors to improve organ donation attitudes using these:

communication modality, including two-sided messages – both positive impact of donation and refuting common myths, include narrative elements as opposed to facts alone and adapting messages to individuals needs including their stage of change. These overlap with the recommendations found from the literature review and systematic review, however, the authors also note a lack of consensus and lack of research into these techniques (Falomir-Pichastor, Berent and Pereira, 2013).

Falomir-Pichastor, Berent and Pereira (2013) critique their theoretical framework and suggest that the predictive power of each variable and its interactions were unable to be established. There is a lack of robust research investigating the causality of these predictors,
and research is predominantly cross-sectional. Additionally, they also comment on the use of TRA and TPB within the literature, and that these theories as a basis could neglect other important theoretical elements. Another critique comes from the application of traditional ‘health promotion' and ‘public health' theory onto organ donation behaviour, when, in fact, organ donation is an altruistic act. The lack of benefit to an individual to donate their organs is unlike typical health behaviours promoted within public health, as it has no intrinsic benefit to the individual. Authors however dispute this, and suggest that organ donation (and registration as a donor) do in fact benefit the registrant.

The concept of ‘pure altruism’ suggests that organ donation is driven purely to help others, without any personal benefit, occasionally at a personal cost. Other authors suggest organ donation is not purely altruistic due to it providing a ‘warm glow’ or positive emotions when someone registers as a donor (Andreoni, 1990; Ferguson et al., 2012; Cohen and Hoffner, 2013). Combining these concepts has been termed ‘Impure Altruism’ where behaviour is driven by both helping others, as well as ‘warm glow’ (Andreoni, 1990; Ferguson et al., 2012). Although important to consider, that organ donation may not be purely altruistic, it could still be considered more altruistic than typical public health behaviours targeted by TRA and TPB, for example dietary changes, stopping smoking or physical activity (Andreoni, 1990; McGregor, Ferguson and O’Carroll, 2012; Cohen and Hoffner, 2013).

Falomir-Pichastor, Berent and Pereira (2013) also state that classical health behaviour change models should not be ignored in their entirety as some elements may apply to certain areas of organ donation promotion. An essential critique for the current intervention development is that the authors found that the cognitive-rational elements of this theory
seem to influence organ donation less so than other health behaviours. This finding indicates that the unconscious processes may have a stronger impact on donation, particularly emotions (Falomir-Pichastor, Berent and Pereira, 2013).

Overall the model by Falomir-Pichastor, Berent, and Pereira (2013) is very comprehensive in understanding the multiple facets of organ donation behaviour (individual behaviour and family consent) and could be used as a theoretical framework to underpin the current intervention. Although a strength of this model is its complexity, that it includes all literature on the topic, this is also a weakness. Some guidance on techniques for intervention was provided; however, specific details into tangible methods by which to change behaviour are not. The model also seems to underestimate the role of registration behaviour and expression of wishes, primarily due to the previously expressed challenges the authors had in attributing predictive power to each variable. Touched on by the authors is a crucial problem with this model; it does little to explain the intention-behaviour or attitude-behaviour gap prevalent in organ donation behaviour. A common finding is that the public have pro-organ donation opinions when surveyed. However, this does not translate to actual registration to be an organ donor (Crano, 2009). It can be considered therefore that basing an organ donation theory or framework in TRA or TPB is flawed, due to the lack of translation of intention to sign a donor card to actual behaviour, or translation of attitudes to expressing an intention to donate via registration. Indeed, examining all the models discussed, there are few variables placed between attitude and intention.
4.1.2 The Transtheoretical Model

The literature review found repeated reference to ‘readiness to change’ and the concept of ‘passive positives’ in organ donation registration. Falomir-Pichastor, Berent and Pereira (2013) briefly mention this concept about messaging strategies and cite Robbins et al. (2001). Robbins et al. (2001) was one of the first papers to investigate two concepts from the Transtheoretical Model of Change (TTM) and organ donation behaviour; stages of change and decisional balance (Robbins et al., 2001). These theories could underpin the ‘readiness to change’ concept discussed in the literature review. They also help overcome some of the limitations with the previous TRA/TPB based models and take into account the processes that may occur between attitude – intention – behaviour.

The Transtheoretical Model was proposed initially regarding smoking cessation and later adapted to apply to therapeutic situations in multiple areas of behaviour change. Four dimensions were proposed; the processes of change, stages of change, pros and cons of change and levels of change (Prochaska and DiClemente, 2005). Processes of change refer to ten processes that people use to change their behaviour. Stages of change refers to six steps through which people progress when changing. The pros and cons of changing (or decisional balance) refers to how people’s perceptions of the positives and negatives alter throughout the stages of change. Finally, the levels of change refers to the types of problem that can be addressed through therapy (Prochaska and DiClemente, 2005).

A search was conducted to find papers using TTM in the context of organ donation, and the following search string was used: AB ( transtheoretical OR "stage* of change" OR "pros and cons" OR “processes of change” OR “levels of change” ) AND AB "organ don*" in Autumn.
2016 – Spring 2017 and again in April 2019 using all databases available in the University of Bedfordshire library catalogue. Seven studies were found which used TTM or one of its components in the context of organ donation, and three studies were found by reviewing the references of these seven studies (Figure 16).
Figure 16: PRISMA Flow Diagram documenting the literature search for studies investigating the Transtheoretical Model (Prochaska and DiClemente, 2005) and organ donation.
Stages of change (SOC) contains six steps through which individuals pass when trying to change their behaviour; Precontemplation, Contemplation, Determination, Action, Relapse, and Maintenance (Prochaska and DiClemente, 1982, 1983, 2005; Prochaska et al., 1994).

Precontemplation is the stage where a person has not considered or thought about organ donation before. Contemplation is where a person has thought about it and is preparing to take action; however, they are still ambivalent about organ donation. Preparation is defined as those who are positively intending to act, and those in the Action stage have actively performed an organ donation related behaviour such as signing the register or talking to their family. Maintenance and relapse stages are less applicable to organ donation behaviour, however, if an individual decides they no longer wish to be a donor, this could be considered a relapse and family discussion could be considered maintenance.

SOC is the most commonly used element of the TTM in the studies found, with five studies using it and two using a modified version. The first of these studies, Robbins, Evans and Kilgallen (1999) surveyed 604 participants via the telephone, and found 28% were in precontemplation, 18% were in contemplation, 20% were in preparation and 33% action/maintenance stages. They also found that White populations and higher educational achievement were associated with being in higher stages (Robbins, Evans and Kilgallen, 1999). Tamburlin and Rice (2004) aimed to validate a measure of SOC in African American populations, and overall found that 90% of people selected at least one precontemplation item in the scale and more were in precontemplation for organ donation than any other stage (Tamburlin and Rice, 2004).
Three studies combined SOC with an additional component of TTM – pros and cons. Robbins et al. (2001) investigated these with families who had previously had to make an organ donation decision, Thompson et al (2004) examined these with 488 people via survey method, and Hall et al. (2007) aimed to validate a measure of SOC and pros and cons in an African American Population (Robbins et al., 2001; Thompson et al., 2004; Hall et al., 2007).

Pros and cons are described as when a person weighs up the positives and negatives of a behaviour. Crucially in TTM, these are linked with SOC, with cons more salient to those in the earlier SOC and pros in the later stages. These are stated to be of equal weight during or just before the contemplation stage, with pros starting to outweigh the cons as a person progresses to preparation (Prochaska and DiClemente, 2005).

Robbins et al. (2001) focused on families who had previously been presented with an opportunity to donate a family members organs and aimed to validate a measure of SOC and a measure of pros and cons. A retrospective telephone survey study sampled 169 participants and found those families who consented to donation were more likely to be in action or preparation stages. Their findings also support pros and cons, as pros increased as stage of change increased, particularly between the pre-contemplation and contemplation stages. It was also found that those who consented to donation rated the pros of it as more important, with the reverse found for those who did not consent (Robbins et al., 2001).

Thompson et al. (2004) also investigated SOC and pros and cons in the context of family consent. However, their focus was on family communication. They found that in the 488 people surveyed, pros positively predicted SOC for donation and also SOC for family communication. Hall et al. (2007) investigated SOC and pros and cons for African American people, and found that those in the pre-contemplation and contemplation stage rated cons
more highly than pros, with the reverse found for pros and the later stages (Hall et al., 2007). The final study investigating pros and cons did not examine SOC. Flemming et al. (2018) found that in 1,339, African Americans who rated more pros as important had significantly higher donation intentions (Flemming et al., 2018).

Four studies used TTM to underpin interventions targeting organ donation, specifically SOC, pros and cons, and processes of change. Processes of change are ten techniques used to help people transition between each SOC: consciousness-raising, dramatic relief, environmental re-evaluation, self-re-evaluation, self-liberation, contingency management, counter conditioning, and stimulus control. Table four shows how these techniques overlap with SOC, and table five describes each of these techniques.
Table 4: Stages of change and processes of change from the Transtheoretical Model (Prochaska and DiClemente, 2005).

<table>
<thead>
<tr>
<th>Stages of Change</th>
<th>Processes of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precontemplation</td>
<td>Consciousness Raising</td>
</tr>
<tr>
<td></td>
<td>Dramatic Relief</td>
</tr>
<tr>
<td></td>
<td>Environmental Re-evaluation</td>
</tr>
<tr>
<td></td>
<td>Social Liberation</td>
</tr>
<tr>
<td>Contemplation</td>
<td>Self-Re-evaluation</td>
</tr>
<tr>
<td></td>
<td>Self-Liberation</td>
</tr>
<tr>
<td>Preparation</td>
<td>Contingency Management</td>
</tr>
<tr>
<td></td>
<td>Counterconditioning</td>
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<tr>
<td></td>
<td>Stimulus Control</td>
</tr>
<tr>
<td>Action</td>
<td>Helping Relationships</td>
</tr>
<tr>
<td>Maintenance</td>
<td></td>
</tr>
</tbody>
</table>

Table 5: Description of the ten processes of change from the Transtheoretical Model. (Prochaska and DiClemente, 2005).

<table>
<thead>
<tr>
<th>Process of Change</th>
<th>Linked Stage of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consciousness Raising</td>
<td>Precontemplation - Contemplation</td>
<td>Helping to raise awareness of behaviour you wish to change, including negatives of not changing usually provided via information.</td>
</tr>
<tr>
<td>Dramatic Relief</td>
<td>Precontemplation - Contemplation</td>
<td>Raise a person's emotions related to changing the behaviour i.e., identifying feelings of fear of not changing or positive feelings for changing.</td>
</tr>
<tr>
<td>Environmental Re-evaluation</td>
<td>Precontemplation - Contemplation</td>
<td>Developing an awareness of how a person's behaviour will and does affect other people.</td>
</tr>
<tr>
<td>Social Liberation</td>
<td>Precontemplation - Contemplation</td>
<td>Developing an awareness that society is favourable towards the behaviour.</td>
</tr>
<tr>
<td>Self-Re-evaluation</td>
<td>Contemplation – Preparation</td>
<td>Elevating the behaviour to becoming a part of who the person wishes to be.</td>
</tr>
<tr>
<td>Self-Liberation</td>
<td>Preparation – Action</td>
<td>Committing to change behaviour.</td>
</tr>
<tr>
<td>Contingency Management</td>
<td>Action - Maintenance</td>
<td>Make positive behaviour more rewarding than the harmful behaviour.</td>
</tr>
<tr>
<td>Counterconditioning</td>
<td>Action - Maintenance</td>
<td>Change from undesirable ways of behaviour and substitute these for desirable ways of behaving.</td>
</tr>
<tr>
<td>Stimulus Control</td>
<td>Action - Maintenance</td>
<td>Adapt a person’s environment to encourage the behaviour.</td>
</tr>
<tr>
<td>Helping Relationships</td>
<td>Action - Maintenance</td>
<td>Ensure positive people can support the person to change their behaviour.</td>
</tr>
</tbody>
</table>
The first intervention by Arriola et al. (2010) targeted African American participants attending church. However, this intervention only used SOC as an outcome assessment measure and did not use TTM to underpin the techniques. They found that the intervention did not transition participants through the SOC (Arriola et al., 2010). The second intervention also targeted an ethnic minority group, American Indians (Fahrenwald, Belitz and Keckler, 2011). TTM was selected by community advisors to underpin the intervention and facilitate transition through the SOC. Unlike Arriola et al. (2010), all ten processes of change and pros and cons were used through audio-visual or print materials. Unfortunately, this study did not report outcomes, only that the materials were found to be acceptable by community groups and students (Fahrenwald, Belitz and Keckler, 2011).

Ahn & Park (2016) investigated using an adapted SOC to examine preferences of financial rewards for donation compared with an honorary medal, in Korean undergraduate students (Ahn and Park, 2016). They found that non-financial rewards were more likely to elicit a higher donation intent, and greater intention was found in those in the contemplation compared with precontemplation stages. Finally, Yokota, Uryuhara and Okada (2017) used a modified SOC to develop an intervention that would progress participants towards registration as a donor. For those requiring transition to the contemplation stage, facilitation of interest in organ donation was used, and for those requiring transition from preparation to action stages, providing information on the importance of wish expression and a registration opportunity were provided to Japanese participants. The intervention ran for five months and targeted university students. Statistically significant transitions through the SOC was found comparing pre-post intervention scores (Yokota, Uryuhara and Okada, 2017).
All authors provide a similar rationale for the use of TTM in organ donation contexts that it can help explain the gap between intention and behaviour. However, considering the promising results described by the authors, there is substantially less work exploring this theoretical model than those based in the attitude-intention-behaviour models of behaviour change, particularly interventions underpinned by it. Therefore for this intervention, although TTM helps fill the intention behaviour gap and could guide the intervention components using processes for change, the evidence base is not strong enough to justify its use without extensive scale testing of its predictive utility.

This review of the theoretical literature poses a challenge for selecting which to base the intervention in. A decision between models needs to be made; some which have a substantial evidence base and moderate support yet do not explain a crucial aspect of organ donation registration (the intention behaviour gap), or those which fulfil this gap theoretically to some extent but which do not have the evidence base to support it. As a result, a subsequent search for other models which could be used in this intervention was conducted.

4.2 The Information, Immediate Sign-up, Focused Engagement and Favorable Activation Model

One model found which helps target the attitude-intention-behaviour gap is the IIFF Model of organ donation registration by Siegel, Alvaro, and Hohman (2010). This model was developed iteratively from a series of studies in collaboration with the Donor Network of Arizona (DNAZ). The authors initially used TPB as a basis for investigations with the DNAZ
who were implementing a new state wide registry in Arizona, United States (Siegel, Alvaro and Hohman, 2010).

The first study investigated a concept of PBC from TPB, with perceived control and perceived difficulty treated as separate components. Perceived control in the context of organ donation refers to whether or not someone believes they can be a donor, with myths such as ‘I am too old’ or ‘I am too sick’ coming into this category. Perceived difficulty, on the other hand, refers to how easy or difficult it is for the person to register as an organ donor. These were tested in the first study by conducting six focus groups to discuss the use of kiosks, where people could sign up to the new register. Participants were included if they held positive attitudes to donation and were not yet registered, i.e., passive positives. The authors justify excluding those with negative attitudes because changing negative attitudes is a very different task to motivating those who already hold positive ones to register.

In the first focus group, all participants held positive attitudes. However, the researchers were surprised by the number of questions asked of the moderator concerning organ donation. These questions concerned registration, eligibility, confidentiality, doctor greed, cost, and immigration. Unexpectedly for the moderator, after this impromptu in-depth Q&A, several participants asked for donor cards. As a result, the final five focus groups were tweaked to include a follow-up question of registration intent if there was a kiosk in the room on the follow-up questionnaire. Fifty per cent of participants stated they would use the kiosk to register after the focus group. The authors theorised that these focus groups addressed both perceived control by combatting myths and perceived difficulty by
expressing it is a simple process to register, resulting in increased likelihood of intention to register (Siegel, Alvaro and Hohman, 2010).

Based on these results, the authors conducted a naturalistic second study capitalising on a campaign to place kiosks at a baseball game by the DNAZ with 'Register here' poster placed above them. The authors were positive about potential registration rates from this method, as kiosk availability would target the perceived difficulty element of PBC in TPB. Less than ten people registered out of 19,000 fans, which was an unexpectedly low result. Unfortunately, they were unable to explore the reasons why people did and did not register. However, they concluded that combatting perceived difficulty alone is not enough to encourage registration. A critical finding on reflection by the staff members was that the attendees did not notice the kiosks (Siegel, Alvaro and Hohman, 2010).

As a result of these poor registration rates, the authors and DNAZ decided to conduct another study placing kiosks in places that were not competing for attention, like at a baseball game. These included a hospital, university, city hall, libraries and a mall. These kiosks were also advertised through a mayors press conference, and some had music playing from them to attract attention. Only 58 people registered in the university kiosk over eight months, 103 in the city hall kiosk over nine months, 43 in one library over five months, and 100 people in another library over five months. This last location had a high footfall of people passing through, and the registration rate was less than 0.0003% of visitors. The authors concluded that kiosks, as a result, are not a magic bullet for donation (Siegel, Alvaro and Hohman, 2010).
Their next study was more methodologically rigorous and used a 4x4x4 quasi-experimental design, changing the messages on the posters above the kiosks. Based on the psychosocial literature, four appeals were designed, four different types of posters were designed for each appeal type, and four different locations were used. This design aimed to control for confounders and appeals were counterbalanced by switching these every two weeks with exemplars switched every week. Positive results were found from this study unlike the previous two, with three times higher registration rates found in the theoretically underpinned messages than the basic ‘register here’ poster, with counter argument the best message (targeting perceived control and aimed to counter myths). The authors make some conclusions based on this study that the message matters even for such a big decision like becoming an organ donor and that perceived control can increase registration rates (Siegel, Alvaro and Hohman, 2010).

Following this, to target awareness of the registry, the researchers and DNAZ decided to implement a series of radio adverts over one month. For two weeks six radio stations were saturated with 10-second slots advertising the organ donation registry using an interrupted time-series design. Approximately 80,000 people were exposed to the radio campaign, yet only 136 people registered during the study period, and only 59 of those people mentioned the radio advert. Ultimately there was no change between registrations during the radio advert period and the non-advert period in registration rates (Siegel, Alvaro and Hohman, 2010).

These results proved challenging to the authors, and a final ‘accidental’ study was conducted in hospitals in Arizona. Hospitals offered to email staff to promote the registry,
and data was collected based on this offer. Emails were sent with the kiosk poster messages and contained a link to the registration page. Three emails were sent over one month, and out of the 7,500 people emailed, 191 registered as a result. The authors concluded that the emails were more successful than kiosks, with more people registering in one month through email than a kiosk in a university for nine months (Siegel, Alvaro and Hohman, 2010).

The authors reflected on this set of perplexing study results, referring to previous models of behaviour change to try and explain them. There was no theoretical reason why the kiosks did not work, but they found four components which made up the successful interventions in this set; an immediate and complete sign-up opportunity, information particularly concerning eligibility, focused engagement and favorable activation (Figure 17).

![Figure 17: IIFF Model of organ donation registration (Siegel, Alvaro and Hohman, 2010)](image)

An immediate and complete sign-up opportunity means that people should be able to sign-up immediately and completely when they are thinking about organ donation. They concluded this element is required based on the request from focus group participants, and
the success of the email campaign. They also discuss that the radio campaign may have activated thoughts on organ donation. However, the opportunity to register was far removed from the listener. The authors also provide evidence of support from other authors, Sanner, Hedman and Tufyeson (1995), for this concept who found that when people were given organ donation information and/or organ donor cards, only those given the cards either alone or with information registered (Sanner, Hedman and Tufveson, 1995). These results also echo those from the systematic and literature review conducted previously in this thesis, which found that immediate opportunities to register were important to encourage sign-up during interventions (Siegel, Alvaro and Hohman, 2010).

Providing information, particularly concerning eligibility, comes from the effect found when examining message salience on the posters above the kiosks. Namely, by providing information through a counter-argument that people are eligible (increasing perceived control) registration increased. Additionally, the authors theorise that the focus group question and answer also dispelled myths surrounding eligibility and provided information, which may have resulted in developing an intention to register as a donor. However, they also point out that information alone is not enough, and should be paired with the three other elements in the model (Siegel, Alvaro and Hohman, 2010).

Focused engagement is evidenced by the difference in registrations at a sports game and in settings where people were not attending to the kiosks or the topic of organ donation, compared with focus groups and emails where people were focused on the topic of organ donation. The importance of activating organ donation in the front of people’s minds is
emphasised to ensure people notice an intervention when it is conducted (Siegel, Alvaro and Hohman, 2010).

Finally, favorable activation refers to the generally ambivalent stance people have toward organ donation. The authors state that people are likely to have both positive and negative attitudes. It is crucial, therefore, that the positive attitudes are activated in an intervention aimed to increase registration rates. This component is based on the different success rates for the kiosk posters, with those activating positive or favourable organ donation attitudes more successful (Siegel, Alvaro and Hohman, 2010).

This model is different from those previously discussed. It was developed iteratively for organ donation registration in passive positives through naturalistic studies, as opposed to developed and subsequently tested. This portfolio of studies demonstrates the complexity of designing organ donation interventions and that as a behaviour, it may not always fit the typical 'behaviour change' models. However, this model was not tested empirically by the authors during these studies to examine the specific predictive ability of the components. Indeed, the authors themselves recommended experimental testing as a priority for the model.

As a result, three further studies were conducted and published by some of the authors of the IIFF Model. Siegel et al. (2010) extended the focus group method across four cities and conducted 13 groups with passive positives. The authors suggest that focus groups allow all four components to be included: an opportunity to sign a donor card presented, the ability to ask questions and be given information, pre and post-test questionnaires focus attention
on organ donation, and focus groups designed to target pro donor beliefs and to debunk
myths will elicit favorable activation. As a result of these groups, 46.6% of participants (N62)
registered. Those who registered were also found to have a higher intention to register pre
and post focus group than those who did not register and stronger intentions to register
were reported for all participants post group. Although these results are promising for the
IIFF model, they cannot infer causality only indicate that these elements may play a role in
intervention. Additionally, the authors found that those participants who expressed death-
related fears were less likely to register. The authors recommend future interventions target
or create contexts where these four components can be present (Siegel et al., 2010).

Alvaro, Siegel, and Jones (2011) investigated the component of ‘immediate and complete
sign-up opportunity’ only and conducted two studies. The first aimed to examine whether
the provision of donor cards alone is enough to elicit registration, or if these need to be
collected as well during interventions. Town halls were used in three US cities who hosted a
one-hour presentation from organ donation experts. Two conditions were present – the
immediacy condition where cards were distributed and collected at the end of the session,
and a non-immediacy condition where participants were instructed to mail cards directly to
the organ donation organisation. In the immediacy condition, 27% of Chicago attendees,
67% of Phoenix attendees, and 41% of Miami attendees registered. No cards were received
in the non-immediacy condition for two cities (Chicago and Phoenix), and 23.4% of non-
immediacy attendees returned a completed card in Miami. The authors explain that a
breach in protocol could be responsible for the higher card returns in Miami, as a ‘helpful’
staff member contacted attendees post-event and encouraged them to return their cards.
Even after this breach, statistically significantly more people registered in the immediacy compared to the non-immediacy condition.

The second study by these authors examined whether the presence of "Register now" signs (immediacy) encouraged higher registration rates than "Donate Life" signs (non-immediacy) at a booth located in a flea market. Targeting mostly Hispanics, statistically significantly more visitors registered at the immediacy booth than non-immediacy (86% vs 54%). However, only 156 people visited the booth equating to 19.5 visitors every weekend the booth was present. Considering that flea market footfall was estimated to be in the thousands every weekend, this is a modest number of registrations. Equally, the same can be said for the town hall sessions which were relatively resource-intensive, i.e. an expert panel was required for one hour alongside additional staff, where only 64 people registered out of the 211 total attendees at six events (Alvaro, Siegel and Jones, 2011).

The final study by Siegel et al. (2016), investigates a setting where the highest number of registrations are collected in the USA - the DMV. At the DMV, people will be routinely asked verbally if they would like to register as a donor; however, there are stereotypes of the DMV that it is a frustrating and negative place to attend. The authors suggest that the DMV, therefore, will likely provide 3 out of the four components of the IIFF model, except favorable activation. Three studies were conducted specifically on this component to assess the impact of emotions at the DMV on registration. The first study examined the emotions participants experienced at the DMV by asking them to recall either a DMV experience (experimental arm) or their current day (control), via survey. Participants (N103) in the DMV condition reported statistically significantly higher levels of negative emotions and
statistically significantly lower levels of positive emotions. However, a floor effect was found for some scales. Therefore the researchers decided to repeat the study with an altered scale – changing a 7 item Likert scale to a 100 item sliding scale. Results found the same pattern as the prior study (N79). The second study examined the effect of positive or negative emotions on registration intent, and found that those participants (N113) who were experiencing higher negative emotions were significantly less likely to intend to register as a donor, and the reverse was found for positive emotions. The final study investigated experimentally how negative emotions specific to the DMV would impact registration intention. They found that participants who were randomised to the DMV vignette and personal DMV reflection condition (as opposed to neutral control) were statistically significantly less likely to intend to register than in the control group (Siegel et al., 2016).

This series of studies helps strengthen the support for the IIFF model as one to underpin an organ donation intervention. As a result, a collection of studies have referred to it when reporting interventions. Redmond et al. (2017) developed a web-based intervention targeting registration as a donor in African American populations. Although they do not specifically refer to how they used the IIFF model, by examining intervention components and website screenshots, it can be inferred. They provided the following; an immediate sign-up opportunity via ‘Register Now' button on the videos, provided information through explanatory videos on common myths and that focused engagement would be obtained when people access the website. It is not clear, however, how favorable activation was implemented. This study tested implementation through a process evaluation, not effectiveness or efficacy (Redmond et al., 2017).
Sharpe et al. (2017) provided a booth at community markets over four days based on the IIFF model – specifically immediate sign-up. Like Alvaro, Siegel and Jones (2011), they examined registration between visitors to the booth in the immediacy condition (who could sign up then and there) vs non-immediacy condition (given a flyer with sign up instructions) (N150). Statistically significantly, more people signed up in the immediacy condition (63%) than non-immediacy condition (11.6%) (Sharpe et al., 2017).

Two studies refer to the IIFF model in primary care settings; Salim et al. (2015) and Li et al. (2017). Previously discussed in the systematic review, Salim et al. (2015) investigated staffed vs non-staffed kiosks in general practice locations, with statistically significantly more registrations from staffed kiosks. The authors did not use the IIFF model to underpin their intervention design. However, they reference in their discussion that their findings provide support for it – unstaffed kiosks only deliver the immediate sign-up component of IIFF whereas staffed kiosks can provide all four components and resulted in more people registering (Salim et al., 2015). The final study to be discussed is a research protocol by Li et al. (2017) of an intervention in general practice. This protocol is of high methodological quality, and explicitly describes the intervention components and how these map to the theoretical domains framework of behaviour change techniques. Immediate sign-up opportunity is used to underpin one intervention component – the provision of a tablet for people to sign up to the register, however, the other elements of IIFF are not referenced too (Li et al., 2017). Given the lack of general practice organ donation intervention research generally, it is promising that two separate research teams would use the IIFF model in the design or reporting of their interventions.
4.3 Selecting Theory to Underpin the Intervention

The challenge of this chapter is selecting a theory which will underpin the intervention. Due to the mixed evidence on each, there is not a clear theory that stands out as having a strong basis of empirical evidence supporting its use. The TRA and TPB have the most papers using or testing them. However, the results of these are moderate and do not tackle the well-discussed intention-behaviour gap. TTM, on the other hand, does not present the same intention-behaviour gap; however, there is minimal high-quality evidence supporting its use in organ donation registration interventions. The IIFF model provides practical strategies to encourage registration behaviour amongst passive positives in applied settings, yet it has had little testing of its components' causal effects on behaviour.

It is repeatedly mentioned in the literature that interventions should be underpinned by theory, and the selected theory should have a strong conceptual basis and have been tested empirically (Glanz and Bishop, 2010; Bartholomew and Mullen, 2011). Davis et al. (2015) in a scoping review of theory use in health interventions, found 82 different theories were used in 276 articles. However, TRA/TPB and TTM were used in 46% of studies (TTM 33% and TPB/TRA 13%), demonstrating the relatively limited use of different theories across the field of health promotion (Davis et al., 2015). Van Den Broucke (2012) discusses that perhaps the sheer volume of theories is overwhelming to intervention developers and this, in turn, relates to an inertia to use theory altogether or use novel theories (Van Den Broucke, 2012). Additionally, if it is recommended to use theories with a strong empirical basis, it stands to reason that clustering of theory use will occur in the theories that have the most empirical evidence behind them.
There has also been an increase in evidence in the past five years contradicting that theoretically based interventions are superior. Of particular importance is a systematic review of reviews by Dalgetty, Miller and Dombrowski (2019). Out of 9 systematic reviews, eight did not find any difference between those interventions underpinned by theory and those not (Dalgetty, Miller and Dombrowski, 2019). An earlier discussion also supports this by Prestwich, Webb, and Conner (2015) who cite mixed evidence on theory-based intervention success (Prestwich, Webb and Conner, 2015). Recently this topic was debated by Professors Martin Hagger and Mike Weed at the Annual Meeting of the International Society of Behavioral Nutrition and Physical Activity in June 2018. Prof. Hagger argued that theoretically based interventions do work; however, the mixed findings in this area reflect reduced application of theory by some intervention developers. Prof. Weed, however, argues that theory-based interventions only prove efficacious in lab or experimental conditions, not effective in real-world applied conditions. Both conclude that there is more work to be done to apply theory in interventions to ensure that theoretical underpinning is well documented, as well as increasing focus on the implementation of the intervention in applied settings (Hagger and Weed, 2019).

For this intervention, it begs the question, should theory be used at all? Moreover, how should theory be used if it is? Reasons for the mixed evidence on theoretically based intervention success are suggested. Glanz and Bishop (2010) pose that the mechanisms of how theory-based interventions work has yet to be explored. Dalgetty, Miller and Dombrowski (2019) reflected on their results and proposed that several moderators could be responsible for them. These include: incorrect use of theory, the theory is fundamentally
wrong, that it does not specify the techniques to change behaviour or how to deliver it or that it is not generalisable. Prestwich, Webb, and Conner (2015) also provide an interesting proposal that there is a reluctance amongst researchers to change flawed theories. This latter proposition seems plausible in the context of organ donation, with a repeated expression of the intention – behaviour gap or attitude – behaviour gap. Attitude – intention – behaviour models are repeatedly used and explored for the topic, even after the authors themselves often criticise the model in this aspect (Falomir-Pichastor, Berent and Pereira, 2013). This also could be defined as a moderator specified by Dalgetty, Miller and Dombrowski (2019) that the theory is fundamentally wrong. Prof. Weed also questions the use of ‘overarching theories’ for many different health behaviours. He states that behaviours are fundamentally different, and interventions should use theories tailored explicitly to the behaviour of interest (Dalgetty, Miller and Dombrowski, 2019).

Assuming then, that theory-based interventions are more successful but only when the correct theory for the behaviour is used, where to go next in selecting a theory for this intervention? This ‘incorrect theory’ hypothesis, although useful does not negate the lack of research on the organ donation specific IIFF model. A solution is provided by Kok (2014) and Bartholomew and Mullen (2011) who discuss a technique called intervention mapping, and critically that this method does not aim to choose a single model or theory as a basis, but combines several (Bartholomew and Mullen, 2011; Kok, 2014). This combined theoretical approach could be ideal due to the challenges stated previously about selecting a theory. This is also supported by Glanz and Bishop (2010), who suggest that interventions are stronger if several theories are used, as long as their contribution to the intervention is clear (Glanz and Bishop, 2010).
The theories previously discussed in this chapter, although not an exhaustive list of the theories used to underpin organ donation interventions, lend themselves to being combined in the manner described above (Figure 18). The stages of change and processes of change from TTM can be mapped onto the TPB, with registration (or behaviour) equating to the action stage, intention to the preparation stage, and pre-contemplation – contemplation to attitudes, social norms, perceived behavioural control and perceived difficulty. The IIFF model then provides a moderating effect on the intention to register – actual registration relationship.

\[ \text{IIFF Model} \]

\[ \text{Immediate Sign-up Opportunity} \]
\[ \text{Information} \]
\[ \text{Focused Engagement} \]
\[ \text{Favourable Activation} \]

Figure 18: Mapped theories to underpin the intervention in this thesis (TRA/TPB; TTM; IIFF).

The next question to be answered, therefore is where in this combined model should the intervention target precisely. Pragmatic considerations can help guide this decision as well as previous findings. As discussed in the literature review, ‘passive positives' are those in the
preparation stage, who already hold pro-organ donation attitudes but have not yet registered to be a donor. This group is also those impacted by the ‘intention – behaviour’ gap. By examining figure 18, the IIFF model aims to close this gap and transition passive positives to actual registrations. Previous research has discussed that it is simpler to encourage registration than it is to change attitudes (Siegel, Alvaro and Hohman, 2010). This somewhat ‘easier’ group (passive positives) would be a pragmatic target considering the lack of UK applied organ donation intervention research. If the field were saturated with studies that successfully intervened with passive positives and encouraged registration, then it would be important to consider intervening at the next ‘step’ in the model – developing an intention. However, as this group has not yet been targeted sufficiently and timeframe and limited resources constrain this research, it is wise to select to intervene with passive positives who require less intensive intervention to transition from intention – behaviour, than those who would require transitioning from attitudes/social norms/PBC - intention. Based on this, the IIFF model was chosen to underpin the present intervention. Additionally, intervention mapping will be used to help ensure that the application of this theory to the intervention is accountable and sound; this will be discussed further in the next chapter.

4.4 Summary

In summary, the theory selected to underpin the intervention developed in this thesis was the IIFF Model of Organ Donation Registration. Theories of organ donation registration behaviour were evaluated, with two sets of authors reviewing and collating theory into single models (Radecki and Jaccard, 1997; Falomir-Pichastor, Berent and Pereira, 2013). These models demonstrate that registration helps facilitate organ donation via simplifying
the process of family consent. However, these are based on the attitude-behaviour-intention model of behaviour. This basis has limitations, namely that it does not explain the gap between intention to register to donate organs and the actual rates of registration. Therefore a further search was conducted for theories that account for this gap, and the findings in the literature review based on ‘readiness’ to register as a donor. The Transtheoretical Model (TTM) was explored, which suggests behaviour is conducted in a series of stages based on a person’s readiness. Although some studies were found which support elements of this model, and some interventions were developed using it, the evidence base is not strong enough to support the use of this model for organ donor registration behaviour.

The IIFF model of organ donation registration proposes that four components are necessary to facilitate registration successfully. Unlike the previous models, the IIFF model provides tangible methods to integrate interventions that, in particular, target passive positives, or those more ready to register. Unlike the previous theories and models, the IIFF model was developed iteratively using a series of applied intervention studies. Although the evidence base to support this model is not as strong as would be ideal, the applied nature of its research basis, targeting specifically of passive positives, explanation of the intention-behaviour gap, and direct expression of components to integrate in interventions, the IIFF Model was chosen to underpin the intervention. As a result, the components – Information provision, an Immediate sign-up opportunity, ensuring Focused engagement and Favorable activation occur, aimed to be included during the development of it in chapter five.
Chapter 5: Intervention Development

The previous chapter discussed the selection of the IIFF Model of organ donation registration to underpin the intervention. The next stage is to examine how the intervention will be designed using it. This chapter addresses this and discusses the methodology used to fulfil objective two - to design, develop, and refine a general practice intervention targeting NHS ODR sign-up. Intervention development methodology is explored, with steps one to four of Intervention Mapping conducted following this. The intervention refinement element of objective two was conducted based on feasibility testing, and is described in chapter eight.

5.1 The Intervention Mapping Method

The term intervention describes the process of doing or giving something to a person to affect change (Hawe and Potvin, 2003). Health interventions aim to improve health using behavioural, psychological, or pharmaceutical techniques (Campbell et al., 2000). Engel revolutionised the field and proposed that disease is not just defined by a complex interplay between biological systems (the biomedical model), but also psychological and social systems (Engel, 1977). Since then, behavioural interventions have been introduced to improve health, and consequently, intervention design and their testing have increased in complexity compared to pharmaceutical interventions. The MRC define these complex interventions as those which contain numerous interacting components (Craig et al., 2013) and specific methods for developing these interventions are required which account for this complexity. Intervention Mapping (IM) is a detailed framework to develop complex interventions and fulfils this gap (Bartholomew, Parcel and Kok, 1998). IM contains six steps.
based on three areas; a needs assessment, intervention development and implementation, and evaluation (Table 6). IM focuses on three elements throughout the six steps. Integrating theory and evidence into interventions, stakeholder involvement in all stages, and an ecological focus integrating complex systems into intervention design (Durks et al., 2017).

Table 6: Intervention Mapping method steps - taken from Bartholomew Eldridge et al. (2016).

<table>
<thead>
<tr>
<th>Intervention Mapping Step</th>
<th>Intervention Mapping Task</th>
</tr>
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<tbody>
<tr>
<td>Step 1: Logic Model of the Problem</td>
<td>• Establish a participatory planning group&lt;br&gt;• Conduct the needs assessment to create a logic model of the problem (PRECEDE Model)&lt;br&gt;• Describe the context for the intervention including the population, setting, and community&lt;br&gt;• Specify program goals</td>
</tr>
<tr>
<td>Step 2: Program Outcomes and objectives – Logic Model of Change</td>
<td>• State expected outcomes for behaviour and environmental change&lt;br&gt;• Specify performance objectives for behavioural and environmental outcomes&lt;br&gt;• Select determinants for behavioural and environmental outcomes&lt;br&gt;• Construct a matrix of change objectives&lt;br&gt;• Create a logic model of change</td>
</tr>
<tr>
<td>Step 3: Program Design</td>
<td>• Generate program themes, components, scope and sequence&lt;br&gt;• Choose theory- and evidence-based change methods.&lt;br&gt;• Select or design practical applications to deliver change methods</td>
</tr>
<tr>
<td>Step 4: Program Production</td>
<td>• Refine Program structure and organisation&lt;br&gt;• Prepare plans for program materials.&lt;br&gt;• Draft messages&lt;br&gt;• Pre-test, refine and produce materials</td>
</tr>
<tr>
<td>Step 5: Program Implementation Plan</td>
<td>• Identify potential program users (adopters, implementers and maintainers)&lt;br&gt;• State outcomes and performance objectives for program use&lt;br&gt;• Construct matrices of change objectives for program use&lt;br&gt;• Design implementation activities</td>
</tr>
<tr>
<td>Step 6: Evaluation Plan</td>
<td>• Write effect and process evaluation questions&lt;br&gt;• Develop indicators and measures for assessment&lt;br&gt;• Specify evaluation design&lt;br&gt;• Complete evaluation plan</td>
</tr>
</tbody>
</table>

Strengths of IM are based on these elements. The first, that it addresses environmental as well as personal factors, due to its ecological focus (O’Cathain et al., 2019). UK general practice is a unique environment and poses specific challenges for intervention developers, for example, Pradeep (2015) reported GP concerns that discussing organ donation with
patients could lead to worries about their health status (Pradeep, 2015). In contrast, a setting such as the DMV in the USA, which raises the topic of organ donation as part of standard practice, will have different context related needs. For example, organ donation being raised by a clerk at the DMV in the USA, may have different implications than it being raised by a doctor or other clinical professional. IM can help take these specific environmental factors into account in intervention design.

IM also emphasises stakeholder involvement throughout the development process, which has been found to improve health intervention outcomes (Baker et al., 2010). However, inclusion alone is not enough, as authors assert that patients and clinicians must be treated as partners, not only as participants when interventions are designed (Naar, Czajkowski and Spring, 2018). IM fulfils this and emphasises that stakeholders should be included at all steps, from the needs assessment to the evaluation, and also be decision-makers in the process (Bartholomew Eldredge et al., 2016). For the present intervention, stakeholders agreed to participate prior to the start of the process, making collaboration in this manner possible and facilitating the correct conduct of IM.

IM has been found to be a robust and comprehensive method of intervention design by reviewers. O'Cathain et al. (2019) conducted a systematic review of intervention development methods resulting in the development of an intervention development taxonomy. Eleven approaches were identified, collated into eight categories, and eighteen actions (O'Cathain et al., 2019). To use the taxonomy, six questions should be answered, and for the present intervention, these have been answered in table seven.
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the intention of the intervention?</td>
<td>To target sign-up to the NHS ODR through encouraging registration and/or providing a new access opportunity.</td>
</tr>
<tr>
<td>2. What is the context?</td>
<td>UK general practice.</td>
</tr>
<tr>
<td>3. What values inform the intervention development?</td>
<td>Due to the dearth of previous research in this area, the intervention to be designed will start at the beginning of the development process.</td>
</tr>
<tr>
<td>4. What skills and experience does the team bring?</td>
<td>The PhD student has previously studied health psychology. The supervisors bring expertise in public health, organ donation, and mixed methods. The NHSBT representative brings expertise in marketing and relationship management, and knowledge of organ donation policy alongside NHSBT strategy.</td>
</tr>
<tr>
<td>5. Which approaches have resulted in interventions shown to be effective?</td>
<td>Previous approaches shown to be effective are not conclusive; indications are that active interventions using the IFFF model could be effective.</td>
</tr>
<tr>
<td>6. What resources are available?</td>
<td>The full-time dedication of a Ph.D. student to this research is the largest resource; no additional financial provision is available. NHSBT recruited a GP practice in Luton, UK before the commencement of the PhD studentship. The patient participation group (PPG) at this practice have agreed to participate.</td>
</tr>
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</table>

O’Cathain et al. (2019) instruct developers to select an appropriate approach for intervention development based on both the responses in table seven and their review findings (O’Cathain et al., 2019). IM is repeatedly mentioned for its strengths by these authors in their taxonomy as it fulfils the most actions for development. It is also well aligned with the responses to the questions for the present intervention in table seven. However, a second strong intervention development method is discussed by O’Cathain et al. (2019) which could also guide the present intervention, the Behaviour Change Wheel (BCW). Although the strengths of IM have been previously discussed, it would be prudent to also examine the BCW as an intervention development method for the present intervention, based on O’Cathain et al.’s (2019) findings.
The BCW (Figure 19) contains three rings; the outer refers to seven policy changes, the middle to nine intervention functions, and the inner to the COM-B model (Figure 20). Developers should conduct 5 steps using the BCW which progress through these rings; starting with the outermost ring and ending with the innermost – the COM-B model. This model, derived from the US Criminal Law system, asserts that behaviour occurs through three components; Capability to conduct the desired behaviour, Opportunity, and Motivation (Michie, Stralen and West, 2011). Positives of the BCW are that, like IM, it targets different contextual levels during intervention development. However, it does not discuss working with stakeholders or the target population, a previously discussed important component (O’Cathain et al., 2019).

**Figure 19: The Behaviour Change Wheel - taken from Michie, Van Stralen and West (2011)**
The BCW has also been criticised for its aim of developing a synthesised pool of behaviour change techniques and neglecting the variability found in behaviour. Ogden (2016) argues that ‘all’ behaviour change techniques should not be applied to ‘all’ behaviours as the BCW attempts (Ogden, 2016a, 2016b). Peters and Kok (2016) also agree that theoretical variability is critical to intervention development, and state that IM can overcome this critique of BCW as it does not synthesise behaviour change theory. Using IM, intervention developers can select the most appropriate theory to use for the target behaviour (Peters and Kok, 2016). Based on this, IM is a superior technique to use for the present intervention, compared to the BCW, particularly as organ donation registration is the target behaviour.

As previously discussed in chapter four, popular models of behaviour (Theory of Reasoned Action, Theory of Planned Behaviour, Transtheoretical Model) are limited in their application to organ donation interventions. The BCW is based on theories which assume the behaviour benefits the target of the intervention. Therefore it can be assumed that this theoretical underpinning is less applicable to organ donation registration - due to it having
less intrinsic benefit for the registrant compared with other health behaviour (McGregor, Ferguson and O’Carroll, 2012). This altruistic component is critical when selecting intervention development methods for the present intervention, as an appropriate theoretical basis should be used in order to develop a successful intervention (Durks et al., 2017). Due to this, IM was selected as the method by which the intervention in this thesis was designed.

It is also important, however, to explore a critique of IM, in order to accommodate for it during development. Although stakeholder involvement is emphasised, a scoping review found that the majority of studies using IM to design interventions only included stakeholders during step 4 (Majid et al., 2018). By not including target users until this step, it is likely the intervention was already well defined before their involvement. Therefore, it can be assumed that in these studies, stakeholders were not decision-makers in all aspects of IM as required. An additional finding by Majid et al., (2018) was that although authors reported involving stakeholders, less than half of these studies reported in sufficient detail how they were involved in the process. The implications of these findings for this thesis are that stakeholders should be included throughout all steps of the process, where possible, and that their involvement in each should be clearly reported. The next section discusses the conduct of IM to design the intervention in this thesis, including reporting clearly on stakeholder involvement throughout each step.

5.2 Intervention Mapping Step 1: Logic Model of the Problem

Step one of IM contains four sub-steps and aims to clearly understand the target health problem in order to develop a logic model of it.
1. “Establish a participatory planning group

2. Conduct the needs assessment to create a logic model of the problem (PRECEDE Model)

3. Describe the context for the intervention including the population, setting, and community

4. Specify program goals” (Bartholomew Eldredge et al., 2016, pp 13)

5.2.1 Establish and Work with a Planning Group.

The planning group consisted of the PhD Student, two supervisors, the National Health Service Blood and Transplant, Partnerships and Development Manager (NHSBT PDM), the Lead GP, Practice Manager, and PPG Chair of the participating practice. Three meetings were held before intervention testing; an introductory meeting (October 2016), an open ideas meeting (March 2017) and an intervention confirmation meeting (July 2017). An NHSBT Specialist Nurse in Organ Donation (SNOD) was later included to aid with training development (August 2017 – March 2018). The training planning sub-group included the PhD student, SNOD, and NHSBT PDM. Additionally, the PhD student attended PPG meetings to discuss the intervention and collaborate with the patient representatives of the practice. The full planning group was involved in steps one to six of IM. The previous chapters of this thesis were produced solely by the PhD student and used to inform the planning group where required.
5.2.2 Conduct a Needs Assessment to Create a Logic Model of Problem

The first step in the needs assessment is to develop the PRECEDE logic model (Figure 21) used to help refine the intervention target. Logic models are typically diagrams which demonstrate the potential causal relationships between the causes and outcomes of health problems. In IM the type of logic model required (PRECEDE) was developed to address what quality of life outcomes are a result of the health problem (Phase 1), the health problem itself (Phase 2), the behavioural and environmental factors that influence the health problem (Phase 3), and the personal determinants derived from theory and evidence-based factors are which relate to the behavioural and environmental factors (Phase 4) (Figure 21).

This model is informed by a needs assessment. Conducting a PhD involves a rigorous literature and theoretical review which can be labelled as the ‘needs assessment’ within the context of intervention mapping (chapters 2-4 of this thesis), and as a result the intervention target was defined as registration on the NHS ODR. The logic model for NHS ODR registration can be viewed in figure 22.

![Example of Intervention Mapping logic model of the problem](image)

*Figure 21: Example of Intervention Mapping logic model of the problem - taken from (Bartholomew Eldredge et al., 2016)*
5.2.3 **Describe Context for the Intervention**

The third sub-step is to conduct an asset assessment. This assessment aims to anticipate potential problems present in specific intervention contexts and identify solutions to improve implementation. (Bartholomew Eldredge *et al.*, 2016). Although the literature review in chapter two, section 2.3.3. discusses some literature on general practice, a detailed exploration of the context – GP practices, has not yet been conducted in this thesis.

5.2.3.1 **Asset Assessment – UK General Practice**

Practices are independent contractors owned by a partnership of GPs (Roland, Guthrie and Thome, 2012). Practice staff include GPs (partners, salaried or locum) practice nurses, healthcare assistants, and pharmacists (British Medical Association, 2018). Support staff
include the practice manager(s), IT manager, and other administrative staff (British Medical Association, 2018). As of 2013 all GP practices in England are members of a Clinical Commissioning Group (CCG) (British Medical Association, 2018). CCGs are governing bodies for GP practices led by GPs to commission services (British Medical Association, 2018), and must include one secondary care doctor and one registered nurse. There are 211 CCGs in England as of December 2018, each cover approximately 226,000 people and CCG funding equates to 60% of the total NHS budget (British Medical Association, 2018). As of May 2019 there were 11,464 active GP practices in England (National Health Service Digital, 2019b), with 44,847 GPs, 38,685 fully qualified GPs (excluding registrars), 23,756 nurses, 19,257 other staff with direct patient contact and 95,189 non-clinical staff as of March 2019 (National Health Service Digital, 2019a).

GPs practice in a holistic manner focusing on whole-person care; physical, psychological, and social elements (National Health Service - Health Careers, 2019). In 1978 GP roles shifted to include prevention as well as treatment of poor health (Baird et al., 2018). A scoping review of health promotion in general practice found that most studies focused on clinical outcomes or patient and staff views rather than organisational factors (Peckham et al., 2017). Pertinent findings from this review, for this research, include that general practice organisational context should be taken into account during IM, particularly the challenges it faces which may influence implementation.

Challenges in particular concern resources and demand. Consultation rates doubled between 2003 – 2013, attributed to an increasing ageing population and the introduction of telephone consultations (Royal College of General Practitioners, 2013a). Additionally, an
increase in the variation of tasks practices have to undertake has occurred, as services
transition from secondary to primary care. A key finding is that the number of staff does not
match the demand for consultations, particularly in areas with high levels of deprivation.
Differences in consultation length, which can influence consultation quality are apparent
between doctors and other staff; GPs spend on average 11.7 minutes and practice nurses
15.5 minutes with patients. Increasing from 8.4 minutes for GP consultations in 1992/1993,
attributed to increasing complexity of problems patients face. Finally, 65.5% of GPs reported
high-stress levels, and 10.7% reported heavy and unmanageable levels of stress (Royal
College of General Practitioners, 2013b). With regard to intervention implementation,
Armstrong, Herbert, and Brewster (2016) conducted an ethnographic study of barriers to
implementation of an intervention within UK primary care. Four features important for
implementation, which help to combat some of these challenges included; GP prioritization
of the intervention, financial incentives, mechanisms for engagement, and staff working
relationships. This context should be taken into account in the subsequent steps of IM.

5.2.3.2 Asset Assessment - Implementation Science

Implementation science can help factor in these contextual challenges into interventions
and was developed to promote evidence-based practice within healthcare settings (Nilsen,
2015). Mixed success in the area was attributed to a lack of theoretical underpinning during
implementation (Davies, Walker and Grimshaw, 2003; Eccles et al., 2005; Michie et al.,
2005). Implementation science researchers use theory to help understand why intervention
implementation is a success or failure (Nilsen, 2015). The field, however, is now saturated
with many models, theories and frameworks (The Improved Clinical Effectiveness through
Nilsen (2015) reviewed and collated implementation models, frameworks, and theories into a taxonomy to provide clear guidance on their application in implementation research. Five categories were developed; Process models, Determinant frameworks, Classic theories, Implementation theories, and Evaluation frameworks (Figure 23). These fulfil three different aims; describing or guiding the process of translating research into practice, understanding and explaining the influencers of implementation outcomes, and evaluating implementation (Figure 23) (Nilsen, 2015).

Process models are defined as models with clear steps to guide the translation of research to practice. Classic theories come from other fields, for example, psychology, and they provide general explanations for behaviour change. Chapter four critiques these in the context of organ donation. In the case of both of these, for the present intervention, these
models do not provide specific guidance on how to implement interventions in a general practice context. Implementation theories, however, focus on elements of organisations and interventions which guide implementation. Although general in nature, they provide practical guidance for intervention development, which classic theories and process theories do not. However, they still do not take into account primary care or general practice specifically. Determinant frameworks provide higher specificity than process models, classic theories or implementation theories, taking into account the contextual elements lacking in the other categories (Nilsen, 2015). They describe implementation barriers and facilitators and are context-specific (Nilsen, 2015). This emphasis on context makes a strong case for the use of a determinant framework as a basis for the implementation of our organ donation intervention.

Lau et al. (2016) developed a determinant framework of how change is achieved in primary care based on the findings from a systematic review of reviews. Formed of 70 reviews, it investigated intervention implementation in primary care settings. Like the IIF model, Lau et al. 's framework was formed in a bottom-up manner based on the implementation literature. They propose that primary care has a distinct individual culture, and rationalise this contributes to challenges experienced when introducing complex interventions. Four levels of context were found: external, organisation, professionals, and intervention. These are comprised of primary and secondary barriers and facilitators to implementation (Figure 24) (Lau et al., 2016).
Barriers to organ donation intervention in primary care were discussed previously and are in line with Lau et al.’s framework. For example, lack of time found by Pradeep (2015) could be attributed to the Organisational level - available resources or the External context – lack of funding. Additionally, this work was produced using actual implementation data, and this approach provides higher certainty that the potential challenges to implementation for the present intervention will be in line with the framework. Lau et al. (2016) also provide practical recommendations on developing interventions in primary care (Appendix 5) (Lau et al., 2016). Unlike other theories, models, and frameworks, these recommendations are specific to primary care and can be used in IM.

5.2.3 Asset Assessment Summary

The key findings from the asset assessment are that GP based health promotion interventions are designed from a clinical perspective. Challenges to conducting interventions in this setting include; competing priorities, increase in consultation demand
without the required increase in staff, and the increased complexity of patient problems. In order to develop an intervention that fits within a general practice context and takes these challenges into account, Lau et al. ’s (2016) framework will be used. This framework provides clear guidance on elements to consider during development (Appendix 5).

5.2.4 State Program Goals

Program goals should be derived from identifying in the PRECEDE Logic Model, where change will occur. The program goal for the present intervention model is; To improve access for patients visiting their GP Practice to opportunities to sign up to the NHS ODR and increase sign-up rates from GP Practices in England. It should be specified that this is the overall goal of the intervention, not the goal of the research described in this thesis.

5.3 Intervention Mapping Step 2: Program Outcomes and Objectives

5.3.1 State Expected Outcomes for Behaviour and Environmental Change

The first stage of step 2 is to state two outcomes; the behavioural outcome, i.e. what the intervention aims to produce and the environmental outcome, i.e. what must change in the environment to fulfil the behavioural outcome. These outcomes are as follows:

- **Behavioural Outcome** – Patients join the NHS ODR
- **Environmental Outcome** - GP Practice staff present existing patients with an opportunity to join the NHS ODR as well as new patients.
5.3.2 *Specify Performance Objectives for Behavioural and Environmental Outcomes*

The next step is to specify performance objectives that will fulfil the behavioural and environmental outcomes (Table 8).

*Table 8: Performance objectives for the behavioural and environmental intervention outcomes.*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Performance Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioural Outcome – Patients join the NHS ODR</td>
<td>P.O. 1. If they wish patients will join the NHS ODR through the new opportunity to register.</td>
</tr>
</tbody>
</table>
| Environmental outcome - GP Practice staff present existing patients with an opportunity to join the NHS ODR as well as new patients | P.O. 2. GP Practice staff can answer patient questions concerning organ donation.  
  P.O. 3. GP Practice staff can implement the new sign-up method with patients. |

5.3.3 *Select Determinants for Behavioural and Environmental Outcomes*

This stage integrates theory into the intervention by using it to select the determinants to be targeted by the intervention. In chapter four, a theoretical review was conducted, and the IIFF Model of organ donation registration selected (Siegel, Alvaro and Hohman, 2010). Therefore the determinants for the behavioural and environmental outcomes are; providing both Information for patients and an Immediate opportunity to sign-up, and ensuring patients are in Focused engagement and Favorable activation.

5.3.4 *Construct Matrices of Change Objectives*

Matrices of change objectives specify how each performance objective will be fulfilled (Table 9 & Table 10).
Table 9: Matrix of change objectives for the behavioural outcome.

<table>
<thead>
<tr>
<th>Determinants</th>
<th>Performance Objectives</th>
<th>Immediate Sign-Up Opportunity</th>
<th>Information</th>
<th>Focused Engagement</th>
<th>Favorable Activation</th>
</tr>
</thead>
<tbody>
<tr>
<td>P.O. 1. If they wish patients will join the NHS ODR through the new opportunity to register.</td>
<td>Im.1. Patient has the opportunity to sign-up immediately in the GP practice.</td>
<td>In.1. Patient gathers information about organ donation to help decide on joining the registry.</td>
<td>Fe.1. Patient has no other distractions during sign-up opportunity, and they are focused on the topic of organ donation.</td>
<td>Fa.1. Patient is in ‘favorable activation’ while sign-up opportunity is presented.</td>
<td></td>
</tr>
</tbody>
</table>

Table 10: Matrix of change objectives for the environmental outcome.

<table>
<thead>
<tr>
<th>Determinants</th>
<th>Performance Objectives</th>
<th>Immediate Sign-Up Opportunity</th>
<th>Information</th>
<th>Focused Engagement</th>
<th>Favorable Activation</th>
</tr>
</thead>
<tbody>
<tr>
<td>P.O. 2. GP Practice Staff can answer patient questions concerning organ donation.</td>
<td>Im. 2. The patient is presented with the opportunity to join NHS ODR immediately in the practice.</td>
<td>In. 2. Staff can answer patients’ questions or direct patients to materials.</td>
<td>Fe.2. Staff ensure the patient is focused and not distracted while being presented with the opportunity.</td>
<td>Fa.2. Staff ensure the patient is not experiencing distress or has the potential to become distressed while being presented with the opportunity.</td>
<td></td>
</tr>
<tr>
<td>P.O. 3. GP Practice Staff can implement the new sign-up method with patients.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5.3.5 **Create a Logic Model of Change**

The logic model of change is similar to the logic models in step 1, except the emphasis is on the outcomes of the intervention as opposed to the health problem of interest (Figure 25).

**Figure: 25 Logic model of change for the intervention.**
5.4 Intervention Mapping Step 3: Program Design

5.4.1 Generate Program Themes, Components, Scope and Sequence

5.4.1.1 Generating Program Ideas

Ideas were generated by the planning group in the October 2016 and March 2017 meetings to fulfil the behavioural outcome. These were best matched to the IIFF model components, as well as categorised into passive or active (the key systematic review finding). The ideas were also mapped to the other literature and systematic review recommendations, and Lau et al.’s primary care intervention implementation recommendations (ease of use, integration with existing workflows, adaptable between practices and patient safety, confidentiality, and privacy). Tables 11 and 12 display the results of the matching exercise; however, more detailed tables of this process can be found in appendix 6. Discussions were converted to rankings for Lau et al.’s recommendations by the PhD student following the meetings, based on the discussions had. The planning group also suggested staff training to guide staff in how best to conduct the intervention chosen, which fulfil the environmental outcome. Training adaptation will be discussed in section 6.7.
Table 11: Mapping of the active methods proposed by the planning group to the literature and theoretical findings.

<table>
<thead>
<tr>
<th>Suggestion</th>
<th>Ease of use (1 simple – 10 complex)</th>
<th>Integration (1 well – 10 poorly)</th>
<th>Adaptability (1 easily – 10 not easily)</th>
<th>Patient Protection (1-low risk – 10 high risk)</th>
<th>Literature, Systematic Review, and Theoretical Review Findings (Chapters 2, 3 &amp; 4)</th>
<th>Literature Findings - Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patients are asked if they would like to join NHS ODR during consultations and information can be provided if required</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>Improve access to NHS ODR sign up opportunities.</td>
<td>2.3.3., 2.2.3.</td>
</tr>
<tr>
<td>2. Receptionists ask patients when they come up to the desk and offer information</td>
<td>7</td>
<td>6</td>
<td>4</td>
<td>7</td>
<td>Verbal sign-up opportunity provided.</td>
<td>2.2.3.</td>
</tr>
<tr>
<td>3. Receptionists give people a paper form</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>6</td>
<td>IIFF model – only information and immediate sign-up opportunity and focused engagement.</td>
<td>4.2.</td>
</tr>
<tr>
<td>4. Using electronic sign-in screens to ask patients</td>
<td>8</td>
<td>4</td>
<td>4</td>
<td>7</td>
<td>Interpersonal but does not provide education.</td>
<td>2.3.3., 2.2.3.</td>
</tr>
<tr>
<td>5. Including a sign-up stall run by the patient participation group in the waiting room</td>
<td>8</td>
<td>2</td>
<td>6</td>
<td>7</td>
<td>Access to most patients who have consultations.</td>
<td>2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A simple intervention with one component.</td>
<td>3.8.</td>
</tr>
</tbody>
</table>
Table 12: Mapping of the passive methods proposed by the planning group to the literature and theoretical findings.

<table>
<thead>
<tr>
<th>Suggestion</th>
<th>Ease of use (1 simple – 10 complex)</th>
<th>Integration (1 well – 10 poorly)</th>
<th>Adaptability (1 easily – 10 not easily)</th>
<th>Patient Protection (1-low risk – 10 high risk)</th>
<th>Literature, Systematic Review, and Theoretical Review Findings (Chapters 2, 3 &amp; 4)</th>
<th>Literature Findings - Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Leaflets with registration forms are provided in the practice</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Improve access to NHS ODR sign up opportunities.</td>
<td>2.3.3., 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IIFF model – only information and immediate sign-up opportunity.</td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Access to most patients who pass through the waiting area.</td>
<td>2.3.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A simple intervention with one component.</td>
<td>3.8.</td>
</tr>
<tr>
<td>7. Adding a message to the ‘news’ section of the website with link to NHSBT sign-up page</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>Improve access to NHS ODR sign up opportunities.</td>
<td>2.3.3., 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IIFF model – only information.</td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A simple intervention with one component.</td>
<td>3.8.</td>
</tr>
<tr>
<td>8. Adding a message on the text message appointment reminder service</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>7</td>
<td>Improve access to NHS ODR sign up opportunities.</td>
<td>2.3.3., 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IIFF model – only information.</td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A simple intervention with one component.</td>
<td>3.8.</td>
</tr>
<tr>
<td>9. The use of television screens to display content regarding organ donation</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>IIFF model – only information.</td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Access to most patients who pass through the waiting area.</td>
<td>2.3.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A simple intervention with one component.</td>
<td>3.8.</td>
</tr>
<tr>
<td>10. Adding hold messages to the telephone appointment line</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>7</td>
<td>IIFF model – only information.</td>
<td>4.2.</td>
</tr>
</tbody>
</table>
5.4.1.1 Mapping of Active Methods Based on Lau et al. (2016) Intervention

Recommendations

**Ease of Use:** Active methods were mapped as more complex to use than the passive methods. Asking patients to join the NHS ODR could be challenging for staff without adequate training. This may be easier for clinicians who are used to discussing sensitive clinical matters with patients. Receptionists providing paper forms as opposed to verbally asking was deemed more complicated due to the logistical requirements of providing all patients with paper forms, pens, and collecting these back from patients following completion. Using electronic screens to provide an NHS ODR sign-up opportunity would be simple for the practice once the intervention was running. However, the practice during planning meetings, expressed they were unsure of the software capabilities of SystmONE – the practice computer system. This barrier, therefore, makes it more complex to use as the software provider TPP would have to be consulted. Finally, a volunteer stall run by the PPG is also complex to use, due to the time investment and organisation required by the PPG and practice.

**Integration with existing workflows:** The technique with the least impact on existing practice workflows is the stall run by the PPG. Clinicians asking patients would impact the time constraints of consultations; however, they are used to conducting discussions with patients during these on unrelated topics as part of the QOF. Receptionists, on the other hand, are not used to asking patients clinical questions, and not every patient visits the reception desk during their practice visit. Giving patients forms for completion in comparison is standard practice for receptionists; however, if this were to increase to giving
every patient a form, it may not integrate well and could increase the workload for receptionists. Using electronic sign-in screens would integrate well as many patients use them to check-in; however, patients may be surprised and not expecting to answer questions on it.

Adaptable between practices: The most adaptable method between practices is for clinicians to ask patients as all practices conduct consultations with their patients. Not all practices, on the other hand, have receptionists or sign-in screens. Additionally, although it is a requirement for all practices to have a PPG, the stall method requires an engaged and active PPG willing to give up their time to conduct the intervention on behalf of the practice.

Patient safety, confidentiality, and privacy: Significant ethical issues are apparent when conducting organ donation interventions in general practice; mainly to ensure that patients are protected from the topic if they are vulnerable or in distress. For example, it would be inappropriate to bring up the topic with a patient who has been diagnosed with a terminal illness in their consultation or who is visiting concerning a mental health problem which could be impacted by death-related discussions. This was discussed at length in the March 2017 meeting, with strong concerns expressed by the practice that patients were protected from potential distress in this manner. The only method which protects patients, and allows discretion to be used over whether the patient should be presented with the topic is being asked verbally by a clinician in consultation. Clinicians would be able to use their professional discretion to determine whether to ask and if in doubt could refrain from asking the patient. Receptionists and the PPG would be less able to determine if it was appropriate to ask the patient, and screens would present the topic to all who used it.
5.4.1.1.2 Mapping of Active Methods Based on The IIFF Model And Literature

Findings

Only one method was found to fulfil all four aspects of the IIFF Model – patients being asked during consultations if they wished to join the NHS ODR (Appendix 6). Clinicians can judge favorable activation during consultations, and if patients are in distress (or negative affective state), they cannot be asked. This method also fulfils all recommendations from the literature; improves access to NHS ODR sign-up, provides an opportunity to sign-up verbally, includes interpersonal and educational elements, targets passive positives, provides access to most patients and is simple.

Active interventions involving receptionists or volunteers manning stalls (asking verbally if they would like to join the NHS ODR or by giving forms) cannot fulfil favorable activation as it will be challenging to determine the affective state of patients they interact with. Additionally, not all patients interact with receptionists during their visit; therefore, these methods cannot access most patients. Stalls, however, could access most patients as typically before consultations patients are seated within waiting rooms. These three suggestions also lack an educational component, as receptionist interactions do not provide enough time for staff to provide information to patients on organ donation or facilitate discussion. Receptionists and volunteers are also not trained healthcare professionals with expertise in the subject. Interventions involving reception, however, are more straightforward than those with volunteers running stalls. Finally, the suggestion to use sign-
in screens would only fulfil one element of the IIFF model – immediate sign-up opportunity, and adheres to the least literature review findings of all the active techniques suggested.

5.4.1.1.3 Mapping of Passive Methods Based on Lau et al. (2016) Intervention Recommendations

Most passive methods are simple and more straightforward to use than active methods, with leaflets the simplest as these have already been designed and printed by NHSBT. The other passive methods require some creative construction, in particular, the waiting room television screen content and audio message played during hold periods via the telephone. All methods would integrate well into practice workflows as they are already methods used to disseminate information. It is important to note however, that some practices, although they may have a website, may not have a ‘news’ section or text message appointment reminders.

Similarly, most passive methods are adaptable to local conditions and between practices, with leaflets the most adaptable. The variation in computer software used by practices is the main barrier towards adaptability, as well as the variation in the technological provision of information, i.e., if text message reminders or screens are used. Leaflets, website and television screen content cause few concerns regarding safety, particularly distress; as information on a variety of topics, including death-related subjects such as cancer, is provided in this manner routinely by practices. Providing a link to the NHSBT website also causes little concern as this external link is well maintained by NHSBT and adheres to strict data protection procedures. However, providing organ donation information via text
message or on telephone hold messages concerning sensitive subjects may take patients by surprise as it is not standard practice.

5.4.1.4 Mapping of Passive Methods Based on The IIFF Model and Literature Findings

All methods were evaluated as simple to conduct, and all provided one IIFF Model component – Information. These could be used in a supplementary manner alongside an active technique(s) to ensure patients have access to information through more than one source. Leaflets with registration forms is the only passive method to provide two elements from the IIFF model – information and an immediate sign-up opportunity and they also provide access to the most patients, alongside information displayed on the patient information screen. Leaflets and registration forms adhere to the most literature and theoretical recommendations of the passive methods suggested by the planning group.

5.4.1.5 Intervention Method Selection and Ethical Issues

This mapping exercise helped inform the selection of intervention methods. Two priority areas emerged– the importance of ethics, including patient safety, and the theoretical underpinning of the study. Clinicians asking patients if they would like to join the NHS ODR was selected as the main intervention component as this method was found to align most strongly with the literature recommendations. It was also the only method which fulfilled all four elements of the IIFF model and allowed clinicians to better protect patients from any potential for distress. Previously discussed in chapter two, as part of the rationale for selecting primary over secondary care, was the lesser likelihood of patients experiencing
distress in general practice from an organ donation intervention – primarily due to the less serious nature of the health issues they visit the setting for. However, although compared to secondary care the possibility for distress is lesser, it was still an important factor to consider when selecting the methods to be used in the present intervention, as well as other ethical issues. Although several active methods were suggested, only one allowed for the protection of patients from distress – clinicians asking patients during consultations if they would like to join the NHS ODR. Clinicians would be able to make professional judgements over whether it would be appropriate for the patient to be asked, based on their reason for visiting their GP and their perception of the patient’s emotional state. Whereas other active methods conducted by the PPG stall or receptionists asking patients would not allow for this protection to occur, i.e. that volunteers or reception staff would be unaware of the reason for a patients visit to their practice, and could inadvertently cause distress to someone for whom the topic of organ donation is not appropriate.

A number of potential challenges were discussed for this method in the October 2016 and March 2017 meetings which required mitigation: ease of use, integration into practice workflows, and the ethical issue of patient coercion to join the NHS ODR. The former mainly concerns a lack of time during consultations which may make this problematic for staff. Also, broaching the topic may be difficult due to the lack of organ donation training in medical school curricula. Regarding coercion, organ donation is typically viewed as an altruistic act and a ‘gift’ from donor to recipient (Shaw, 2010). It is vital, therefore, that when conducting organ donation discussions with patients, that GP staff are respectful of this relationship and are not trying to persuade. They are simply offering patients an access opportunity to the NHS ODR and providing factual information if the patient requests it.
Ideas were suggested by the planning group to include health professional training, which fulfils the environmental outcome and helps overcome some of these challenges. In particular, training clinicians to broach the topic with patients sensitively, without coercion, and provide strategies to integrate this into their consultation workflow could be crucial to the intervention success.

An additional intervention component from the passive methods suggested was added to ease the impact of a lack of time in practice consultations. The other active methods require time investment from the practice; however, passive methods were all evaluated as simple to use. All of these methods were able to provide information for patients concerning organ donation which could support clinicians performing the active component – patients could be referred to additional materials if they had questions clinicians were unable to answer in a ten-minute consultation. The passive method which fulfilled the most findings from the literature was the provision of leaflets containing registration forms within the practice. Due to the limited patient safety concerns associated with this method and the ease with which these could be implemented, i.e., NHSBT already print and produce these materials, leaflets were selected to support the active method of clinicians being asked in consultations if the wished to join the NHS ODR.

5.4.1.2 Program Themes

A program theme is the general organizing construct for the program and often acts as the intervention ‘brand.’ As the key component for the intervention is clinicians asking patients
to join the NHS ODR, the theme ‘Prompted Choice’ was selected for this intervention by the planning group.

5.4.1.3 Program Components, Scope and Sequence

At the third planning group meeting in July 2017, the following questions were answered in table 13.

Table 13: Intervention Mapping questions for developing program components, scope and sequence, with answers from the planning group.

<table>
<thead>
<tr>
<th>Question</th>
<th>Planning Group Answer for Prompted Choice</th>
<th>Planning Group Answer for Leaflets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who will get what part of the program?</td>
<td>All patients who have a consultation with a clinical staff member at the practice.</td>
<td>All patients who use the waiting room have the opportunity to take a leaflet.</td>
</tr>
<tr>
<td>When will they get it?</td>
<td>Clinicians will be able to use their discretion to determine when they will conduct prompted choice during their consultations.</td>
<td>When patients are situated in practice waiting rooms.</td>
</tr>
<tr>
<td>How will they get it?</td>
<td>Clinicians will be able to use their discretion to determine how they will conduct prompted choice. However, training will guide on this while adhering to ethical principles and respecting patient safety.</td>
<td>Leaflets will be displayed on a table and in racks currently used by the practice for this purpose.</td>
</tr>
<tr>
<td>How long will it last overall?</td>
<td>Three options will be provided for clinicians to select regarding patient responses – yes patient wishes to join; the patient is unsure and do not ask the patient again. If the patient expresses they are unsure, then they will be asked again at their next appointment.</td>
<td>Exposure to leaflets and posters will occur for as long as prompted choice is being carried out in the practice.</td>
</tr>
<tr>
<td>How long will each interaction be?</td>
<td>Clinicians will be able to use their discretion to determine how long they choose to devote to prompted choice in their consultations.</td>
<td>Interactions with leaflets and posters will occur for as long as the patient is situated in the waiting room.</td>
</tr>
</tbody>
</table>
The intervention aims to target as many patients as possible with prompted choice, to give them access to an NHS ODR sign-up opportunity. Therefore it was decided that all staff groups who conduct clinical consultations would take part in prompted choice. It was also decided that clinician discretion should be used to determine the specifics of how the patient should be asked and when in consultations. It was also felt that patients should be protected against being repeatedly asked to join the NHS ODR, specifically if they had responded negatively to the topic, or the clinician determined that they should not be asked again. To accommodate this, only patients who responded they were unsure and reacted well to being asked received prompted choice at a subsequent appointment. Leaflets were displayed as per standard practice. However, the addition of NHSBT posters to information was also included as it was felt that some patients may not wish to pick up leaflets but may appreciate information being displayed. Posters for health information are also used in this manner as standard by the practice. Table 14 displays the components, scope, and sequence of the intervention as per IM.

Table 14: Components, scope and sequence of the intervention.

<table>
<thead>
<tr>
<th>Component</th>
<th>Timeframe</th>
<th>Conducted by</th>
<th>For/with</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training</td>
<td>Before the start of prompted choice.</td>
<td>Study team</td>
<td>All staff</td>
</tr>
<tr>
<td>Prompted Choice</td>
<td>Within each 10 minute consultation</td>
<td>All clinical staff members</td>
<td>Patients</td>
</tr>
<tr>
<td>Leaflets and Posters</td>
<td>Displayed in the waiting room during prompted choice period.</td>
<td>N/A</td>
<td>Patients</td>
</tr>
</tbody>
</table>
5.4.2 Choose Theory and Evidence-Based Change Methods to Address Program Objectives. Select or Design Practical Applications to Deliver Change

Methods

The next step was to select theory and evidence-based change methods. The theory-based change methods selected were taken from the tables provided in the 4th Edition textbook to guide IM (Bartholomew Eldredge et al., 2016). A strength of using the IIFF Model as the theoretical underpinning for this intervention is that the change methods are described within it. For example, an intervention based in the Theory of Planned Behaviour (TPB) would state that attitudes need to be changed, but the theory does not specify explicitly how to do this. The IIFF model on the other hand already provides detail on methods to be used; providing information, providing an immediate sign-up opportunity, ensuring the person is focused on the topic of organ donation and are in a favourable affective state. It is useful, however, to examine how this model relates to the methods of behaviour change provided by IM.

The first change method is called “Facilitation” taken from Social Cognitive Theory (Bandura, 1986). Facilitation is defined as “Creating an environment that makes the action easier or reduces barriers to action.” Presenting patients with a verbal opportunity to join the NHS ODR in their GP surgery facilitates the sign-up process. An additional technique used is "Structural Redesign" based in organisational development theory (Cummings and Worley, 2014). Where organisational elements are changed to promote a health behaviour, in this case, integrating the question into a consultation, providing leaflets and posters, ensuring the patient is focused only on the consultation and in a positive affective state. "Individualisation" (Prochaska, Redding and Evers, 2015) is where participants are provided
the opportunity to have questions answered, which is conducted by staff during consultations. How these methods align with the behavioural outcome, performance objectives, determinants and change objectives can be viewed in table 15.

**Table 15: Change methods and their applications for the behavioural outcome.**

<table>
<thead>
<tr>
<th>Behavioural Outcome</th>
<th>Performance Objectives</th>
<th>Determinants and Change Objectives</th>
<th>Method</th>
<th>Application</th>
</tr>
</thead>
</table>
| Patients join the NHS ODR | P.O. 1. Patients have enough knowledge and understanding of organ donation to decide to register | Information  
• In.1. Patient gathers information about organ donation to help decide on joining the registry. | Individualisation | Clinical Staff member offers the opportunity for the patient to ask questions. |
|                     |                        |                                     | Structural Redesign | Leaflets and posters about organ donation are displayed in the practice. |
|                     | P.O. 2. Patients have a clear opportunity to register presented to them. | Immediate Sign-up Opportunity  
• Im.1. Patient has the opportunity to sign-up immediately in the GP practice. | Facilitation | Providing immediate and verbal opportunity for patients to register on NHS ODR. |
|                     |                        |                                     | Structural Redesign | Clinical staff integrate new question into consultation flow how they see fit. |
|                     | Favorable Activation   | • Fa.1. Patient is in ‘favorable activation' while sign-up opportunity is presented. | Structural Redesign | Clinical staff only ask a patient if there is little risk of distress. |
|                     | Focused Engagement     | • Fe.1. Patient has no other distractions during sign-up opportunity, and they are focused on the topic of organ donation. | Structural Redesign | Question is asked at a time where the patient is focused only on one thing – the consultation. |
5.5 Intervention Mapping Step 4: Program Production

5.5.1 Refine Program Structure and Organisation

The authors of IM state that the first ‘reality check’ program planners have with the intervention is regarding feasibility. They highlight that if the program is not feasible, then it may need to be refined. This element was considered critical by the planning group, that the feasibility of a GP intervention requires testing, before examining efficacy or effectiveness.

The program structure and organisation was decided on before ethical approval at a planning group meeting in July 2017. Once ethical approval was granted, training occurred before intervention start, patients were exposed to leaflets and posters before their appointment, and finally, during their appointment, they were exposed to prompted choice. Training content was provided by NHSBT and based on training conducted previously by the NHSBT PDM (Asghar and NHS Blood and Transplant, no date). Leaflets and posters were those already available from NHSBT. For the prompted choice element, the primary delivery method used the practice computer system. The practice requested that a ‘prompt’ should be used to remind staff to conduct prompted choice via the computer, and patient registration preferences should also be recorded in this way.

5.5.2 Prepare Plans for Program Materials

Table 16 contains the materials required for the intervention, and this was used to guide their development. The authors of IM highlight that in the preproduction phase of planning materials, primary research is often conducted, e.g., focus groups or informal feedback on the materials by the target users. This was integrated into a single practice feasibility study.
where all program materials were tested and evaluated with the participating practice (Chapters 7-8.)

Table 16: Program materials required for the intervention as guided by Intervention Mapping.

<table>
<thead>
<tr>
<th>Intervention Component</th>
<th>Material</th>
<th>Design Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prompted Choice</td>
<td>Computer Prompt</td>
<td>The SystmONE prompt appears to remind staff to ask the patient if they would like to join the NHS ODR. The prompt opens up into a data collection form where responses to this question can be recorded.</td>
</tr>
<tr>
<td>Leaflets &amp; Posters</td>
<td>Leaflets available from NHSBT</td>
<td>The leaflets currently available from NHSBT should be used.</td>
</tr>
<tr>
<td></td>
<td>Posters available from NHSBT</td>
<td>The posters currently available from NHSBT should be used.</td>
</tr>
</tbody>
</table>

5.5.3 Draft Messages, Materials and Protocols

5.5.3.1 Computer Prompt and Data Collection

The practice informed the planning group that they used the computer system SystmONE. Unfortunately, no member of the planning group had experience of implementing a prompt or questionnaire (in the manner desired) using this system. Investigation was required into how this could be conducted. A critical barrier to this, however, was that NHS Research Ethics approval is required before researchers being able to view or access SystmONE in the practice.

Consequently, an estimate of what could be achieved had to be developed for the ethical approval process, including a statement of what the planned prompt and data collection form would contain. To develop this, several telephone calls were made to SystmONE head
office by the PhD student, and advice was sought from practice staff to guide this to the best of their ability. It was decided that once ethical approval had been obtained, the implementation of this was to be reviewed by the PhD student. More details of the ethical approval process, protocol amendments for this element and the final version used in the study can be viewed in chapter seven. Figure 26 displays a flowchart of the planned SystmONE prompt and data collection form.

![Flowchart of the computer system prompt and data collection form process.](image)

**Figure 26: Flowchart of the computer system prompt and data collection form process.**

5.5.3.2 Leaflets and Posters

NHSBT produced the leaflets and posters for the intervention at the time the intervention was conducted. This allowed for the intervention to be replicated in several practices.
5.5.4  Pre-test, Refine and Produce materials

The authors of IM emphasise the importance of piloting materials to establish whether the implementation of the intervention can occur. This pretesting in the current research occurred during feasibility testing described in chapters seven and eight.

5.6  Intervention Mapping Step 5: Program Implementation Plan

The aim of step 5 is to produce a plan for the implementation, adoption, and maintenance of a health promotion program. Although a very important step, this is not one which this thesis will cover. The objectives of this research only include intervention design and feasibility testing. If the result of this is that the intervention is indeed feasible, suggestions for implementation, adoption, and maintenance will be made in the discussion section of the thesis.

5.7  Intervention Mapping Step 6: Evaluation Plan

Step 6 concerns the evaluation of the intervention and consists of four steps: Writing evaluation questions, selecting and developing measures, specifying designs for process and effect evaluations, and completing the evaluation. The authors of IM include both effect assessment and process assessment. Effect evaluations determine whether the intervention delivers the desired effect, whereas process evaluations examine elements of the intervention such as its reach, the dose required, and the fidelity of intervention delivery. Although ‘process evaluation’ is recommended, prior testing of interventions for feasibility is not emphasised or discussed in depth.
5.8 Training Adaptation Using Intervention Mapping

A training team was appointed consisting of the PhD Student, NHSBT PDM and SNOD. In summary, the training was provided by NHSBT based on previous training given to GPs by the NHSBT PDM. A new section was added by the PhD student briefly outlining study procedures – namely data collection and the previous content was extended on the advice of the SNOD (based on other training) that included interactive elements. It was important to ensure that although this training was already developed that it adhered to IM. This section outlines this, first detailing IM Step 3 – Training Program Design, including the generation of training components, which were then refined and mapped to the change methods provided in IM. This is followed by IM Step 4 – Training Program Production, where the training session materials were produced and details refined.

5.8.1 Step 3: Training Program Design

5.8.1.1 Generate Program Themes, Components, Scope and Sequence - Training

Training group meetings were had once the prompted choice, and leaflets and poster elements were designed. Four meetings were conducted in November 2017, December 2017, January 2018, and February 2018.

The training content was based on previous NHSBT GP training. The original slides consisted of the following sections, and participants were also presented with a FAQs sheet:

1. Introduction – Who is NHSBT
2. Aims of the session
3. People touched by organ donation
4. The need for more organs in the UK
5. Research on the public perception of organ donation
6. The benefits of organ donation
7. Organs and tissues that can be donated
8. The taking organ transplantation to 2020 strategy
9. How organs are retrieved
10. Organ donation myths
11. Importance of sharing your decision
12. Real-life stories – organ recipients
13. Q&A

The following suggestions were produced by the SNOD and NHSBT PDM as additional ideas to include: Interactive elements – role play, theatre forum and Q&A, Training slide content - previous marketing campaigns, videos and case studies, videos on having the conversation, videos from other organ donation campaigns, the NHSBT attitudes and behaviours survey, the need for BAME donors, combatting myths, ethical issues and NHSBT strategic objectives, supplementary materials – a training manual or crib sheet. The original slides presented by NHSBT PDM were adapted by the PhD student on the guidance of the rest of the planning group to include all the suggestions described above. The planning group decided these were too lengthy to fit within a one-hour training slot. Additionally, the group then discussed that higher emphasis should be placed on practically guiding staff through the interactive elements. This was suggested by the SNOD who has extensive experience of training clinicians to have conversations with patients concerning organ donation. The
training was decided to consist of 30 minutes of slide content and 30 minutes of interactive content. The final components, scope and sequence of the training is in table 17.
### Table 17: Components, scope and sequence of the training element of the intervention.

<table>
<thead>
<tr>
<th>Component</th>
<th>Content</th>
<th>Timeframe</th>
<th>Delivered by</th>
<th>Medium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introductions</td>
<td>Introduce presenters and outline the objectives for the session.</td>
<td>20 minutes</td>
<td>PhD Student</td>
<td>Slides</td>
</tr>
<tr>
<td>Organ Donation Facts &amp; Figures</td>
<td>Rationale for why we need an organ donation intervention based on statistics.</td>
<td></td>
<td>SNOD</td>
<td>Slides</td>
</tr>
<tr>
<td>The intervention – prompted choice</td>
<td>Description of prompted choice, how the intervention was developed, rationale for normalization of donation, and why we can do this in general practice.</td>
<td></td>
<td>NHSBT Partnerships and Development Manager</td>
<td>Slides</td>
</tr>
<tr>
<td>Previous campaigns and testing</td>
<td>Account of previous marketing campaigns how these use prompted choice and results from the Enfield pilot study.</td>
<td></td>
<td>NHSBT Partnerships and Development Manager</td>
<td>Slides</td>
</tr>
<tr>
<td>The study – data collection</td>
<td>Description of the study data collection methods for both registration on SystmONE and feasibility.</td>
<td></td>
<td>PhD Student</td>
<td>Slides</td>
</tr>
<tr>
<td>NHS Ethics committee requirements</td>
<td>Description of inclusion criteria and vital ethical issues – distress and coercion.</td>
<td></td>
<td>PhD Student</td>
<td>Slides</td>
</tr>
<tr>
<td>SystmONE demonstration</td>
<td>A practical demonstration on the projector of how to register a patient on the ODR and complete data collection form.</td>
<td>10 mins</td>
<td>PhD Student</td>
<td>Computer Demonstration via projector</td>
</tr>
<tr>
<td>Asking the question - introduction</td>
<td>Introduction of how to ask the question</td>
<td>10 mins</td>
<td>SNOD</td>
<td>Slides</td>
</tr>
<tr>
<td>Barriers to organ donation</td>
<td>Description of some of the common barriers that staff may be presented with</td>
<td></td>
<td>SNOD</td>
<td>Slides</td>
</tr>
<tr>
<td>Relatives accounts of organ donation</td>
<td>Real-life quotes from relatives the SNOD has experienced.</td>
<td></td>
<td>SNOD</td>
<td>Slides</td>
</tr>
<tr>
<td>Facts for patients</td>
<td>A list of facts that patients may ask about and facts to help bust myths.</td>
<td></td>
<td>SNOD</td>
<td>Slides</td>
</tr>
<tr>
<td>Introductory questions</td>
<td>4 example phrases staff can use to introduce the question to patients in their consultations.</td>
<td></td>
<td>SNOD</td>
<td>Slides</td>
</tr>
<tr>
<td>Theatre Forum</td>
<td>Four examples of role-play with four different patients. Each example uses a different case study.</td>
<td>10 mins</td>
<td>SNOD</td>
<td>Practical theatre forum</td>
</tr>
<tr>
<td>Q&amp;A</td>
<td>SNOD will open up the floor to questions from staff members</td>
<td>10 mins</td>
<td>SNOD</td>
<td>Q&amp;A session with staff</td>
</tr>
<tr>
<td>Close</td>
<td>Thank staff for their attendance</td>
<td>1 min</td>
<td>PhD Student</td>
<td>Slides</td>
</tr>
</tbody>
</table>
5.8.1.2 Choose Theory And Evidence-Based Change Methods to Address Program Objectives. Select or Design Practical Applications to Deliver Change Methods - Training

The theory-based change methods are taken from the tables provided in the IM Book (Bartholomew Eldredge et al., 2016, p.381-391). Framing, planning coping responses, environmental re-evaluation, modelling, and individualisation were used in the training session (Table 18).
Table 18: Change methods and applications for environmental outcome.

<table>
<thead>
<tr>
<th>Environmental Outcome</th>
<th>Performance Objectives</th>
<th>Determinants and Change Objectives</th>
<th>Method</th>
<th>Application</th>
</tr>
</thead>
</table>
| GP Practice staff present existing patients with an opportunity to join the NHS ODR as well as new patients. | P.O. 3. GP Practice Staff can answer patient questions concerning organ donation. | Information  
- In. 2. Staff can answer patients’ questions directly following training or direct patients to leaflets. | Framing | Slides – Information concerning myths is presented in a positively framed manner, e.g., higher eligible age than most people expect, disease does not rule out donation. |
| | | Planning coping responses | Slides and Q&A – information on myths is presented, which helps guide staff in how to tackle difficult questions they may be fearful of. |
| | Immediate Sign-up  
- Im. 2. Ask patients during consultation if they wish to join the NHS ODR | Framing | Framing Slides – Information concerning myths is presented in a positively framed manner, e.g., higher eligible age than most people expect, disease does not rule out donation. |
| | | Modelling | SystmONE demonstration – showing staff how to register patients and complete data collection forms. |
| | | Theatre Forum – showing staff how to ask the question. |
| | | Environmental Re-evaluation | Slides – facts figures concerning organ donation, displays to staff importance of asking patients and increasing registration rates. |
| | | Individualisation | SNOD Q&A – staff, can ask SNOD open questions concerning organ donation, the intervention, and training content. |
| | Focused Engagement  
- Fe.2. Staff ensure the patient is focused and not distracted while being asked if they wish to join the NHS ODR. | Modelling | Theatre Forum session – example patients could be dismissive, not engaged, shows an example to staff of how to deal with that. |
| | Favorable Activation  
- Fa.2. Staff ensure the patient is not experiencing distress or has the potential to become distressed before being asked to join NHS ODR. | Modelling | Theatre Forum session – For example, patients could be actively distressed or show signs they may become distressed at organ donation discussion. |
| | Planning coping responses | Planning coping responses | Theatre forum session – for example, patients, show how staff can cope with negative patient responses they could perceive as a barrier. |
5.8.1.3 Summary

The adaptation of the training slides was an iterative fluid process which included refining slide content in several meetings spanning from December 2017 to February 2018. The final slides delivered to staff in March 2018 can be viewed in appendix seven. As well as the slides theatre forum case studies were also developed, which can be viewed in appendix eight. Finally, the training manual was adapted from a crib sheet used previously by the NHSBT PDM and contained content from the slides including - organ donation facts, a description of the intervention, the four opening questions staff can use to ask patients if they would like to join the NHS ODR, common organ donation myths they may encounter and how to respond, and instructions for using the SystmONE prompt and data collection system (Appendix 9).

5.8.2 Step 4: Training Program Production

The final training ran for one hour, and on the advice of the Practice Manager, the training took place in two sessions during the lunch break, on two different days of the week and two different weeks. This was to maximise the number of staff able to attend, and to further encourage attendance lunch was provided for staff. Additionally, leaflets and posters were displayed to staff during training, which allowed staff to familiarise themselves with these. The final training dates were Wednesday 14th March 2018 and Tuesday 20th March 2018. Table 19 describes the program materials required to run the training session.
Table 19: Program materials required for the training element of the intervention.

<table>
<thead>
<tr>
<th>Material</th>
<th>Design Document Highlights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slides</td>
<td>Training slides should be used to support the deliverers and consist of the elements described above in step 3.</td>
</tr>
<tr>
<td>Training Manual</td>
<td>Supportive manual which includes a copy of the slides for staff, but also information on organ donation facts, potential myths, and how to use the SystmONE prompt.</td>
</tr>
<tr>
<td>Leaflets and Posters</td>
<td>The leaflets and posters to be displayed in the practice should also be displayed in the training sessions to familiarise staff with their content.</td>
</tr>
</tbody>
</table>

5.9 Summary

IM was selected as the intervention development method used in this thesis, due to its emphasis on stakeholder involvement, integration of theory and evidence into interventions, and its ecological approach. Steps one to four of IM were conducted between October 2016 and July 2017, with steps three to four for the training component conducted between November 2017 and February 2018. The stakeholders, consisting of the Lead GP, Practice Manager, Chair of the PPG, NHSBT PDM, PhD Student and Supervisors, developed a three-component intervention based on the IIFF Model, the literature and systematic review findings, and Lau et al.’s (2016) recommendations for implementing primary care interventions. The primary intervention component was termed ‘prompted choice’ and consisted of clinicians in GP practices asking their patients, in consultations, if they wished to join the NHS ODR. This was supported by two supplementary components; training of staff to conduct the intervention, and leaflets and posters displayed within the practice to provide more information for patients. Step four of intervention mapping requires that the intervention and its materials be pre-tested prior to implementation. The next chapter discusses this pre-testing conducted via a single practice feasibility study.
6 Chapter 6: Single Practice Feasibility Study – Methodology and Methods

The previous chapter discussed the design of the intervention; the next stage is to examine how the intervention was tested. The first part of this chapter discusses feasibility studies, followed by mixed methods approaches, post-positivism, pragmatism, and the two-stage embedded mixed methods approach used in this thesis. The second part of this chapter outlines the methods used to conduct the single practice feasibility study and the ethical approval process. This chapter contributes to the fulfilment of objective two (to design, develop and refine a general practice intervention targeting NHS ODR sign-up) and objective three (to assess the feasibility and acceptability of an NHS ODR sign-up intervention implemented in UK general practice), through outlining the methods used to refine and test the intervention for feasibility.

6.1 Feasibility Studies

The UK Medical Research Council (MRC) developed guidelines aiming to help researchers use appropriate methods to develop and evaluate complex interventions (Craig et al., 2006). These specify that following intervention development, a feasibility and piloting stage should be conducted (Craig et al., 2006). They state that it is essential to conduct this work as often evaluations are undermined by implementation issues (Craig et al., 2013). Although ‘process evaluation’ is recommended by the authors of the IM, discussed in the previous chapter, prior testing of interventions for feasibility is not emphasised or discussed in depth using this method. It is stated in IM “In general, if the planning group considers feasibility in terms of producing and delivering materials in step 3, then no dramatic changes in program
structure and organisation are expected.” (Bartholomew Eldredge et al., 2016, p.438) It is unlikely that the planning group was able to anticipate all feasibility issues with GP surgeries in order to design an intervention that counters these. Therefore, it is important to explore feasibility methodology further than that which is specified in IM, in order to select methods to test it appropriately.

The MRC Guidelines do not distinguish between feasibility and pilot studies and view them as interchangeable (Craig et al., 2013). However, there are mixed opinions on the definition of feasibility and pilot studies. Some authors believe, like the MRC Guidelines, that they are interchangeable (Arnold et al., 2009; Thabane et al., 2010; Lancaster, 2015); however, some researchers disagree (Arain et al., 2010; Shanyinde, Pickering and Weatherall, 2011). To address this, Eldridge et al. (2016) in consultation with experts, found agreement that pilot studies sit within the sphere of feasibility studies, and that they are not entirely distinct. (Eldridge et al., 2016). Differences included that pilot studies are miniature versions of future studies, whereas feasibility studies investigate whether an intervention can be conducted (Eldridge et al., 2016).

In this thesis these distinctions were adhered to, which categorise pilot and feasibility studies in three ways; randomised pilot studies, non-randomised pilot studies and feasibility studies that are not pilot studies (Eldridge et al., 2016). According to IM, intervention components require pre-testing before effectiveness testing, and they may be refined based on this (Bartholomew Eldredge et al., 2016). Therefore, it was deemed inappropriate to adopt a pilot study design at this stage of intervention development - due to the requirement that pilot studies examine interventions in nearly final form. If a pilot study
were conducted, feasibility or acceptability issues with the materials could be discovered during this. Accordingly, the intervention could be adapted, invalidating the results of the previous pilot. Therefore to ensure resources were not wasted in this manner, the present intervention was refined using a feasibility study that was not also a pilot study (Eldridge et al., 2016).

### 6.2 Study Design

Following the decision to test the study using a feasibility approach, which study design to use was examined. Cluster randomised controlled trials (RCTs) are often used in general practice research, where randomisation occurs at the practice level, with the patient the unit of analysis (Eldridge and Kerry, 2012). However, there were two issues with selecting this approach to test the intervention for feasibility in this thesis. The first issue was the primary outcome measure – NHS ODR Registration. The intervention proposed in this thesis, focused on the number of NHS ODR registrations the practice facilitated – meaning the unit of analysis and unit of randomisation was the practice, not the patient. Therefore, a non-clustered RCT was required with practices randomised into either intervention or control groups.

The second issue is that RCTs are time-consuming and expensive to conduct. As a consequence, the planning group needed to be reasonably sure that the intervention was not likely to change after a feasibility RCT had been conducted (Eldridge and Kerry, 2012). As no pretesting or refinement of materials was conducted during chapter five, this required assessment before an RCT design was used. Based on this, the practice involved in the planning group volunteered to conduct this pre-test and run the intervention to examine
this. The final methodological approach chosen consisted of two stages; stage one, a single practice feasibility study and stage two a feasibility RCT. The single practice feasibility study aimed to pre-test the intervention (IM Step 4) and conduct examinations of feasibility and acceptability in the planning group practice. Following this, the multi-practice feasibility RCT aimed to assess the intervention further for feasibility and acceptability.

6.3 Development of Research Questions

A number of authors have specified areas to be examined when conducting feasibility studies. These were collated into Table 20, which helped inform the research questions developed in this chapter (Lancaster, Dodd and Williamson, 2004; Arain et al., 2010; Bowen et al., 2010; Thabane et al., 2010; Tickle-Degnen, 2013).

Table 20: Recommendations of areas to examine in feasibility and pilot studies (Lancaster, Dodd and Williamson, 2004; Arain et al., 2010; Bowen et al., 2010; Thabane et al., 2010; Tickle-Degnen, 2013).

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Sub-Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptability</td>
<td>Intervention</td>
</tr>
<tr>
<td></td>
<td>Data Collection methods</td>
</tr>
<tr>
<td></td>
<td>Randomisation procedure</td>
</tr>
<tr>
<td>Intervention Fidelity</td>
<td></td>
</tr>
<tr>
<td>Protocol Fidelity</td>
<td></td>
</tr>
<tr>
<td>Recruitment</td>
<td>No. participants</td>
</tr>
<tr>
<td></td>
<td>Willingness of participants to be recruited</td>
</tr>
<tr>
<td></td>
<td>Eligibility criteria</td>
</tr>
<tr>
<td>Compliance</td>
<td></td>
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<tr>
<td>Blinding</td>
<td></td>
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<tr>
<td>Retention/Attrition</td>
<td></td>
</tr>
<tr>
<td>Informing a sample size calculation</td>
<td></td>
</tr>
<tr>
<td>Protocol fit for purpose/integrity</td>
<td></td>
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<tr>
<td>Resources</td>
<td>Financial</td>
</tr>
<tr>
<td></td>
<td>Other (including time, environmental, equipment)</td>
</tr>
<tr>
<td>Implementation</td>
<td>Ease of and Challenges to</td>
</tr>
<tr>
<td>Study Management</td>
<td></td>
</tr>
<tr>
<td>Outcome assessment</td>
<td></td>
</tr>
<tr>
<td>Indications intervention works in the way it was intended.</td>
<td></td>
</tr>
</tbody>
</table>
Findings by Shanyinde, Pickering and Weatherall (2011) also helped inform the design of the feasibility studies conducted. The authors distinguish between elements that should be assessed using an RCT, and those that can be evaluated using other types of design. They specify that eligibility, compliance/adherence to the intervention, acceptability, resources and outcome assessment should be examined using non-RCT methods (Shanyinde, Pickering and Weatherall, 2011). Therefore these components were examined in the single practice feasibility study. On the other hand, recruitment, consent, randomisation procedures, blinding procedures, retention, logistics of a multi-centre trial, and protocol integrity should be examined using an RCT. These elements were, therefore, integrated into the research questions to be answered in stage two, the feasibility RCT.

An element present in table 20; the assessment that an intervention works in the way that it is intended, also requires further discussion. Feasibility and pilot studies are typically not powered to test efficacy or effectiveness adequately. However, suggestions have been made that some researchers label studies retrospectively as pilots to improve publication chances (Shanyinde, Pickering and Weatherall, 2011). Concerns over this a posteriori labelling of trials as ‘pilot’ or ‘feasibility’ trials is discussed by Shanyinde, Pickering and Weatherall (2011) and Arain et al. (2010) who found that 56% of studies examined focused on efficacy and that hypothesis testing was reported inappropriately in 81% respectively (Arain et al., 2010; Shanyinde, Pickering and Weatherall, 2011). It is crucial, however, to distinguish hypothesis testing from indications that an intervention works in the way it was designed. Examining indications of success, even in feasibility studies, is vital as resources would be wasted if it does not produce the effect intended. Therefore indications of NHS ODR registration behaviour were examined in stage one and proposed in stage two, under
the category ‘outcome assessment’ (as defined by Shanyinde, Pickering and Weatherall, 2011). However, no significance testing was conducted. Following this, additional literature was found to guide the refinement of the research questions further.

The most recent study (at the time of study design) to synthesise the literature on feasibility studies was conducted by Orsmond and Cohn (2015). From this review, the authors produced objectives, research questions and sub-research questions that should be addressed in feasibility studies (Orsmond and Cohn, 2015). These span five areas; recruitment and sample, evaluation of data collection procedures, acceptability and fidelity, resources, and intervention promise (Orsmond and Cohn, 2015) (Table 20). In addition to table 20 and the findings by Shanyinde, Pickering and Weatherall (2011), the recommendations by Orsmond and Cohn (2015) in table 21, were used to develop specific objectives to examine in the feasibility study of this intervention. Table 22 displays the research questions for both stage one and stage two.
Table 21: Research questions for feasibility studies - taken from Orsmond and Cohn (2015).

<table>
<thead>
<tr>
<th>Objective</th>
<th>Main Question</th>
<th>Sub-Question</th>
</tr>
</thead>
</table>
| **Objective 1: Evaluation of Recruitment Capability and Resulting Sample Characteristics.** | Can we recruit appropriate participants? | 1. How many potential eligible members of the targeted population are accessible in the local community?  
2. What are the recruitment rates?  
   a. How many participants enter the study at a time?  
   b. How long does it take to recruit enough participants into the study?  
3. How feasible and suitable are eligibility criteria?  
   a. Are criteria clear and sufficient or too inclusive or restrictive?  
4. What are the obstacles to recruitment?  
   a. Are colleagues and local organizations willing to assist with recruitment?  
   b. What are the reasons for refusal or ineligibility?  
5. How relevant is the intervention to the intended population?  
   a. Do study participants show evidence of the need for the intervention?  
   b. Are the characteristics of the study participants consistent with the range of expected characteristics as informed by the research literature? |
| **Objective 2: Evaluation and Refinement of Data Collection Procedures and Outcome Measures.** | How appropriate are the data collection procedures and outcome measures for the intended population and purpose of the study? | 1. How feasible and suitable are the data collection procedures?  
   a. Do participants understand the questions and other data collection procedures?  
   b. Do they respond with missing or unusable data?  
2. How feasible and suitable is the amount of data collection?  
   a. Do the participants have the capacity to complete the data collection procedures?  
   b. Does the overall data collection plan involve a reasonable amount of time, or does it create a burden for the participants?  
3. Do the measures appear to be performing consistently with the intended population as compared to measurement information available in the research literature?  
   a. Are internal consistency indicators of measures with the recruited sample congruent with expectations based on prior studies reported in the research literature?  
   b. Do planned outcome measures appear to be sensitive to the effects of the intervention?  
   c. Does a suitable outcome measure need to be developed? |
| Objective 3: Evaluation of Acceptability and Suitability of Intervention and Study Procedures. | Main Question: Are study procedures and intervention suitable for and acceptable to participants? | 1. What are the retention and follow-up rates as the participants move through the study and intervention?  
2. What are the adherence rates to study procedures, intervention attendance, and engagement?  
   a. Does the intervention fit with the daily life activities of study participants?  
   b. Do the participants have enough time and capacity to complete the intervention?  
   c. Does the intervention involve a reasonable amount of time, or does it create a burden for the participants?  
   d. To what extent is the intervention acceptable and appealing to participants?  
   e. If appropriate, how many participants agree to be randomized to a group?  
3. What is the level of safety of the procedures in the intervention?  
   a. Are there any unexpected adverse events? |
| Objective 4: Evaluation of Resources and Ability to Manage and Implement the Study and Intervention. | Does the research team have the resources and ability to manage the study and intervention? | 1. Does the research team have the administrative capacity, expertise, skills, space, and time to conduct the study and intervention?  
2. Can we conduct the study procedures and intervention in an ethical manner?  
   a. To what extent does staff comply with the approved human participants’ protocol?  
   b. How effectively are adverse events during implementation identified, documented, and reported?  
3. Can the study and intervention be conducted within the designated budget?  
4. Is the technology and equipment sufficient to conduct the study and intervention, including collection, management, and analysis of data?  
   a. Is equipment available when needed?  
   b. What is involved in training personal and/or participants to use the equipment?  
5. Are we able to efficiently and effectively manage data entry and analysis? |
| Objective 5: Preliminary Evaluation of Participant Responses to Intervention. | Does the intervention show promise of being successful with the intended population? | 1. Does the examination of quantitative data suggest that the intervention is likely to be successful?  
   a. Does the examination of the data at the participant level suggest that changes in crucial outcome variables occurred?  
   b. Are the changes in the outcome variable(s) in the expected direction?  
   c. Do the estimates of effects suggest that the intervention has promise?  
2. Do participants or relevant others provide qualitative feedback that may be indicative of the likelihood that the intervention will be successful?  
3. If the quantitative and/or qualitative data suggest that the intervention is not promising:  
   a. Are the data collection procedures and outcome measures appropriate for the population and study?  
   b. Are the outcome measures and intervention theoretically aligned?  
   c. Is there evidence that the intervention does not produce change in the desired outcomes?  
   d. Is there evidence that the intervention was not implemented in the intended manner?  
   e. Have too many adaptations been made in the intervention process to assess the participants’ responses to the intervention adequately?  
   f. Are the findings congruent with the proposed theoretical model for the intervention? |
Table 22: Research questions for both study stages mapped to those by Ormond and Cohn (2015), and the feasibility study design recommendations by Shanyinde, Pickering and Weatherall (2011).

<table>
<thead>
<tr>
<th>Research Stage</th>
<th>Research Questions</th>
<th>Category based on Ormond &amp; Cohn (2015)</th>
<th>Category based on Shanyinde, Pickering and Weatherall (2011)</th>
<th>Category based on other literature (Table 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 &amp; 2</td>
<td>• How feasible and suitable are each of the data collection tools used in this study?</td>
<td>Data Collection Materials</td>
<td>Acceptability</td>
<td>Acceptability – Data Collection Methods</td>
</tr>
<tr>
<td></td>
<td>• How acceptable and feasible is the training to staff?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How acceptable and feasible is the intervention to staff?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How acceptable is the intervention patients?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can staff training be run per-protocol?</td>
<td>Acceptability</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can monitoring be run per-protocol?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• What are the staff adherence rates and engagement with the intervention?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can staff within the GP practice be recruited to carry out the intervention?</td>
<td>Recruitment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• What monitoring resources are required to run the studies and intervention?</td>
<td>Resources and Expertise</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How many leaflets and posters are required to run the studies and intervention?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• What practice resources are required to run the studies and intervention?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• What technological resources are required to run the studies and intervention?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>• What expertise is required to run the studies and intervention?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Does the intervention show promise in increasing sign-up rates to the NHS ODR and who does the intervention target?</td>
<td>Intervention Promise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>• How many practices are eligible in the recruitment target area?</td>
<td>Recruitment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How many practices were approached for participation?</td>
<td>Recruitment &amp; Consent</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How many practices declined to take part in the study?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How many practices did not respond to recruitment invitations?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How many practices expressed an interest in participating in the study?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>• How many practices formally enrolled in the study?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How many practices were randomised?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>• How acceptable was the randomisation procedure used?</td>
<td>Data Collection</td>
<td>Acceptability – Randomisation Procedure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How acceptability of participants to be recruited, willingness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• How acceptability of participants to be recruited, eligibility criteria.</td>
<td></td>
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</tbody>
</table>


6.4 Mixed Methods Approaches

Following the production of these research questions, the next stage was to establish which methods should be used to address these. Researchers recommend that feasibility studies for non-clinical interventions use a mixed-methods approach to data collection, combining qualitative and quantitative methods (Bowen et al., 2010; Craig et al., 2013; O’Cathain et al., 2015; Donald, 2018). Qualitative approaches aim to capture a person’s subjective reality through exploring their experiences in depth (Clough and Nutbrown, 2012). Quantitative approaches, on the other hand, aim to capture objective truth, by examining cause and effect to generalise results to a broader target population (Clough and Nutbrown, 2012). Mixed methods has been a popular methodology for feasibility studies due to its ability to include the strengths of both qualitative and quantitative research (Creswell, 2014). The former has been criticised due to lack of generalisability, whereas the latter for its inability to capture subjective depth of experience (Creswell, 2014). Creswell (2014) states that mixed methods allow experimental results to be understood by combining them with individual perspectives. Within feasibility studies, this helps gather data on whether an intervention can successfully be implemented - through quantitative elements such as low participant recruitment numbers, and qualitative elements such as interviews with staff and patients to establish acceptability (Sekhon, Cartwright and Francis, 2017).

There are, however, researchers that consider qualitative and quantitative methods to be incompatible (Robson and McCartan, 2016). They are suggested to capture separate and distinct phenomena so cannot be combined. It is recommended to establish the priority of each aspect to the research questions, to overcome some of these criticisms (Robson and
McCartan, 2016). To do this, it is vital to examine how a mixed-method approach has been practically implemented in previous feasibility studies.

An example in primary care comes from a diabetes screening study in Ireland (Tierney et al., 2015). They found that primary care was not a feasible setting in which screening should occur. Initial quantitative data showed low uptake of screening opportunities; however, this data alone did not help explain why this was the case. The inclusion of qualitative interviews showed that resource constraints and resistance to change were areas that contributed to this finding. Another example examined the effect of prompting GPs that a patient required a prescription review in four GP practices in Scotland (Barnett et al., 2014). They found that although quantitatively, no change in actual review of some drugs occurred, these prompts were still valued by the GPs. The lack of prescription change following prompt was mainly due to the patients on these medications being prescribed by hospital consultants. GPs often followed up with consultants, which reassured them about these drugs.

These studies show how mixed methods approaches complement investigations of feasibility. Discovering ‘why?’ a particular quantitative result occurred in both of these studies had important implications for the intervention. Based on the recommendations and these examples a mixed-methods approach to testing the intervention for feasibility was used in this thesis. Quantitative methods collected prompted choice engagement rates, reasons for lack of participation and NHS ODR sign-up rates, with qualitative methods used to collect data to help explain these results from staff and patients.
6.5 Post Positivism and Pragmatism

As well as exploring the methodological approach to be taken when designing research, it is also important for researchers to understand the philosophical paradigms that underpin the approach, as well as exploring their own stance.

Two paradigms are associated with qualitative and quantitative research; the interpretivist and the positivist stance, respectively (Creswell, 2014). These two paradigms are absolutes for qualitative and quantitative researchers, in so far that the interpretivist stance based in relativism views reality as subjective, whereas the positivist stance based in realism views reality as observable and objective (Creswell, 2014). A question proposed, therefore from understanding these, is how can they be combined in the present thesis when their views of reality are so opposed? The ‘incompatibility thesis’ has been suggested that qualitative and quantitative are innately incompatible (Robson and McCartan, 2016). Researchers have extensively discussed this, and through this debate, the following research paradigms were suggested to oppose it, which align with mixed methods research; Pragmatism and Critical Realism.

Pragmatism, views reality as transient, its interpretation variable in light of how it is to be applied or studied (Morgan, 2007; Cornish and Gillespie, 2009; Dures et al., 2011). A key feature of pragmatism is its acceptance of using research methods appropriate to answer the research question. The paradigms closely associated with qualitative (interpretivist) and quantitative (positivist) research, have a clear distinction between their ontology, epistemology, and methodologies. Pragmatism rejects this distinction. It perceives both
perspectives as equally important and uses both qualitative and quantitative approaches in research. Primarily, pragmatism focuses on research outcomes (Morgan, 2007).

Another paradigm used in mixed methods research is critical realism. Critical realism is a complex paradigm proposed by Ray Bhaskar (Shannon-Baker, 2016). A fundamental premise of critical realism is that the combined use of qualitative and quantitative methods can overcome the shortcomings inherent in each. This stance combines both an objective perception that reality exists outside of a person’s perception of it and also that the world is a place constructed by individual perceptions. Critical realism also emphasises the importance of context in research (Shannon-Baker, 2016).

As a researcher new to the concept of a research paradigm and the need to align oneself with one, both pragmatism and critical realism have their merits. The current project is not one which has been created and developed solely by myself the PhD student. It is funded research with the ultimate aim of assessing the feasibility of an organ donation intervention in general practice. This aligns well with pragmatism that this research question is the focus when determining methodology, and consideration must be given to the needs of the stakeholders involved as well as my own. Critical realism also has benefits, however. The literature on feasibility studies highlight the importance of both an observable reality, e.g., resources the intervention takes up, which can be observed and measured quantitatively, as well as a subjective one, e.g., acceptability to patients and staff observed qualitatively.

It is challenging to reconcile the need to adopt a stance applicable to the research project, but also to consider my perceptions of reality and knowledge as a researcher. I was first
introduced to research during my studies for a BSc in Psychology at an institution that prized quantitative research over qualitative. This was consolidated with two years of research experience post-graduation working on the running of oncology clinical trials. This grounding in quantitative research, I believe, caused me to lean more towards a positivist stance and view of reality at the time. However, during the exploration of the stance for this thesis, I do not believe reality to be truly objectively observable, and reject the purely positivist paradigm. Indeed, my part-time study for an MSc in Health Psychology introduced me to the more subjective nature of reality and qualitative research methods. I also saw, however, that generalisability in quantitative research was, on personal reflection, something I believe to be important in the research I conduct. I, therefore, also reject the purist stance of interpretivism.

I believe mixed methods research to have merit and as in critical realism, that the weaknesses in each method can be overcome by combining both within the same research project. However, unlike critical realism, due to my quantitative grounding, I place higher weight on quantitative research that can be generalised and applied to populations. I also believe that although not all reality can be objectively captured, some can and more importantly should be. Therefore, I do not believe I can solely align with a critical realist or the pragmatist approach to research, as I do not view qualitative and quantitative results in their true form, equally.

This contrast between the typical paradigms associated with mixed methods, and my leanings more towards experimental methods and objective capture of reality, has caused difficulties in the selection of a paradigm to align with. Through reading and exploring
various other paradigms however, post-positivism is one with which I believe I align with personally as a researcher. It was Meyer's (2005) writings on health research and paradigms which I found particularly relevant, and helped guide my exploration on this topic. She discusses how the ‘mixing of methods' is actively promoted by researchers in health in the UK; however, only within a post-positivist paradigm (Meyer, 2005). Randomised controlled trials, systematic reviews, and evidence-based practice all dominate the area, and qualitative methods are used in a ‘supplementary' manner. This is further supported by Giddings (2006), who suggests that the use of qualitative data only concerns ensuring ‘accuracy' of quantitative results (Giddings, 2006). This guided me to explore the post-positivist paradigm.

Post-positivists view reality in a similar way to positivists that it exists (Robson and McCartan, 2016). However, they do not believe it can be observed in its entirety; only probabilities can be examined. It is not possible to view reality as true, but to observe to form conclusions that some beliefs concerning reality are untrue. Post-positivists sometimes use qualitative methods to help explain quantitatively based conclusions (Robson and McCartan, 2016). An example of this is in systematic reviews, where a quantitative methodology of systematically reviewing literature is supplemented by a narrative synthesis of the data discovered (Meyer, 2005).

Considering then, the present research study, and my leanings towards post-positivism; a primarily quantitative mixed methods approach is being taken. The nature of feasibility testing is to determine an answer to the question, is the intervention feasible? If the intervention is feasible, then a full experimental trial using quantitative methods could be
conducted in the future. Additionally, the focus of the intervention (although not this thesis) is to increase sign-up to the NHS ODR, which also aligns with the post-positivist paradigm. It is not the processes with which an organ donation decision is made which will be examined in this thesis, only the decision of ‘Yes I wish to join the NHS ODR or ‘No I do not wish to join the NHS ODR,” which can be captured. Although the complexity of these decisions may be introduced during the feasibility study, it is not the aim of the research to explore.

It must be noted, however, that there is little research in the UK and internationally concerning organ donation interventions in general practice or primary care. Although this could be due to a lack of researcher and funder interest in the topic, it could also be due to issues found in these settings, which could prevent interventions being successfully implemented. Indeed, Pradeep (2015), in her thesis, expresses these, such as a refusal of GPs to take part in an active intervention she designed (Pradeep, 2015). Therefore a pragmatic approach will also be taken due to the unexpected challenges that may arise during this research. Pragmatism is often stated to ‘reject’ traditional epistemological stances and approaches research by selecting methods which are best suited to the research question. It is mindful to employ a pragmatic stance during this thesis when facing the inevitable challenges that can occur during field research in relatively unexplored settings.

6.6 Embedded Experimental Mixed Methods

The final step before determining the specific methods to be used in the mixed methods single practice feasibility study (stage one) and feasibility RCT (stage two), is to determine the weighting given to each (quantitative/qualitative). Teddlie & Tashakkori recommend
examining the research questions, or objectives researchers are trying to answer, to determine whether qualitative or quantitative approaches provides the best fit for answering these (Teddlie and Tashakkori, 2009).

In the context of the present study and taking into account the pragmatic post-positivist philosophical stance; throughout both studies, higher weight was placed on quantitative methods with qualitative methods providing a supporting role. A typology used when a higher weight is given to one methodology over another is embedded mixed methods, and this was also used in both stage one and stage two (Creswell, 2014). The embedded typology views one method as primary and the other as supportive of the primary data, in this case, quantitative the primary method and qualitative the supportive one (Creswell, 2014). A ‘type’ of embedded mixed methods design is the Embedded Experimental with qualitative data providing a supplementary role to an experimental study (Creswell, 2014). Embedded designs do not aim to converge their data following collection and answer the same research questions. Instead, the data support one another with qualitative used to explain quantitative results. Based on this, it was important to determine which research questions would be addressed with which methodology. Both quantitative and qualitative methods will be used to address all research questions except those relating to intervention promise – which will only be assessed quantitatively. To determine whether the intervention and study is deemed ‘feasible’ to progress to further testing, quantitative results will be prized over qualitative in both studies.

In summary, a two-stage, sequential, embedded experimental mixed methods approach will be used, taking a pragmatic post-positivist stance which prioritises quantitative findings
over qualitative. In stage one a single practice feasibility study will be conducted to fulfil step four of intervention mapping, pre-testing materials. In stage two a feasibility randomised controlled trial will be conducted to understand the feasibility and acceptability of the study and intervention further, in multiple general practices.

6.7 Method

6.7.1 Objectives

The sub-objectives for the single practice feasibility study were developed based on Orsmond and Cohn (2015) and were split into those assessed quantitatively and those qualitatively (Table 23). The final protocol was published in Pilot and Feasibility studies in November 2018 (Jones et al., 2018). The Standard Protocol Items: Recommendations for Interventional Trials checklist was used to develop and structure the methods section (Appendix 10).
Table 23: Sub-objectives to be answered in the single practice feasibility study.

<table>
<thead>
<tr>
<th>Areas to examine based on Orsmond &amp; Cohn (2015)</th>
<th>Sub-Objectives</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment</td>
<td>Can staff within the GP practice be recruited to carry out the intervention?</td>
<td>Quantitative Qualitative</td>
</tr>
<tr>
<td>Data Collection Materials</td>
<td>How feasible and suitable is the training survey as a data collection tool? How feasible and suitable are the prompted choice data collection tools? How feasible and suitable are staff focus groups and online survey as data collection tools? How feasible and suitable is the patient online survey as a data collection tool?</td>
<td>Quantitative Qualitative</td>
</tr>
<tr>
<td>Acceptability</td>
<td>How acceptable and feasible is the training to staff? How acceptable and feasible is the intervention to staff? How acceptable is the intervention patients? Can staff training be run per-protocol? Can monitoring be run per-protocol? What are the staff adherence rates and engagement with the intervention?</td>
<td>Quantitative Qualitative</td>
</tr>
<tr>
<td>Resources and Expertise</td>
<td>What monitoring resources are required to run the studies and intervention? How many leaflets and posters are required to run the studies and intervention? What practice resources are required to run the studies and intervention? What technological resources are required to run the studies and intervention? What expertise is required to run the studies and intervention?</td>
<td>Qualitative Quantitative</td>
</tr>
<tr>
<td>Intervention Promise</td>
<td>Does the intervention show promise in increasing sign-up rates to the NHS ODR and who does the intervention target?</td>
<td>Quantitative</td>
</tr>
</tbody>
</table>

6.7.2 Study Design

A one-group post-test study design was used despite the criticism of these in health research. Primarily that no conclusions of causality, efficacy, or effectiveness can be made due to the lack of a control group (Knapp, 2016). However, as the current study takes an exploratory approach and aims to examine the feasibility and acceptability of an intervention, the weaknesses of this study design do not apply to the aims of the present study. Additionally, this study aimed to pre-test the intervention and materials as part of step four of IM. With the resources available, in order to obtain adequate depth of
evaluation of these, only one practice was chosen to participate. This facilitated multiple data collection methods and results to be obtained, which provided a suitable level of depth from which adequate intervention refinements could be made.

6.7.3 Study Setting

A GP Practice in Luton, UK were recruited by the NHSBT Partnerships and Development Manager before the involvement of the University of Bedfordshire in this research. The practice consisted of 25-35 staff members, served between 10-15,000 patients, and approximately 1000 consultations with patients were held each week. These figures were reported by the Practice Manager and have been adapted to ensure the anonymity of the participating practice is maintained.

6.7.4 Intervention - Prompted Choice

‘Prompted Choice’ asks patients during a consultation if they would like to join the NHS ODR and was conducted from 5th April 2018 – 9th July 2018. Clinical staff members who had received training took part - GPs, nurses, and healthcare assistants. If staff members had not attended the training session, then they were excluded from conducting prompted choice, primarily due to ethical concerns described in section 7.5. The inclusion and exclusion criteria for conducting prompted choice were as follows:

_Inclusion Criteria_

a. The patient is aged 18 years or above

b. The patient has the capacity to consent to the NHS ODR
**Exclusion Criteria**

a. The patient is aged 17 years or below

b. The patient does not have capacity to consent to the NHS ODR

Children (<18) although they can register on the NHS ODR were excluded due to the ethical complexities of collecting data on these patients. Patients without the capacity to consent to the NHS ODR were protected in this study. This is determined by general practice staff as standard practice, and during training, staff were instructed to use their professional discretion to determine this (errring on the side of caution when unsure).

**6.7.5 Intervention - Training**

Training was conducted in two one hour sessions on 14\textsuperscript{th} March 2018 and 20\textsuperscript{th} March 2018 at the participating practice during the lunch break. Training was open to all staff members at the practice, including administrative and reception staff. Although this group does not have consultations with patients, they regularly interact with them via telephone, email, or face to face. It was essential to ensure all staff were aware that the intervention was being conducted and were able to answer questions on it or direct patients to the correct sources of information.

**6.7.6 Intervention - Leaflets and Posters**

The following leaflets and posters produced by NHSBT were ordered on 19\textsuperscript{th} February 2018 and displayed in the practice during the intervention period.
Posters

- Yes I donate poster – Black and Asian
- Yes I donate poster – 50+
- Yes I donate poster – Card in Hand
- Yes I donate poster – Family Conversation
- Yes I donate poster – Gift of Sight

Leaflets

- Organ Donation Your Questions Answered (English)
- Religious Perspectives Summary (English)
- Religious Perspectives Sikhism (English & Punjabi)
- Religious Perspectives Islam (English, Urdu, Gujarati, Bengali, Somali, Punjabi, Arabic)
- Religious Perspectives Hinduism (English, Punjabi, Gujarati, Tamil, Hindu)
- Religious Perspectives Christianity (English, Polish)
- Religious Perspectives Judaism (English)

One leaflet contained a sign-up form, and a secure key locked box was provided behind reception for staff to collect completed forms if these were handed to them. Leaflets and posters were displayed as standard practice – on dedicated leaflet tables and poster boards in all waiting areas of the practice. All available languages produced by NHSBT were displayed. Unfortunately, although the general questions answered leaflets was requested,
this had gone out of print by NHSBT and would not be restocked. Only 20 of these were provided for the duration of the intervention without an alternative leaflet.

### 6.7.7 Timeline, Sample Size and Recruitment

The intervention period ran from the first training session to the last day of prompted choice. Training occurred one month before the start of prompted choice and prompted choice ran for three months. The stakeholders pragmatically chose this timeframe.

### 6.7.8 Monitoring

The intervention was monitored weekly by the PhD student to examine raw intervention data on the computer system for issues, leaflet and poster fidelity, and to provide staff with an opportunity to raise issues or queries with the research team. A monitoring form was developed to facilitate this (Appendix 11).

### 6.7.9 Data Collection

An embedded experimental mixed methods approach was taken to collect data for this study, with higher weight placed on quantitative data than qualitative data. Following the selection of this approach the specific methods to use were selected; a quantitative and qualitative paper survey, a quantitative computer-based prompt and questionnaire on SystmONE, a quantitative and qualitative monitoring form, qualitative focus groups, a qualitative online survey, and quantitative and qualitative simple observation.
6.7.9.1 Training Evaluation

Training sessions were evaluated using four methods; a paper survey, field notes and reflection, focus groups, and an online survey. The aim of these was to address the training related sub-objectives. Field notes and reflection, focus groups, and the online survey were conducted as part of the post-intervention data collection and are discussed in subsequent sections.

Kirkpatrick’s hierarchy of training evaluation, one of the most widely used models in medical education, was used as a basis for the training evaluation (Swanwick, 2014) (Figure 27). The first level of the hierarchy is evaluation of participant reaction to the training, the second to evaluate the level of knowledge acquisition facilitated by the training, the third is evaluation of how the training translates to behaviour in the workplace, and the final level is to evaluate the results of the training on tangible health outcomes (Kirkpatrick, 1979) (Figure 27).

![Kirkpatrick's hierarchy of training evaluation](image)

**Figure 27: Kirkpatrick’s hierarchy of training evaluation (Kirkpatrick, 1979).**

Further up the hierarchy, the more complex, resource-intensive, and expensive it is to perform a training evaluation (Kirkpatrick, 1996). To assess levels two – four, it is
recommended that an experimental design with a control group is used to assess learning, behaviour, and results (Kirkpatrick, 1996). This was not feasible to conduct in this study due to the time and resource constraints expressed by the practice. As a consequence, evaluation of the training sessions focused on understanding the feasibility and acceptability for staff of attending these, as well as whether staff felt adequately prepared to conduct prompted choice. Therefore evaluation occurred only at level one – reaction, which Kirkpatrick refers to as assessing ‘customer satisfaction’ (Kirkpatrick, 1979, 1996).

### 6.7.9.1.1 Training Evaluation survey

The training evaluation survey aimed to answer the following questions:

- What are staff perceptions of training acceptability?
- What are staff perceptions of training feasibility?

#### 6.7.9.1.1.1 Participants and Recruitment

All training session attendees were invited to take part in the survey. It was provided to staff at the beginning of the session along with a pen, referred to, and explained in the PhD student section of the training. Staff were reminded at the end of the session to complete it, and that participation was voluntary.

#### 6.7.9.1.1.2 Materials and Procedure

A participant information sheet (PIS) was developed based on the World Health Organisation Informed Consent Templates (Appendix 12) (The World Health Organization, 2019) and a separate consent form was developed based on the Health Research Authority
(HRA) templates (Appendix 13) (NHS Health Research Authority, 2019a). The PIS described the study in lay language, its purpose, duration, procedure, risks and benefits, reimbursements, confidentiality, anonymity, dissemination, right to withdraw, ethical approval, and contact details. Additionally, telephone numbers for Samaritans and local bereavement support services were provided in case staff were distressed by the topic of organ donation.

The survey was developed based on Kirkpatrick’s five steps for capturing trainees reaction to a program: to determine what you wish to discover, to develop a paper survey based on these, design this survey so that answers can be quantified, make the survey anonymous, and provide the opportunity for participants to write additional comments (Kirkpatrick, 1996) (Appendix 14). The survey contained the PIS, consent form, 13 quantitative questions, and three qualitative questions. Quantitative questions concerned participant reaction on; preparation to discuss organ donation, acceptability of training generally, acceptability of location and time taken to attend, complexity of the content, knowledge, self-efficacy, presentation styles and use of resources. Questions 1-9 were scored on a 10 point Likert scale where 1-Disagree and 10-agree. Questions 10-13 were scored on a 10 point Likert scale where 1- Unsatisfied and 10- Satisfied. Three free text qualitative questions followed the quantitative, which focused on strengths, weaknesses, and recommendations. Finally, participants were asked to report their staff group, Clinical-Doctor, Clinical-Nurse, Clinical-Other, Administrative-with clinical training & Administrative – with no clinical training.
6.7.9.2 Prompted Choice Data Collection

The following questions were answered quantitatively during prompted choice using computer-based data collection:

- How many staff receive prompted choice reminders for patients?
- How often do staff complete data collection forms?
- How often are errors or missing data found from data collection forms?
- How often do staff complete the prompted choice element compared with the number of overall consultations they have?
- How many staff complete the prompted choice element for the full intervention period?
- How many patients joined the NHS ODR at the end of the intervention period?
- What is the demographic profile of those targeted by the prompted choice intervention?

6.7.9.2.1 SystmONE

6.7.9.2.1.1 Prompted Choice Responses

Data collection on SystmONE, the practice computer system, had to be estimated before NHS Research Ethics Committee (NHS REC) review with a view to submit amendments once approval to access the practice computer system had been obtained. This section will describe the final SystmONE Prompt and Questionnaire used to collect prompted choice data. Changes required by the NHS REC, Health Research Authority (HRA), and Confidentiality Advisory Group (CAG), alongside the amendments process will be described
in section 7.12. The practice requested that data for the prompted choice element be collected via computer – specifically a ‘reminder’ that opens into the data collection form.

Following HRA approval to commence study set up (based on NHS REC and CAG favourable opinion), the PhD student was granted access to SystmONE. Development was conducted on a ‘test system’ located on one computer in the practice. This system has no connectivity to the live system, protecting it from any errors made during the development process. Several calls to TPP were made for instructions on how to build the prompt and questionnaire required, and they suggested that a ‘protocol’ (a term on SystmONE) could be created to pop up and open into questionnaires (which practices commonly use). Unfortunately, TPP could not provide detailed guidance on how to conduct this over the telephone. The SystmONE trainer for the practice was consulted on this.

The final prompt appeared when a clinician clicked the ‘Start Consultation’ button on SystmONE. When this button was selected a box would appear (Figure 28) and the staff member could select one of two questionnaires a ‘Prompted Choice Questionnaire’ which opened if the clinician conducted prompted choice and captured patient responses or a ‘Feasibility Questionnaire’ which opened if the clinician did not conduct prompted choice and could record reasons for this.
Figure 28: Organ donation study prompt for clinicians using a test patient.

Prompt text instructed staff on which questionnaire to select and also not to press the red X. If staff did press this button, no data would be collected regarding reasons for not completing prompted choice. Staff were instructed during training not to press this; however, if staff did (Figure 29), they were given the option by SystmONE to stop or pause the protocol. This was not an editable function. However, staff were also encouraged in the prompt text and training to pause it, and reopen it once the consultation was complete if this appeared.
Figure 29: SystmONE screen if staff press red x to cancel the prompt.

If the staff member clicked the Prompted Choice Questionnaire, the first question they had to answer concerned patient eligibility (Figure 30). SystmONE has provision for prompts to only appear to specific staff members and particular patients, therefore an eligibility question concerning age was not required (as the prompt could be limited to those 18 and over) nor a question asking staff whether they had conducted the training.

Figure 30: Eligibility question on ‘Prompted Choice Questionnaire’ on SystmONE.
Figure 31: SystmONE Protocol amendment screen to restrict prompt appearing to only patients aged 18 and over.

Figure 32: SystmONE Protocol amendment screen to restrict prompt appearing to only trained staff members.

Only staff who had participated in the training sessions received the prompt, and figures 31 and 32 show these restriction screens for the prompt appearing. Once staff had selected that the patient was eligible in the ‘Prompted Choice Questionnaire’ the option to record NHS ODR preference opened (Figure 33) and these were based in the GMS1 Form organ donation question responses (Appendix 2). To ensure minimal text was present on the opening of the ‘Prompted Choice Questionnaire,’ all sub-questions were hidden unless selected. For example, if a patient stated they did want to register but only selected organs,
the selected organs options would only appear if the staff member selected "Yes – Selected Organs" (Figure 34).

Figure 33: SystmONE Promted Choice Questionnaire NHS ODR selection preferences.

Figure 34: SystmONE Promted Choice Questionnaire with ‘Yes -Selected organs’ selected.
It was decided that an additional option should be added to the questionnaire ‘Patient believes they are already on the register.’ It was deemed necessary to record whether a patient was a new registrant or someone who is registering again. If staff selected this option, they were instructed to ask the patient if they would like to re-register (Figure 35). This was included to ensure that those who believed to be registered were and would be added to the register as per standard practice by administrative staff.

Figure 35: SystmONE Prompted Choice Questionnaire providing the patient the opportunity to re-register on the NHS ODR if they believe they are already on it.

Due to limitations on SystmONE staff had to choose at the beginning of a consultation if they were going to conduct prompted choice. It could be challenging for staff to anticipate whether they will or will not conduct prompted choice and to address this, during training it was emphasised that if they were in any doubt, please select the Prompted Choice Questionnaire. An option to specify that the patient was not asked was also included in the
Prompted Choice Questionnaire for those staff members who did not end up conducting prompted choice (Figure 36).

![Figure 36: Prompted Choice Questionnaire on SystmONE with 'Patient not asked' selected.](image)

A crucial part of prompt and questionnaire development was ensuring patients were not repeatedly exposed to prompted choice - if they responded Yes they did wish to join the NHS ODR, that they believed they were already on the register, or that the staff member selected do not ask the patient again. SystmONE is built on a concept called ‘Read-codes.’ These are codes added to a patient record that can be searched for and extracted according to the needs of the practice. If the staff member selected the options which required the prompt to be switched off, a read-code would be added to their patient record accordingly. The ‘Read-codes’ available can only be changed or adapted by NHS England to ensure uniformity throughout practices that use SystmONE in England. The SystmONE protocol was
developed to scan a patient file when the staff member selected ‘Start Consultation’ for these ‘switch off’ codes. If these read-codes were present, the prompt would not appear for that patient (Figure 37).

![Diagram of SystmONE protocol](image)

*Figure 37: The SystmONE protocol used to display the prompt and questionnaires only for patients without the read-codes which denote they have already joined the NHS ODR, or they should not be asked again.*

To add read codes to a file, staff would be presented with the screen in figures 38 and 39. Staff should select yes to this screen. Unfortunately, this is also not editable; therefore, it was possible that staff (if they were unsure) could select not to add the read codes. To help mitigate this, staff were given instructions during training and in the training manual.
Figure 38: SystmONE request to add read-codes to test patient file indicating they had joined the NHS ODR.

Figure 39: SystmONE request to add read-codes to test patient file indicating they should not receive prompted choice again.
Finally, figure 40 shows the ‘Feasibility Questionnaire.' This was designed to be as brief as possible to encourage busy clinicians to complete it and provide data on the feasibility of prompted choice. This questionnaire did not contain any read-codes.

![Figure 40: SystmONE No patient not asked questionnaire.](image)

6.7.9.3 Monitoring

The questions aimed to be answered by study monitoring were:

- Are leaflets and posters displayed as per protocol continually throughout the intervention?
- How long does intervention set-up, monitoring, and close take?
- How many leaflets and posters are required for the intervention period of 3 months, which leaflets and in languages?

The PhD student monitored prompted choice, and leaflets and posters weekly. SystmONE Registration Data was examined to ensure that no untrained staff members were conducting prompted choice; it was also examined to see if errors in data collection were made that needed to be addressed. Leaflets and Posters were checked for their positioning,
counted, and restocked if necessary. Finally, staff were approached regarding the study, and any issues or queries they had recorded. Descriptive quantitative data were collected on the number of leaflets taken, whether leaflets and posters were positioned correctly, and whether untrained staff members were participating in prompted choice. Field notes were used to capture staff issues and queries.

6.7.9.3.1.1 Staff Consultation Numbers

To examine fidelity of prompted choice – i.e., how often is prompted choice conducted by staff - the number of staff consultations held during the intervention period was collected. Unfortunately, SystmONE was unable to provide this data for specific staff members, only all staff at the practice. As not all staff were participating in prompted choice, this would not be applicable. It was pragmatically decided that the PhD student would manually count appointments at weekly monitoring visits for the previous week, for each participating staff member. Telephone and face to face consultations were colour coded separately via the appointment screen, and no identifiable patient data was displayed or accessed during this collection. This element was added to the study retrospectively due to an oversight and staff consultation data commenced collection after 2nd May 2018.

6.7.10 Post Intervention Data Collection

Two methods of data collection were used post-intervention; focus groups with patients and staff, and an online survey for staff only. Focus groups were the primary qualitative method due to their ability to capture many people’s views in a short space of time and assess how the practice team worked together to deliver the intervention (Stewart &
Shamdasani, 2014). To ensure as many staff views were captured as possible, an online survey was given to all participating staff regardless of focus group participation. Key to ensuring focus group recruitment is that staff were not informed of the online survey element until all staff focus groups were completed.

6.7.10.1 Staff Focus Groups

The staff focus groups aimed to address the following sub-objectives:

- Staff perceptions of the data collection tools
- Staff perceptions of acceptability
- Staff perceptions of feasibility

Both focus groups and interviews are commonly used qualitative methods in health research (Gill et al., 2008). Focus groups aim to collect collective views on a topic, whereas interviews aim to collect individuals' views (Gill et al., 2008). The present intervention has an organisation-wide focus and will be implemented by many staff members who fulfil different roles within the practice. To capture acceptability, feasibility, and perceptions, it is important to examine the collective views of staff who typically work collaboratively within General Practice. Due to this collective working approach, focus groups were deemed a more congruent method than individual interviews.

Additionally, taking a pragmatic stance, in order to fulfil both a single practice study and an RCT within the three year PhD period, time-efficient data collection methods were selected. Individual interviews with up to 35 staff members are more time-intensive than four focus
groups. The use of focus groups to assess the sub-objectives in the single practice study was in itself a pilot – to examine whether it is possible to recruit to, conduct and answers these using this method. Therefore the topic guides, PIS, consent, recruitment processes were evaluated following this pilot to determine whether they are appropriate for use in the RCT.

6.7.10.1.1 Participants and recruitment

Four one hour focus groups were planned to be conducted with staff (6-12 members per group), at the practice during the two hour lunch break when the practice is closed to consultations (12 pm - 2 pm). The Practice Manager was consulted on the best time to conduct focus groups, and the lunch break was specified. One hour's duration was specified to enable discussion over a long enough period but still allowing staff one hour of their lunch break in which to fulfil their duties and have an adequate break. Focus groups were also split between staff groups – two focus groups with doctors, one with nurses & healthcare assistants and one with administrative & reception staff. Two focus groups with doctors were planned as the practice discussed the likelihood of this group being on home visits during the lunch hour. Therefore to ensure as many doctors as possible could attend, two groups were planned.

A key part of focus groups is the comfort of participants to interact and discuss issues (Gill et al., 2008). In hierarchical organisations, those participants lower down may not feel able to express their views candidly in front of their senior colleagues (McInnes et al., 2015). Therefore, groups were split according to staff group due to the hierarchical nature of general practice (McInnes et al., 2015). Staff were recruited to the focus groups via email
sent by the Practice Manager on behalf of the PhD student and were conducted on days to maximise staff availability.

6.7.10.1.2 Materials and procedure

Focus groups ran from 9th July 2018 – 9th August 2018. The PIS and consent forms were based on the World Health Organisation Informed Consent Templates (Appendix 15 & 16) (The World Health Organization, 2019) and HRA templates (NHS Health Research Authority, 2019a). These were adapted to detail the specific risks, benefits, procedure for focus groups. Particularly pertinent is ensuring participants are aware that their answers, although anonymised, could be linked back to the practice in publication. Although every effort was made to anonymise the practice during this research, the name of the practice may be available in their communications or PPG communications outside of the researcher’s control.

To develop topic guides, Stewart and Shamdasani’s guidance was used (Stewart and Shamdasani, 2014). Topic guides set the agenda for focus groups discussion, they should not elicit yes, or no answers and questions should be open. The sub-objectives guided the development of the topic guides and primarily aimed to assess feasibility, acceptability, and the data collection tools. Stewart and Shamdasani suggest questions should be ordered to start with more general questions and end with more specific ones and should be ordered with those most critical to the research agenda asked first (Stewart and Shamdasani, 2014). They highlight that these guidelines are somewhat contradictory, and researchers have to make trade-offs between them during design. They also suggest that typical topic guides
have no more than 12 questions and that homogenous groups (like those in our focus groups) will move more quickly between questions than heterogeneous groups. Finally, they also recommend using probes or prompts as some participants may require these when asked questions, particularly more general ones (Stewart and Shamdasani, 2014). Two separate topic guides were produced; one for clinical staff (doctors, nurses, and healthcare assistants, Appendix 17) and one for administrative or reception staff (Appendix 18). These were separated due to only clinical staff completing prompted choice; however, it was essential to capture views of administrators and receptionists concerning the overall impact of the intervention on the practice.

The priority for focus group discussion was the prompted choice element and SystmONE data collection forms – as these were the key intervention components. General questions concerning acceptability were included later in the topic guide; however, it was anticipated that acceptability findings would be discussed in all sections. Lau et al. 's conceptual framework was mapped onto the topic guide, and prompts were included which covered all four contextual levels; external context, organisation, professional and intervention (Lau et al., 2016).

Focus groups took place in an available room at the practice and were audio-recorded using a digital audio recorder. Incentives were used in the form of lunch for staff. Staff were presented with the PIS and consent form and given time to re-read this again, ask questions, and complete the consent form. Once consent was confirmed from participants, the focus groups commenced according to the topic guide. Following the focus groups, participants
received a verbal debrief and were instructed to take their PIS with them in case they require the contact details present on them.

6.7.10.2 Staff Online Survey

The primary limitation for the focus groups is that the PhD student/focus group moderator was present in the practice throughout intervention development, training, and the 3-month intervention period. This introduces a level of social desirability bias for the participating staff – that they may not wish to be honest or express negative views about the intervention to prevent offending the PhD student. This element was moderated by the inclusion of the following sentence in the ‘welcome & introduction’ section of the topic guide – "Emphasise that the project is assessing feasibility and that honest views are really important. Even if they are negative." However, although this attempts to reduce this bias, it cannot be eliminated. A further challenge to the focus groups and eliciting honest views is that organ donation is a challenging topic, centring around death, which participants may not feel comfortable sharing verbally with their colleagues. Therefore an anonymous online survey formed of predominantly open-ended questions, was also developed to capture staff views – to mitigate some of these limitations by providing staff with a platform to share views they may not be comfortable sharing in front of a group or the PhD student/moderator. The online survey, like the focus groups aimed to capture the following sub-objectives:

- Staff perceptions of the data collection tools
- Staff perceptions of acceptability
- Staff perceptions of feasibility
A survey containing open-ended questions was chosen due to the exploratory nature of this research. It is challenging to anticipate the areas of feasibility, acceptability, and perceptions that staff will wish to discuss. Open-ended questions allow for a variety of themes to be captured rather than those predetermined by the researcher according to the literature or theory (Fielding, Lee and Blank, 2017). The online nature of the survey was chosen due to the ability for staff to complete this as and when they wished, fitting in with their day to day duties (Lau et al., 2016). A paper survey would require the researcher to be present in practice hours to distribute and collect this, and it was anticipated that staff might also feel similar social desirability bias if the researcher was distributing this in person.

6.7.10.2.1 Participants and Recruitment

The Practice Manager sent the online survey link on behalf of the PhD student to all staff participating in prompted choice (Appendix 19). A reminder email was sent approximately two weeks after the first email and a final reminder four weeks after the first email, with the survey closing after six weeks.

6.7.10.2.2 Materials and Procedure

Online survey platform Qualtrics hosted the survey which ran from 9th August 2018 – 20th September 2018. The PIS (Appendix 20) and consent form (Appendix 21), as above, were based on the World Health Organisation and HRA templates and presented on the first pages of the online survey. The PIS included information on the aim of the survey, that is was intended to capture views staff did not express in group discussion. Staff were directed to the consent form page and denoted their consent by ticking the boxes next to consent
statements digitally. The online survey consisted of 13 open questions based on the following topics: general experience, training, prompted choice, data collection form – SystmONE, leaflets and posters, acceptability, other issues and views on potential rollout. Questions concerning recommendations were integrated to appear after each intervention element. Questions were also constructed to be open and encourage expansion on each topic by integrating prompts within them in the form of examples (Appendix 22).

6.7.10.3 Patient Focus Groups

Patient focus groups, although planned, were not conducted in the final study. Recruitment was to be conducted via practice text message to patients who visited the practice during the 3-month intervention period. The text messaged contained a study-specific telephone number of the PhD student. The topic guide was framed using the sections – introduction, prompted choice, leaflets and posters, acceptability, recommendations, and concluding questions (Appendix 23). As in the staff focus group topic guides prompted choice was of the highest priority to assess for acceptability and feasibility with patients. However, some sections from the staff focus group topic guides were not included as they did not apply to patients, e.g., professional role and training.

6.7.10.4 Patient Online Survey

In June 2018, a concern was raised that no screening of patients before focus group participation was built into the protocol. All patients who wished to participate either via email, text message, or telephone call would be invited to attend. It was deemed unsafe for the PhD Student to conduct these without suitable safety precautions, such as asking
patients to complete a screening questionnaire before participation, or requesting information on participating patients from the practice regarding any safety concerns. These would require a substantial amendment to the HRA to be submitted which includes NHS REC approval. As this issue was only raised in June 2018, time constraints would not allow for this submission and approval process. Therefore patient views were explored through an online survey in place of a focus group.

6.7.10.4.1 Participants and Recruitment

The patient online survey was live between 26th July 2018 – 6th September 2018. The recruitment text message (adapted from the focus group content – Appendix 24) was sent to patients for whom the practice completed a Prompted Choice Questionnaire via SystmONE. Initially, only patients who had a Prompted Choice Questionnaire completed in the last two weeks of the intervention were contacted. However, due to low response rates after two weeks, the text message was sent to patients who had a Prompted Choice Questionnaire completed for two additional weeks (one month in total). A week later, the decision was made to send a text message to the remaining patients throughout the full three months of the trial due to low response rates.

6.7.10.4.2 Materials and Procedure

Qualtrics was used to host the patient online survey. The focus group PIS based in the WHO template, consent form based in HRA template and topic guide were adapted in a minor manner for this survey (Appendix 25 – highlighted sections show adapted elements). Patients were presented with the PIS and then directed to the consent form and denoted
their consent by ticking the boxes next to consent statements digitally. The online survey consisted of 3 demographic questions (age, ethnicity, and gender), 3 closed questions (were you asked, did you see the leaflets and posters and which staff member asked you) and 9 open questions based on the following topics: experience of being asked, if prompted choice/leaflets and posters helped them make a decision, appropriateness and acceptability of intervention, and recommendations (Appendix 2).

6.7.10.5 Reflective Practice and Field Notes

Reflective practice and field notes are commonly used in feasibility studies (O’Cathain et al., 2015). They were used to answer the following:

- What were the barriers to training session attendance?
- What were the facilitators to training session attendance?
- How close are the actual training sessions to the planned sessions?
- How many staff attended the training sessions?
- How many staff attend the full training session?
- What expertise is required to perform the training, administrative, set-up, monitoring, and close tasks for the prompted choice element?
- What are the technological requirements for training, set-up, monitoring, and close of all elements of the intervention?
- What are the practice resources involved in running the intervention?

Reflection on these questions occurred once all elements of the intervention ceased, including other post-intervention data collection. Field notes from all stages of the intervention were consulted alongside monitoring forms.
6.7.11 Data Management

Data management for this study concerned three areas – registration data captured from SystmONE, paper, and digital mediums. Once all ethical approvals were granted, the PhD student was given access to SystmONE via chip card and password via the practice. As part of this, the PhD student signed a practice confidentiality agreement. Only data pertinent to the study was accessed via SystmONE, including prompted choice data and patient demographics. The PhD student anonymised data and extracted it via encrypted memory stick provided by the University of Bedfordshire. Paper data, including consent forms, training evaluation forms, and field notes were stored in a locked filing cabinet at the University of Bedfordshire. Digital monitoring forms and audio files were also stored on the encrypted memory stick. Finally, online survey qualitative data was exported from Qualtrics into the encrypted memory stick; however, the data was also stored by Qualtrics who adhere to the data protection act, General Data Protection Regulation (GDPR) and online data protection procedures. All study-related data will be stored for five years before being destroyed.

6.7.12 Data Analysis

6.7.12.1 Quantitative Analysis

Quantitative data included training attendance and evaluation survey responses, monitoring form data, and prompted choice data from SystmONE. Descriptive analyses were conducted using SPSS version 23 on the SystmONE and the training evaluation survey responses. Monitoring form data and training attendance were reported without conducting analyses.
No inferential statistics were calculated due to the small sample size anticipated to be collected from the training evaluation and monitoring form data. Additionally, no inferential statistics were conducted on SystmONE data as the questions to be answered could be fulfilled by descriptive statistics.

6.7.12.1 SystmONE Data Preparation

‘Age’ was converted from a string variable (XXyrs) to a numeric variable. A new variable was created for age to correspond with NHSBT age categories to allow for direct comparison to their reporting (18-20, 21-30, 31-40, 41-50, 51-60, 61-70, 71+). Ethnic categories collected were those used by the practice. Unfortunately this is not consistent, and several categories were present. Further categorisation was required of these according to the Office of National Statistics ethnic groups (2011) (Office for National Statistics, 2011), appendix 27 details this process. Ethnicities were further categorised as BAME or Non-BAME according to the NHSBT Activity Reports. As with age, direct comparison to these reports is vital for understanding our results in context with NHSBT findings. BAME ethnicities are those categorised as ‘Mixed/Multiple Ethnic Groups, Asian/Asian British, Black/African/Carribean/Black British and ‘Other ethnic group’.

6.7.12.2 Qualitative Analysis

All focus groups were transcribed by the PhD student verbatim and inputted into NVivo 11. Online survey responses and qualitative training evaluation questions were also inputted. Framework analysis proposed by Ritchie and Spencer is a qualitative method of analysis commonly used in healthcare research and was selected to analyse qualitative study data. It
consists of five steps familiarization, identifying a framework, indexing, charting, and mapping and interpretation (Ritchie and Spencer, 2002). Framework analysis allows for themes to be compared across the medium they were captured, and by their participant group (Gale et al., 2013). In this instance, by method; focus group, online survey or training evaluation, and by participants (patients or staff). In the context of the present study themes were categorised based on the underpinning theoretical framework- Lau et al. 's (2016) framework and the IIFF Model (Siegel, Alvaro and Hohman, 2010; Lau et al., 2016). Framework analysis lends itself well due to the emphasis on; context, the different methods and participant groups through which the qualitative data is captured, and that the method is not appropriate for heterogeneous data (Gale et al., 2013). Finally, the flexibility of the Framework Method and lack of affiliation with a philosophical stance also lends itself to the current study. Based on this, a mixture of apriori frameworks (IIFF Model and Lau et al. 's conceptual framework) and additional themes from within the data were used to develop the framework and conduct the analysis. The data was analysed using separate frameworks for each population; in this case, patients and staff, allowing for the identification of both common and divergent themes between them.

To conduct framework analysis list of preliminary themes was created based on the data first impressions (Appendix 28). An apriori framework was developed containing Lau et al. 's conceptual framework and the IIFF model. The data was then coded according to this framework (Appendix 29). A second set of additional themes were identified separately to the apriori framework (Appendix 30). Finally, this framework was combined and refined to integrate the additional themes within the apriori framework (Appendix 31). Responses were invivo coded to the framework (Appendix 32), following this invivo coding, additional
themes were added to the network via nodes which summarized the key issues presented in the transcript. A chart was then populated and summaries recorded for each cell in the framework, where rows are data sources and columns themes (Appendix 33).

6.7.12.3 Stop-Go Criteria for Feasibility

Thabane et al. (2010) suggest that four potential outcomes can result from a feasibility study (Thabane et al., 2010).

1. To stop the trial entirely due to the results, indicating the intervention is not feasible.
2. To continue with the trial, however, modifications must be made to the protocol.
3. To continue the trial without modifications but monitor its progress closely.
4. To continue without modifications or additional monitoring.

These assessed whether the transition to the RCT should be made and how to modify the intervention. The prompted-choice element of the intervention is the central component; therefore it is this component, not training or leaflets and posters which was used to determine which of the above four outcomes occurred at the end of the single practice study. In order to determine whether Thabane et al. (2010) outcome one should occur, the minimum number of times prompted choice should be performed by the minimum number of staff members was defined. If one staff member conducted prompted choice on one or more occasions, the RCT would go ahead. Thabane’s outcome number two, three, four will commence for the RCT if any staff member completes the prompted choice element for any patient. These relatively minimal and straightforward stop-go criteria were selected as
feasibility issues present in the participating practice could potentially be rectified and that the feasibility issues may not apply to other practices.

6.7.13 Ethics

Some ethical issues were considered during the design of this study using the British Psychological Society (BPS) Code of Human Research Ethics as a basis (The British Psychological Society, 2014). These were distress, consent, anonymity and confidentiality, coercion, and the impact on the regular running of the practice.

6.7.13.1 Distress

A critical ethical concern was highlighted by the stakeholder group, in particular, the Practice Manager, Lead GP and Chair of the PPG - potential patient distress. That patients attend their GP practice for potentially distressing health issues. The topic of organ donation could be inappropriate in some circumstances and increase patient distress further. The BPS Code of Human Research Ethics (The British Psychological Society, 2014) states that any risk to participants should be minimised where possible, and if not possible to eliminate, weighed against the benefits of the research to society (The British Psychological Society, 2014).

To minimise potential distress, training was conducted by the NHSBT Specialist Nurse in Organ Donation (SNOD) to inform staff to use their professional discretion in whether to conduct prompted choice. If in any doubt they were advised not to conduct prompted choice. This training was also conducted by an experience SNOD who has frontline
experience of discussing organ donation with bereaved families and who has participated in training other SNODs previously. However, not all potential distress could be eliminated in this manner. Another element of distress was distress to the staff members conducting the study. To mitigate this element, study posters containing the telephone numbers for Samaritans and local bereavement services were displayed in the practice. The importance of registration as an organ donor and the potential impact of this intervention was deemed a high enough benefit for society for the intervention to go ahead as designed.

6.7.13.2 Consent

As previously stated, the practice were recruited to conduct the intervention before the involvement of the University of Bedfordshire. Importantly, however, patients were not going to be ‘recruited’ into the intervention as in a typical intervention evaluation study; they were going to be exposed to it based on their use of the participating practice. Informed consent is a crucial component of researching human participants according to the BPS code (The British Psychological Society, 2014). They specify that participants should be given enough time to understand the study and ask questions of researchers before officially confirming that they consent to participation. This element was a challenge to resolve in the present study. The aim of prompted choice was for trained clinical staff to ideally ask every eligible patient if they would like to join the NHS ODR. Typically obtaining informed consent requires patients to read through a detailed information sheet, be allowed to think about participation, to ask questions regarding the study and finally sign a consent form in the presence of a researcher (The British Psychological Society, 2014). Consultations in general practice on average range from 8 minutes to 15 minutes in length
(Royal College of General Practitioners, 2013b). It would not be feasible, therefore for staff to obtain informed consent for each patient who visited the practice during three months (estimated to be 10,000 consultations).

It was decided at the stakeholder meeting on 13th July 2016 that individual informed consent of each patient would not be sought. As anticipated by the research team, the Practice Manager and Lead GP stated it would not be possible for them to conduct the intervention if they had to obtain informed consent for every patient for whom a consultation was held. Although the importance of informed consent was appreciated by the stakeholder group, ultimately the Chair of the PPG, Practice Manager and Lead GP, expressed that the potential public good of the intervention outweighed the ethical issues associated with not obtaining informed consent. To mitigate this it was agreed that only the minimum anonymised amount of data on patients would be collected, NHS ODR preference and the demographics age, ethnicity and gender. No other information medical or otherwise would be collected. This data is already collected by NHSBT on their NHS ODR sign-up forms (Appendix 2).

6.7.13.3 Anonymity and Confidentiality

Another key principle to adhere to during research is participant anonymity and confidentiality. All PIS's outlined that data collected would be anonymous, only staff group but no other staff identifiers would be collected, and anonymisation of transcripts would occur before their analysis during transcription. Participants were also informed that responses were confidential; however, that they could be traceable back to the participating
practice. At the time of this application, GDPR was not in place; however, it came into place before study start. GDPR was adhered to throughout the study and PIS's updated before their use according to HRA guidelines on GDPR. The GDPR principle on data minimisation was adhered to throughout, that data was only used as previously stated in the protocol, NHS REC, HRA and CAG submissions.

6.7.13.4 Coercion

Another ethical issue mitigated through training was that of coercion. During prompted choice staff members may coerce participants to join due to their belief in organ donation. This however, would be unethical. During training, staff were instructed to inform but not coerce participants to join, that the intervention is only to offer a sign-up opportunity and information – not to persuade. This training was conducted by an experience SNOD who has conducted training on the topic of ‘discussing organ donation’ previously and has an in-depth understanding of the process, including its ethical principles. Indeed, the SNOD role is to conduct conversations with families who are grieving to establish whether they wish to donate their loved ones organs. The SNOD who led the training, therefore, discussed this with GP practice staff, particularly highlighting the altruistic ‘gift’ that organ donation is and the importance of respecting this when discussing it with patients.

6.7.13.5 Practice Impact

The final ethical issue was the impact of the intervention on the regular running of the practice. This, again, was mitigated during training as staff were instructed to prioritise patient care over the intervention. Additionally, the feasibility nature of the study was
outlined to them, that we wish to capture whether this can be done, and not being able to conduct prompted choice is just as much a finding as being able to conduct it. Also, the collaboration and co-design of the intervention with the practice helped limit the impact on the data to day running of the practice, as the Practice Manager and Lead GP were able to contribute to the design to prevent this.

6.7.14 Ethical Approval Process

To research in the National Health Service (NHS), specific ethical approval should be obtained from two bodies – the NHS Research Ethics Committee (NHS REC) and the Health Research Authority (HRA). The NHS REC address ethical issues that will predominantly impact on patients (staff research does not need NHS REC approval), and the HRA is responsible for the administrative aspects of the review and oversee the process (NHS Health Research Authority, 2019b). To produce an application for the NHS REC, a detailed form must be completed and submitted, alongside study protocol, study documents (i.e., topic guides, PIS, consent form), sponsor indemnity insurance, investigator and supervisor CVs, and funding documentation. The application for this study was submitted on 21st July 2017 and was deemed valid to be reviewed by the London-Brent NHS REC on 21st August 2017. As this study involves implementing a new intervention, it was required that the PhD student attend this meeting to discuss the study with the committee.

The application was reviewed by the HRA on 11th August 2017 and appendix 34 details their request for clarification. The HRA highlighted that due to the use of patient data without informed consent and the possibility of incidental exposure to identifiable patient data by
the PhD student during SystmONE prompt development, an application to the Confidentiality Advisory Group (CAG) should be submitted. To submit an application to CAG a separate form on IRAS should be completed along with CAG specific documentation – data protection registration, data flow diagram, and a written recommendation from the Caldicott Guardian. This application detailed the data to be used, how it will be used, how it will be accessed, and measures to limit incidental exposure. This application was submitted on 29th September 2017, following the receipt of provisional opinion and a request for further information provided by the NHS REC on 30th August 2017 (Appendix 35). The study protocol and additional documents were amended according to NHS REC and HRA requirements resulting in favourable opinion being granted by the NHS REC on 3rd November 2017 (Appendix 36).

In addition to a submission, CAG required that an Information Governance (IG) Toolkit be completed and assessed by both the practice and NHS Digital before CAG approval being given. Unfortunately, the IG toolkit for the practice had not been reviewed by NHS Digital, which delayed the granting of CAG favourable opinion. A letter of CAG favourable opinion was provided on 8th December 2017 (Appendix 37). Finally, once NHS REC and CAG favourable opinion were granted, the HRA approved the study to commence on 11th December 2017 (Appendix 38). As part of this approval process, the study was registered on the ISRCTN database (ISRCTN44530504). The study was also approved by the Institute for Health Research, University of Bedfordshire Research Ethics Committee on 20th November (IHREC800) (Appendix 39).
Based on the development of the SystmONE prompt and questionnaire, two non-substantial amendments were submitted to the HRA for approval to conduct the study. Amendment one was submitted on 21st February 2018, and amendment two submitted on 23rd February 2018. The amendments outlined that now the PhD student could access SystmONE changes to the prompt and questionnaire text were required to fit within the constraints of this system. Appendix 30 contains the HRA approval letters for these received on 23rd February 2018 and 1st March 2018 respectively. A third non-substantial amendment was submitted to include the collection of staff consultation data on 21st April 2018, and approval of this amendment was received on 2nd May 2018. A final non-substantial amendment was submitted on 27th June 2018 regarding the conversion of patient focus groups to an online survey, and approval was received on 2nd July 2018 (Appendix 40).

6.8 Summary

In summary, a two-stage sequential embedded experimental mixed methods approach was adopted – with stage one a single practice feasibility study and stage two a feasibility RCT proposed. This chapter outlines the methodological approach for both stages and the methods for stage one. The intervention was conducted in a single GP practice between March 2018 and September 2018, following ethical approval. The research questions were answered using a training evaluation survey, SystmONE data collection forms, monitoring forms, focus groups with staff, an online survey with staff and patients, and field notes. The next chapter will discuss the results of the single practice feasibility study. Following this, the intervention will be refined in chapter eight and the challenges which led to the eventual abandonment of stage two outlined.
Chapter 7: Single Practice Feasibility Study – Results

The following chapter describes the results of the single practice feasibility study. This study fulfils part of objective two - refinement of the intervention, and objective three - to test the intervention for feasibility and acceptability. This chapter also aims to answer the research questions described in the previous chapter (section 6.3) and throughout these are used as headings.

7.1 Staff Training Results

7.1.1 Can staff within the GP practice be recruited to carry out the intervention?

Twenty-four staff attended the training in total equating to nine administrative or reception staff, two managerial office staff, six GPs, two practice nurses, one pharmacist, two nurse practitioners, and two healthcare assistants. Eighteen staff attended on 14th March 2018 and six attended on 20th March 2018. One healthcare assistant and three GPs had to leave the training session early. The second training session was adapted to ensure the GP who had to leave early completed the theatre forum session.

The Practice Manager also spoke to staff and encouraged them to attend on 14th of March 2018, however on 20th March 2018 this did not occur as they were not at the practice. Barriers to staff not attending the training were found to be clinics overlapping with the training period, or the training occurred on staff member’s days off.
7.1.2 Can staff training be run per-protocol?

Session one (14\textsuperscript{th} March) was delivered as planned and adhered to the time frames specified. Session two (20\textsuperscript{th} March) did not run as planned. A GP could only attend for 30 minutes due to a clinic starting at 1 pm. As a team, we felt it important that this GP receive the theatre forum section of the training above the section on NHSBT marketing. These sections of training were switched, with marketing and intervention background moved to the end of the session and the theatre forum section moved in place of the marketing. This allowed the staff member to receive training on prompted choice.

7.1.3 How feasible and suitable is the training survey as a data collection tool?

Fifteen out of the twenty-four staff who attended the training completed the training evaluation survey. Four doctors, two healthcare assistants, and three administrative, reception or managerial staff did not complete the survey. Five participants did not provide any comments on training strengths, nine participants provided no comments on training weaknesses, and twelve participants provided no comments on recommendations.

7.1.4 How acceptable and feasible is the training to staff?

Staff responses to the training evaluation survey showed agreement or satisfaction with the majority of questions, indicating overall, it was feasible and acceptable to attend (Table 24). Administrative staff with clinical training showed the most overall favourable responses, followed by administrative staff with no clinical training, then doctors and nurses equally then other clinical staff (Q1). All staff groups, except other clinical staff, scored highly that the training was worth attending (Q2) and that the time taken to attend the training was
acceptable (Q3). Other clinical staff and nurses felt less prepared than doctors and administrative staff to conduct conversations and answer questions from patients concerning organ donation (Q4 & Q5). Other clinical staff found training to be both more complex (Q6) and more basic (Q7) than other staff groups, with doctors finding the training to be more complex than nurses and administrative staff. All staff groups, except other clinical staff, felt the training increased their knowledge of organ donation (Q8). After other clinical staff, doctor confidence appeared to be the least improved after training to conduct conversations with patients, followed by nurses (Q9). All staff groups scored similarly highly that they were satisfied with the training venue, presentation styles and resources provided (Q10-Q13).

Table 24: Mean scores for the quantitative training evaluation survey questions.

<table>
<thead>
<tr>
<th>Staff Group</th>
<th>All Staff (N=15)</th>
<th>Doctor (N=2)</th>
<th>Nurse (N=4)</th>
<th>Clinical – Other (N=1)</th>
<th>Admin – with clinical training (N=3)</th>
<th>Admin – with no clinical training (N=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1*</td>
<td>Overall the training successfully prepared me to implement the organ donation intervention.</td>
<td>8.73</td>
<td>8.50</td>
<td>8.50</td>
<td>7.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q2*</td>
<td>The training was worth attending.</td>
<td>9.53</td>
<td>9.50</td>
<td>9.75</td>
<td>7.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q3*</td>
<td>The time taken to attend this training was acceptable.</td>
<td>9.40</td>
<td>9.50</td>
<td>9.00</td>
<td>8.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q4*</td>
<td>The training successfully prepared me to conduct organ donation discussions with patients.</td>
<td>8.30</td>
<td>8.50</td>
<td>7.75</td>
<td>7.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q5*</td>
<td>The training successfully prepared me to answer questions about organ donation.</td>
<td>8.27</td>
<td>8.50</td>
<td>7.50</td>
<td>6.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q6*</td>
<td>The training content was too basic</td>
<td>1.80</td>
<td>2.00</td>
<td>2.00</td>
<td>6.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Q7*</td>
<td>The training content was too complex</td>
<td>1.73</td>
<td>2.50</td>
<td>1.75</td>
<td>5.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Q8*</td>
<td>The training has increased my knowledge of organ donation.</td>
<td>9.07</td>
<td>9.00</td>
<td>9.00</td>
<td>5.00</td>
<td>9.67</td>
</tr>
<tr>
<td>Q9*</td>
<td>The training has improved my confidence in conducting organ donation conversations with patients.</td>
<td>8.56</td>
<td>8.00</td>
<td>8.75</td>
<td>6.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q10^</td>
<td>Satisfaction – Venue</td>
<td>9.67</td>
<td>10.00</td>
<td>9.50</td>
<td>7.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q11^</td>
<td>Satisfaction - NHSBT Presentation Style</td>
<td>9.73</td>
<td>10.00</td>
<td>9.75</td>
<td>7.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q12^</td>
<td>Satisfaction - PhD Student Presentation Style</td>
<td>9.80</td>
<td>10.00</td>
<td>9.75</td>
<td>8.00</td>
<td>10.00</td>
</tr>
<tr>
<td>Q13^</td>
<td>Satisfaction - Slides &amp; Resources</td>
<td>9.73</td>
<td>10.00</td>
<td>9.75</td>
<td>7.00</td>
<td>10.00</td>
</tr>
</tbody>
</table>

* 1=Disagree – 10 = Agree  *1= Unsatisfied 10= Satisfied
Ten participants provided responses concerning strengths of the training, which were the normalization of organ donation, the information provided especially statistics, the length, and the discussion and role-play session (Table 25). Only one staff member provided a weakness of the training. Finally, three staff provided recommendations to include more ‘stories’, that they would need to familiarize themselves with the computer-based data collection elements, and to record the sessions. This latter recommendation was provided as an answer to the question concerning training strengths.

**Table 25: Qualitative responses from training evaluation survey.**

<table>
<thead>
<tr>
<th>Question</th>
<th>Comments</th>
<th>Staff Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengths of the training</td>
<td>“It is done in a tone that “normalises” for us a difficult conversation. I feel as if I have been given “permission”!”</td>
<td>Clinical – Doctor</td>
</tr>
<tr>
<td></td>
<td>“Record the session and excellent information”</td>
<td>Clinical – Doctor</td>
</tr>
<tr>
<td></td>
<td>“Good all round discussion concerning organ donation”</td>
<td>Clinical – Nurse</td>
</tr>
<tr>
<td></td>
<td>“Interesting, good length of training, clear comprehensive training”</td>
<td>Clinical - Nurse</td>
</tr>
<tr>
<td></td>
<td>“Focused and outlined all relevant information. All speakers able to answer queries and give further information when asked.”</td>
<td>Clinical - Nurse</td>
</tr>
<tr>
<td></td>
<td>“Extremely interesting, useful”</td>
<td>Administrative – with clinical training</td>
</tr>
<tr>
<td></td>
<td>“Very informative, interesting, eye opening on some of the statistics.”</td>
<td>Administrative – with no clinical training</td>
</tr>
<tr>
<td></td>
<td>“Very informative and interesting well prepared training session”</td>
<td>Administrative – with no clinical training</td>
</tr>
<tr>
<td></td>
<td>“Enjoyed the role play. I am an administrator so I will not be able to implement.”</td>
<td>Administrative – with no clinical training</td>
</tr>
<tr>
<td></td>
<td>“Informative, positive”</td>
<td>Administrative – with no clinical training</td>
</tr>
<tr>
<td>Weaknesses of the training</td>
<td>“Experience will tell the weaknesses”</td>
<td>Clinical - Nurse</td>
</tr>
<tr>
<td>Recommendations</td>
<td>“More stories may be useful”</td>
<td>Clinical – Doctor</td>
</tr>
<tr>
<td></td>
<td>“Nothing to add - all informative”</td>
<td>Clinical - Nurse</td>
</tr>
<tr>
<td></td>
<td>“Will need to look at template in further detail to familiarise myself before I feel confident to have conversation with patients.”</td>
<td>Clinical - Nurse</td>
</tr>
</tbody>
</table>
7.2 Prompted Choice Results

7.2.1 What are the staff adherence rates and engagement with the intervention?

Twelve clinical staff attended the training and received the prompt. In total, 10,144 consultations were had during three months, 6,569 of these were face to face (64.8%), and 3,575 were telephone consultations (34.2%). In 8.0% of both face to face and telephone consultations (N10144) staff recorded that prompted choice was conducted through the Prompted Choice Questionnaires (N812). For only face to face consultations, prompted choice was conducted 12.4% of the time; doctors 46 times (1.6% fidelity rate), nurses 471 times (23.4% fidelity rate) and healthcare assistants 295 times (17.1% fidelity rate). Four Doctors, two healthcare assistants and four nurses completed prompted choice on at least one occasion. Two doctors completed zero questionnaires. One doctor only completed the prompted choice for the first month due to sabbatical leave. In total staff recorded that patients were asked on 812 occasions.

The Feasibility Questionnaire (or patient not asked option on a Prompted Choice Questionnaire) was completed 2,906 times (28.64% of all consultations). Five doctors, four nurses and two healthcare assistants completed a Feasibility Questionnaire. The Practice Manager who also undertakes clinical activities completed two Feasibility Questionnaires also. On 56 occasions, the Prompted Choice Questionnaire was completed to record patient not asked. On 1,690 face to face consultations a Feasibility Questionnaire was completed (25.72%). Telephone consultations prevented prompted choice was being conducted 1051 times (36.2% of Feasibility Questionnaires). Of the 56 times, the patient was not asked using
the Prompted Choice Questionnaire 54 (96.4%) were due to a lack of time. Tables 26 & 27 display a summary of the reasons given for not conducting prompted choice.

Table 26: Reasons why prompted choice was not carried out, as recorded on SystmONE.

<table>
<thead>
<tr>
<th>Response</th>
<th>Frequency</th>
<th>Per cent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of time</td>
<td>943</td>
<td>34</td>
</tr>
<tr>
<td>Lack of time &amp; Other</td>
<td>41</td>
<td>1.5</td>
</tr>
<tr>
<td>Not appropriate for consultation</td>
<td>520</td>
<td>18.8</td>
</tr>
<tr>
<td>Other</td>
<td>1268</td>
<td>45.7</td>
</tr>
<tr>
<td>Total</td>
<td>2772</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 27: ‘Other’ reasons why prompted choice was not carried out, as recorded on SystmONE.

<table>
<thead>
<tr>
<th>Response</th>
<th>Frequency</th>
<th>Per cent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative</td>
<td>163</td>
<td>12.7</td>
</tr>
<tr>
<td>Data Entry Error</td>
<td>7</td>
<td>0.5</td>
</tr>
<tr>
<td>Home Visit</td>
<td>2</td>
<td>0.2</td>
</tr>
<tr>
<td>Lack of capacity</td>
<td>2</td>
<td>0.2</td>
</tr>
<tr>
<td>Language Barrier</td>
<td>43</td>
<td>3.4</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>0.4</td>
</tr>
<tr>
<td>Telephone Consultation</td>
<td>1051</td>
<td>82.1</td>
</tr>
<tr>
<td>Over eligible age limit</td>
<td>7</td>
<td>0.5</td>
</tr>
<tr>
<td>Total</td>
<td>1280</td>
<td>100</td>
</tr>
</tbody>
</table>

7.2.2 How feasible and suitable are the prompted choice data collection tools?

On eight occasions, the Prompted Choice Questionnaire was selected, but no data was entered. Ethnic category was not recorded for 147 patients. Of those with an ethnic category recorded, 171 of these were recorded as ethnicity not stated. In total, 318 patients had ethnicity recorded as missing. One patient had missing gender, one missing patient age, two patients did not have an eligibility question completed, and four did not have capacity to consent. On 134 occasions the Feasibility Questionnaire was selected by staff but no response selected. For 58 patients, a Prompted Choice Questionnaire was completed on
more than one occasion incorrectly. On four occasions, patients who should not be asked again, were asked again. On three occasions, the patient responded that yes they would like to join the NHS ODR, were incorrectly asked a second time and responded Yes again. Before subsequent analysis, two duplicate ‘Yes' responses were removed from the data set.

7.2.3 Does the intervention show promise in increasing sign-up rates to the NHS ODR and who does the intervention target?

Of 812 patients, 244 joined the NHS ODR (30.0%), and 112 patients believed they were already on the register (13.8%). Of those who said yes, 216 registered to donate all their organs and 28 selected organs. Of those who believed they were already registered, 97 (86.6%) wished to re-register all organs and tissues, and 11 (9.8%) wished to re-register selected organs. In total, 352 patients requested to be registered as organ donors for either the first or second time on the NHS ODR as a result of this trial (43.3%). On 327 occasions, patients were unsure (40.2%) and 129 occasions ‘Do not ask again’ was selected (15.8%). For doctors’, patients stated that they would join the NHS ODR 39.1% of the time, Nurses 27.3% of the time and healthcare assistants 33.4% of the time (Table 28).

Table 28: Patient responses to prompted choice by staff group, as recorded on SystmONE.

<table>
<thead>
<tr>
<th>Patient Preference</th>
<th>Doctor</th>
<th>Nurse</th>
<th>Healthcare assistant</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes – Any</td>
<td>15</td>
<td>112</td>
<td>89</td>
<td>216</td>
</tr>
<tr>
<td>Yes – Selected</td>
<td>3</td>
<td>16</td>
<td>9</td>
<td>28</td>
</tr>
<tr>
<td>Believes already on register</td>
<td>9</td>
<td>66</td>
<td>37</td>
<td>112</td>
</tr>
<tr>
<td>Unsere</td>
<td>19</td>
<td>204</td>
<td>104</td>
<td>327</td>
</tr>
<tr>
<td>Do not ask again</td>
<td>0</td>
<td>73</td>
<td>56</td>
<td>129</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>46</strong></td>
<td><strong>472</strong></td>
<td><strong>296</strong></td>
<td><strong>870</strong></td>
</tr>
</tbody>
</table>
In total 187 BAME patients were asked, 39 said yes to joining the NHS ODR, 18 believe they were already on the register, 94 were unsure, 36 should not be asked again (Table 29).

Table 29: Cross-tabulation displaying ethnicity and patient preferences about joining the NHS ODR – as recorded on SystmONE.

<table>
<thead>
<tr>
<th>Patient Preference</th>
<th>BAME</th>
<th>Non-BAME</th>
<th>Not Stated</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes – Any</td>
<td>38</td>
<td>103</td>
<td>75</td>
<td>179</td>
</tr>
<tr>
<td>Yes – Selected</td>
<td>1</td>
<td>13</td>
<td>14</td>
<td>20</td>
</tr>
<tr>
<td>Believes already on register</td>
<td>18</td>
<td>53</td>
<td>41</td>
<td>91</td>
</tr>
<tr>
<td>Unsure</td>
<td>94</td>
<td>113</td>
<td>120</td>
<td>284</td>
</tr>
<tr>
<td>Do not ask again</td>
<td>36</td>
<td>44</td>
<td>49</td>
<td>99</td>
</tr>
<tr>
<td>Total</td>
<td>187</td>
<td>326</td>
<td>299</td>
<td>812</td>
</tr>
</tbody>
</table>

Of those asked, 135 female patients said yes - all organs and 81 male patients said yes – all organs. Of those who said yes-selected organs, 20 were female, and eight were male, 72 female patients believed they were already on the register and 39 male patients, and 214 female patients and 113 male patients were unsure. Finally, 72 female patients and 57 male patients were specified not to be asked again (Table 30).

Table 30: Cross-tabulation displaying gender and patient preferences about joining the NHS ODR – as recorded on SystmONE.

<table>
<thead>
<tr>
<th>Patient Preference</th>
<th>Female</th>
<th>Male</th>
<th>Missing</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes – Any</td>
<td>135</td>
<td>81</td>
<td>0</td>
<td>218</td>
</tr>
<tr>
<td>Yes – Selected</td>
<td>20</td>
<td>8</td>
<td>0</td>
<td>28</td>
</tr>
<tr>
<td>Believes already on register</td>
<td>72</td>
<td>39</td>
<td>1</td>
<td>112</td>
</tr>
<tr>
<td>Unsure</td>
<td>214</td>
<td>113</td>
<td>0</td>
<td>327</td>
</tr>
<tr>
<td>Do not ask again</td>
<td>72</td>
<td>57</td>
<td>0</td>
<td>129</td>
</tr>
<tr>
<td>Total</td>
<td>513</td>
<td>298</td>
<td>1</td>
<td>812</td>
</tr>
</tbody>
</table>

The mean age of participants for whom a Prompted Choice Questionnaire was completed was 50.2 years (SD = 17.62, Min-Max = 18 - 91, Median = 50, Mode = 67). The age group with the highest number of patients who said Yes was 51-60 (Table 31).
Table 31: Cross-tabulation displaying patient registration preferences for the age groups used by NHS Blood and Transplant – as recorded on SystmONE

<table>
<thead>
<tr>
<th>Patient Preference</th>
<th>Age Groups NHSBT 18-20</th>
<th>21-30</th>
<th>31-40</th>
<th>41-50</th>
<th>51-60</th>
<th>61-70</th>
<th>71+</th>
<th>Missing</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes - Any</strong></td>
<td>1</td>
<td>34</td>
<td>35</td>
<td>33</td>
<td>45</td>
<td>42</td>
<td>28</td>
<td>0</td>
<td>216</td>
</tr>
<tr>
<td><strong>Yes - Selected</strong></td>
<td>1</td>
<td>6</td>
<td>4</td>
<td>7</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>28</td>
</tr>
<tr>
<td><strong>Believes already on register</strong></td>
<td>2</td>
<td>21</td>
<td>24</td>
<td>15</td>
<td>22</td>
<td>16</td>
<td>11</td>
<td>1</td>
<td>112</td>
</tr>
<tr>
<td><strong>Unsure</strong></td>
<td>5</td>
<td>53</td>
<td>53</td>
<td>53</td>
<td>57</td>
<td>50</td>
<td>56</td>
<td>0</td>
<td>327</td>
</tr>
<tr>
<td><strong>Do not ask again</strong></td>
<td>2</td>
<td>17</td>
<td>23</td>
<td>24</td>
<td>17</td>
<td>22</td>
<td>24</td>
<td>0</td>
<td>129</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>11</td>
<td>131</td>
<td>139</td>
<td>132</td>
<td>145</td>
<td>132</td>
<td>122</td>
<td>1</td>
<td>812</td>
</tr>
</tbody>
</table>

7.3 Monitoring & Implementation Results

7.3.1 Can monitoring be run per-protocol?

On two occasions, monitoring of the intervention was not conducted, week beginning 25th June 2018 due to PhD student illness and week beginning 2nd July due to PhD student annual leave (Table 32).

Table 32: Monitoring visit details throughout the three month prompted choice period.

<table>
<thead>
<tr>
<th>Visit No.</th>
<th>Visit Date</th>
<th>Day</th>
<th>Visit time</th>
<th>Visit duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12th April 2018</td>
<td>Thursday</td>
<td>12:55pm - 3:15pm</td>
<td>2 hours 20 mins</td>
</tr>
<tr>
<td>2</td>
<td>19th April 2018</td>
<td>Thursday</td>
<td>11:45am - 3:00pm</td>
<td>3 hours 15 minutes</td>
</tr>
<tr>
<td>3</td>
<td>26th April 2018</td>
<td>Thursday</td>
<td>1pm - 3pm</td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>HRA Approval for staff appointment counts</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>3rd May 2018</td>
<td>Thursday</td>
<td>11am - 12:30pm</td>
<td>1 hour 30 mins</td>
</tr>
<tr>
<td>5</td>
<td>9th May 2018</td>
<td>Wednesday</td>
<td>12:00pm - 14:51pm</td>
<td>2 hours 50 minutes</td>
</tr>
<tr>
<td>6</td>
<td>18th May 2018</td>
<td>Friday</td>
<td>1:45pm - 3:20pm</td>
<td>1 hour 35 mins</td>
</tr>
<tr>
<td>7</td>
<td>24th May 2018</td>
<td>Thursday</td>
<td>12:15 - 1:15pm</td>
<td>1 hour</td>
</tr>
<tr>
<td>8</td>
<td>29th May 2018</td>
<td>Tuesday</td>
<td>1:20pm - 2pm</td>
<td>40 minutes</td>
</tr>
<tr>
<td>9</td>
<td>7th June 2018</td>
<td>Thursday</td>
<td>2:30pm - 3:10pm</td>
<td>40 minutes</td>
</tr>
<tr>
<td>10</td>
<td>13th June 2018</td>
<td>Wednesday</td>
<td>3:15pm - 4:15pm</td>
<td>1 hour</td>
</tr>
<tr>
<td>11</td>
<td>22nd June 2018</td>
<td>Friday</td>
<td>9:45am - 11:15am</td>
<td>1 hour 30 mins</td>
</tr>
<tr>
<td>12</td>
<td>Illness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Annual Leave</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
During the first four visits, staff discussed the intervention with the monitor. After visit 5, staff did not have any comments for the monitor when asked. Comments for visit 1 included that it was challenging for staff to ask the questions during telephone consultations and that staff did not know how to report this. Staff were selecting ‘not appropriate for consultation’ in this instance. An email was sent to participating staff that they should select ‘other’ and in the free text box use the initials TC following this finding. Monitor comments included that some staff members are completing the ‘No’ questionnaire incorrectly for patients who are saying no to signing up on the register. When examining the data, this only occurred on day 1 of the intervention and by one staff member, whom the practice nurse assisted in using SystmONE. This nurse telephoned the PhD student to clarify the issue with the ‘yes’ ‘no’ questionnaire on the second day of the intervention. Additionally, some patients were repeatedly asked when the prompt should have turned off, and a reminder email was sent to staff by the Practice Manager to clarify this.

Comments for visit 2 were from the Lead GP who stated that some staff would like refresher training to help clarify prompted choice now they were conducting it. No comments were listed for visit three except that the Practice Manager and office manager were unavailable – however the intervention was discussed with other staff with no issues raised. Comments for visit 4 were from the practice nurse who called on day 1. She requested that she needed more of the general information leaflets rather than the religious specific leaflets. It was explained that no more of these were available from NHSBT but to direct patients to the NHSBT website concerning organ donation instead. Comments for visit five state that leaflets were no longer being counted and only restocked due to the low numbers being
taken. The final comments from monitoring were captured on the last visit that the majority of the Prompted Choice Questionnaires were being completed by two staff members, a practice nurse and healthcare assistant.

7.3.2  What monitoring resources are required to run the studies and intervention?

Intervention set-up took 1 hour 45 minutes on 5th April 2018, the prompt and questionnaires were tested with two test patients at 7:45 am before being made live at 8 am. Following this, leaflets and posters were placed in the practice. The practice chose the location of these before the setup day. These were displayed before the practice doors opened for patients. Monitoring visits took a maximum of 3 hours, 15 minutes and a minimum of 40 minutes (Table 3). From week four staff consultations were counted and, intervention close was conducted on Monday 9th July for 2 hours. The prompt was switched off, posters and leaflets were removed before 8 am, SystmONE data was then exported in full, and the last staff consultations counted manually. Discussion was also had with the Practice Manager concerning the best provisional dates for focus groups.

7.3.3  How many leaflets and posters are required to run the studies and intervention?

Leaflets and posters were kept in place throughout the intervention period. For the first four weeks, leaflets on display were counted to examine how many were taken (Appendix 41). After visit four due to the low number of leaflets being removed and the length of time it took to count these during visits, it was decided that leaflets would only be restocked
when numbers appeared noticeably low. The most leaflets taken were those regarding Hindu religious perspectives written in English, followed by the questions answered leaflets and Islam written in English (Table 33). The questions answered leaflets were all removed by visit 4. The fourth highest leaflet taken were the Christianity leaflets written in Polish. Other leaflets taken in very small numbers in other languages were Hinduism in Tamil, Islam in Punjabi and Arabic. In total, 100 leaflets were taken over the three months.

Table 33: Leaflets displayed and taken during the three month prompted choice period.

<table>
<thead>
<tr>
<th>Name</th>
<th>Language</th>
<th>Total displayed</th>
<th>Total number taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hinduism</td>
<td>English</td>
<td>50</td>
<td>23</td>
</tr>
<tr>
<td>Questions Answered</td>
<td>English</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Islam</td>
<td>English</td>
<td>50</td>
<td>17</td>
</tr>
<tr>
<td>Christianity</td>
<td>Polish</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Religious perspectives</td>
<td>English</td>
<td>50</td>
<td>13</td>
</tr>
<tr>
<td>Judaism</td>
<td>English</td>
<td>50</td>
<td>3</td>
</tr>
<tr>
<td>Hinduism</td>
<td>Tamil</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Christianity</td>
<td>English</td>
<td>50</td>
<td>2</td>
</tr>
<tr>
<td>Islam</td>
<td>Punjabi</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Buddhism</td>
<td>English</td>
<td>50</td>
<td>1</td>
</tr>
<tr>
<td>Islam</td>
<td>Arabic</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Sikhism</td>
<td>English</td>
<td>50</td>
<td>0</td>
</tr>
<tr>
<td>Hinduism</td>
<td>Hindi</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Hinduism</td>
<td>Punjabi</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Islam</td>
<td>Somali</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Islam</td>
<td>Bengali</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Islam</td>
<td>Gujarati</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Islam</td>
<td>Urdu</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Sikhism</td>
<td>Punjabi</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

7.3.4 What practice resources are required to run the studies and intervention?

To set up the intervention, once the SystmONE prompt and questionnaire had been created, several steps had to take place. Access to SystmONE had to be provided to the PhD student as well as access to a computer to implement the prompt and questionnaire post-
training session. Practice manager and office manager time was required to grant access to these, as well as to organise appropriate dates for training sessions which most staff would be able to attend and for the start of prompted-choice. Practice resources were used to develop the SystmONE prompt and intervention, for example, computer and Practice Manager time for discussion and meetings. However this is a one-off and will not be applicable going forward. Finally, Lead GP and Practice Manager time was required for reading and signing off on ethical documentation before study start and during the intervention for any amendments to the study.

Practice resources required for the training sessions were to provide a room with computer and projector which could host the training, as well as Microsoft PowerPoint. An hour of staff members time was required for the training session as well as staff effort during this session to complete the training evaluation survey. This latter part, however, is study-specific rather than an intervention resource. Study resources included lunch for staff and presenters, example leaflets, training slides, training manual and three people to run the training session (PhD student, SNOD and Representative from NHSBT).

Resources required for prompted choice are staff time to familiarize themselves with the prompt and questionnaires, time within consultations to ask the patient if they would like to join the NHS ODR and staff time to complete the questionnaire accordingly. Concerning leaflets and posters, a table to display leaflets, a location to place the lockable box for any completed forms and noticeboards for posters in both patient and staff areas.
Monitoring resources required are access to weekly computer at the practice for an average of 1 hour and 40 minutes, as well as discussing the intervention with the monitor briefly. Additionally, Practice Manager time was taken up with arranging suitable dates for monitoring visits to occur. Data collection resources required from the practice are access to the computer and SystmONE at close, staff time to partake in focus groups and online surveys and space in the practice to conduct these focus groups. Also required is administrator time to send patient online survey text messages to all patients who received prompted choice.

7.3.5 What technological resources are required to run the studies and intervention?

The main technological elements required are computer-based. As described previously, access to SystmONE is required on a computer in the practice. To gain access to this a chip card issued by the NHS has to be requested then practice staff can grant investigator access to the system. An encrypted USB stick is required for setting up the SystmONE prompt and questionnaire, and also for exporting anonymised SystmONE data. Excel is also required for exporting this data. To integrate this data two separate reports are required to be pulled off SystmONE, these can then be anonymised and merged according to questionnaire ID number – a unique identifier for questionnaire completion which does not contain any patient identifiable data. Also required is a computer with projection facilities at the practice for the training sessions.
7.3.6 What expertise is required to run the studies and intervention?

The expertise required to run the intervention will be separated into two elements; training and computing. The expertise required to run the training session is a SNOD nurse who can conduct Q&A with staff concerning their job and organ donation questions, as well as conducting the theatre forum element to demonstrate how staff may ask patients to join the NHS ODR. Additional expertise is required from a member of the training team who can comfortably present the statistics, facts and figures concerning organ donation, as well as the marketing elements. The final element of expertise required for training is the PhD student to demonstrate the SystmONE processes and data collection processes. Computing expertise is the other element required, particularly SystmONE expertise. The ability to not only use SystmONE but to understand protocols, questionnaire design and export, and exporting reports of demographic factors is vital to set-up, monitoring and close of the intervention. Expertise in Excel is also vital as data needs to be anonymised and two separate excel spreadsheets merged.

7.4 Focus Groups & Staff Online Survey Results

7.4.1 How feasible and suitable are staff focus groups and online survey as data collection tools?

In total, 11 staff members attended focus groups, and 7 of those were clinical staff who conducted the intervention. Table 33 shows the occasions where focus groups were arranged with the Practice Manager, food incentives brought, emails sent out at least one week prior and a reminder email sent out the morning of the focus group by the Practice
Manager. The Practice Manager ensured that all staff who attended the training would be available at least one of the sessions listed in Table 34 during their lunch break.

Table 34: Focus group session details.

<table>
<thead>
<tr>
<th>Date (2018) and Time</th>
<th>Staff Member Category</th>
<th>Number of attendees</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday 16th July – 12:00</td>
<td>Doctors</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Tuesday 17th July – 12:00</td>
<td>Nurses and Healthcare Assistants</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Tuesday 17th July – 14:00</td>
<td>Nurses and Healthcare Assistants</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Thursday 26th July – 12:30</td>
<td>Nurses and Healthcare Assistants</td>
<td>5</td>
<td>39 mins</td>
</tr>
<tr>
<td>Friday 27th July – 12:00</td>
<td>Doctors</td>
<td>1</td>
<td>11 mins</td>
</tr>
<tr>
<td>Tuesday 7th August – 12:00</td>
<td>Administrative and Receptionists</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Tuesday 7th August – 13:00</td>
<td>Administrative and Receptionists</td>
<td>4</td>
<td>13 mins</td>
</tr>
<tr>
<td>Thursday 9th August – 12:00</td>
<td>Doctors</td>
<td>1 (1 GP participating in intervention, one trainee GP shadowing participating GP)</td>
<td>20 mins</td>
</tr>
<tr>
<td>Thursday 9th August – 13:00</td>
<td>Doctors</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

The researcher was present in the practice on nine occasions, and on only four occasions, did staff attend to conduct the focus group. In all but the nurses and healthcare assistant focus group, these discussions were very brief due to staff lack of time, and they required to leave early. The subsequent analysis will be conducted with caution, due to this, as it was anticipated, focus groups would be run for one hour and would include more staff. The online staff survey was sent to eligible staff by the Practice Manager after the focus groups had been conducted on 9th August 2018. One response was received to the online survey on this day, and a reminder was sent by the Practice Manager on 14th August 2018 5 days later. Only two additional response was received, making a total of three responses to the staff online survey.
7.4.2 How acceptable and feasible is the intervention to staff?

7.4.2.1.1 External context

Fewest discussions had in the data concerned the impact of the intervention and the external context. Five themes were found regarding external context – Normality of organ donation discussion, Driver and Vehicle Licensing Agency (DVLA) registration, Media exposure, External pressures on general practice and opt-out. There seemed to be an acceptance that organ donation is not a ‘normal’ thing to discuss, and that discussion potentially can make people uncomfortable.

“Well normally it’s a no no, you don’t talk about things like that do you”
(Focus Group – Administrative and Reception)

Registration opportunities given when applying or renewing a driving license also appear to be a dominant theme and could be a source of public awareness.

“...they were just doing it when they did their driving license. That seems to be the way most people, put themselves on the register, from what I got”
(Focus Group – Nurses and Healthcare Assistants)

As well as awareness through driving license registration, media coverage that was released during the intervention period was discussed by staff.

“It’s on actually advertised on the radio that um, to discuss this, because we discuss everything with the family, have a discussion with your family about the organ”
(Focus Group – GP)
“this program was all about the heart, because the heart there’s something like 70% of people can’t donate their heart because it’s already too damaged, but there is a machine that you can put the heart into and it keeps it alive."

(Focus Group – Nurses and Healthcare Assistants)

There was also some discussion of GP practices generally and how well placed they are to conduct this intervention. Although some staff were positive that general practice could conduct an intervention with their skillset, other practical issues could prevent the intervention being successful, namely lack of staff.

“In the general world of general practice, we’ve got the knowledge and the expertise, and especially with a little bit of training I think that’s fine.”

(Focus Group – GP)

There was only one mention of the ‘opt-out' system of organ donation; this was by a GP who when asked about improvements to the intervention suggested an opt-out system.

“But probably if we had a system where we opt-out…from you know like..in spain.”

(Focus Group – GP)

7.4.2.1.2 Organisation Context

Several themes were apparent about the organisation context: telephone consultations, days of the week when prompted choice was easier, translation services available, the inclusivity of the training, practice culture of collaboration and prioritising patient care, the societal good of the intervention and the type of clinics they offer. Telephone consultations are commonplace in this practice and staff discussed that they could not ask during these consultations.
“But when you’re doing telephone consultations you can’t do it and that’s a huge chunk of our of our day” (Focus Group – GP)

A GP also stated they asked most patients on a Saturday due to the issues they presented with.

“…then people come in, probably because it’s a Saturday, they have very quick problems to deal with, so then you’re left with time, to make, to have that discussion” (Focus Group – GP)

One nurse stated that the translation services they use are challenging to use generally without having to introduce the topic of organ donation.

“Sometimes it can be difficult even just in a normal consultation.. really. With the translator, sorry, services and that sort of thing....” (Focus Group – Nurses and Healthcare Assistants)

Administrative and receptionist staff were not typically included in more clinical types of training. When discussing their inclusion in training, one staff member stated that their inclusion was positive.

“I thought it was a positive way of reinforcing that there is such a thing available and it is open to everybody... I just though it gave me a little bit more of a boost” (Focus Group – Administrative and Reception Staff)

There was a clear demonstration of a positive culture of intra-staff support throughout the practice. One GP mentioned that they sought help from a nurse champion and administrative and reception staff discussed the intervention with their GPs to be able to give feedback on it.
“one of our nurses was heavily involved in this and was really keen to participate, she had excellent ways of, of bringing up subjects and explaining things and she was my go to person, how did you say that when they asked you this, and that was very helpful”

(Focus Group – GP)

“I have discussed it anecdotally with doctors and clinicians to ask them how it was going, and have you asked any people…”

(Focus Group – Administrative and Reception Staff)

To one GP, the patient-doctor relationship was explicitly mentioned as a concern, mainly that it may be tarnished by asking the patient to join the NHS ODR.

“… because you know I don’t want to patient doctor relationship to be….tarnished you know, awkward…”

(Focus Group – GP)

Further examples of this strong prioritisation of patient care in the practice is that a GP stated that they often finished clinics half an hour late usually and that consultations are patient dependent.

“it’s just a matter of fitting it all in, because, my consultations I always end up finishing a clinic at least 30 minutes late, so if I were to add a minute to each consultation that would be another half an hour”

(Focus Group – GP)

Staff also discussed the societal good of the intervention to patients on the transplant list, which demonstrates a positive philosophy of patient care, extending to patients outside of their practice as well as those they see personally.

“it depends and, a lot on the patients themselves as well, but.. very few of the problems that we see on a daily basis are attending in a consultation, usually it takes a bit longer, so we do have to catch up..”

(Focus Group – GP)
“I found it very interesting study to conduct actually, and beneficial for the service and for patients as well.”
(Focus Group – Nurses and Healthcare Assistants)

“you know, for those people, the impact of people waiting and waiting and waiting, their whole lives revolving around a telephone call is so, is so hard and stressful and and stuff...then when you hear so many people ‘oh yeah I think it’s a good idea but I’ve never got round to it’ they might be one of those people that could donate…”
(Focus Group – Nurses and Healthcare Assistants)

“I still think general practice would probably be the best place for these things to happen and it’s a real shame, if we cannot do this”
(Focus Group – GP)

The final element of the organisation context was the skill mix of staff in the practice. This was mentioned and discussed numerous times in the nurse and healthcare assistant focus group. Different staff conducted different types of consultation in the practice; some of these facilitated conducting prompted choice more than others.

“your whole thing is different isn’t it, you’ve got to listen to the patient, you’ve got to examine the patient, you’ve got to figure out what’s wrong, you’ve then got to you know prescribe, do the prescribe then give the advice, so that’s completely different to a practice nurse session.. or maybe even your phlebotomy session, and you know what you’re doing”
(Focus Group – Nurses and Healthcare Assistants)

7.4.2.1.3 Professional Context

At the professional contextual level, the following themes were found: the wide variety in attitudes to change between staff members, that the training improved staff competence and how prompted choice fits within each different professional role. There was a distinct difference in attitudes to change regarding implementing prompted choice. Within the
nurse and healthcare assistant group, two staff members reported asking nearly all or many patients; these staff members were favourable to prompted choice.

“But it’s alright... got quite good feedback from them, you know, no one was rude or nothing. I did upset one person once but then, we resolved that afterwards you know. But then that was it... it was alright”.

(Focus Group – Nurses and Healthcare Assistants)

Two staff members were less favourable, one suggesting it is not appropriate but not giving a reason, and one was stating that they found a way to access patient notes without triggering the prompt because it was annoying.

“I always, always I run a little bit behind anyway when I’m doing minor illness, so, so it just sort of like got a bit annoying if I’m being honest”

(Focus Group – Nurses and Healthcare Assistants)

“But do you know what I used to do, I used to go on to... erm, not consultation view... content...view records, and it never used to bring that screen up *laughs* sorry”

(Focus Group – Nurses and Healthcare Assistants)

One GP was favourable towards prompted choice stating that it is beneficial, another GP was not favourable stating they believed it should not be conducted in primary care.

“I didn’t find any problems asking the questions, because I think it is a good idea”

(Focus Group – GP)

“I don’t know if a GP consultation is the right place, mainly because of lack of time. And as I said I’m worried that the patients, might kind of get, that it put them off, worry them”

(Focus Group – GP)
Administrative and reception staff stated that the training was beneficial and influential for
them. However, one staff member believed prompted choice should not be conducted by
practice staff but by an independent person whom patients can approach if they wish.

“I think that a little stall, at reception, with somebody advertising organ donation I think, I
personally think that would be an easier way to approach it, because somebody who is
interested will approach you, rather than us approaching them, when they’re sick.”
(Focus Group – Administrative and Reception Staff)

Overall staff generally have positive attitudes to prompted choice, believing it to be a good
idea. However, their attitudes to it being conducted in GP practices and actively changing
their consultations to include it, were mixed. For some staff, the societal need for organ
donors appeared to lead to more positive attitudes to change their practice to include the
intervention.

“I would be happy to continue asking my pts if intervention was reintroduced as I feel it is a
tremendously worthwhile/beneficial process to contribute towards”
(Staff Online Survey)

However, other staff members discussed barriers; predominantly time and it not being
appropriate, which could be interpreted as more negative attitudes towards change due to
these.

“It’s a great idea but the consultation time does not allow for informed choices to be made”
(Staff Online Survey)

Training was stated to be influential in increasing staff competency and confidence in asking
patients.
“...Felt the info given in pre session gave me confidence to give relevant/factual information”  
(Staff Online Survey)

“I think following the training, I was quite confident, I think without that I wouldn’t have been, really...”  
(Focus Group – Nurses and Healthcare Assistants)

However, one staff member still was concerned that she lacked the confidence to answer potential patient questions in the nurse and healthcare assistant group.

“I think one of the barriers for me was if they started asking a lot of questions, would I be able to answer them, and I was a bit... do I know enough about this to, to be able to answer...”  
(Focus Group – Nurses and Healthcare Assistants)

Other staff within the nurse and healthcare group believed they conducted the intervention reasonably and asked many patients.

“because I asked every single patient, virtually every single patient I saw.. where I possibly could, and so I suppose when you’ve asked that many I actually knew the template and I could work through the template when the person had gone”  
(Focus Group – Nurses and Healthcare Assistants)

GPs reported feeling confident and competent to conduct the intervention; it was merely barriers which prevented them. Practice was mentioned by both GPs and nurses and healthcare assistants to be necessary.

“and particularly if you’re not doing it very often... you get quicker when you get more oh fe with doing things but if you’re not doing it that often, it it yeah it probably took me much quicker to do it”  
(Focus Group – Nurses and Healthcare Assistants)
The final element in the professional context is how staff believe the intervention fits within their professional role. Administrative and reception staff discussed that they did not experience much involvement with the intervention, and it had a low impact on their day to day activities.

“..in fact we didn’t notice an impact”  
(Focus Group – Administrative and Reception)

“I didn’t as a receptionist have a lot of involvement in it”  
(Focus Group – Administrative and Reception)

A GP believed that it is within their professional role to have discussions with patients because they have the knowledge. It was also mentioned that medical professionals have a medical view of organ donation, which was in contrast to the patients on occasion, for example, concerning eye donation.

“I think we’re probably, don’t understand that the medical an organ is an organ, so if you take a lung then taking the cornea is fine, but yes a lot of people said they didn’t want it...And when you ask them, why do you think that is, and even with the explanation they would say, it just doesn’t feel right, it just doesn’t sit right, ok”  
(Focus Group – GP)

As previously discussed another GP discussed that she was concerned about prompted choice affecting the patient-doctor relationship.

“Yeah...I think, I think I could feel that some of them were a bit uncomfortable”  
(Focus Group – GP)
The nurse and healthcare assistant focus group stated they felt that patients would get more from prompted choice intervention than from signing up via the driving license or just posters.

“Ummm...so just a quick chat and reinforce that information or um queries that they have I think is better in this environment, than say just a poster on the wall”
(Focus Group – Nurses and Healthcare Assistants)

However, as in skill mix from the organisational context, some nurses who run minor illness clinics believed that in these clinics, it was less appropriate than in other clinics, such as practice nurse of phlebotomy.

“Yeah yeah, I think, as erm..as you said, if you’re doing minor illness they come in with a problem they just wanna get on with talking to you, you know if it’s a rash they’ve got it out before they’ve even sat down”
(Focus Group – Nurses and Healthcare Assistants)

7.4.2.1.4 Intervention Context

The intervention context proved to be the largest context in this analysis. The results will be discussed in four sections – training, prompted choice, leaflets and posters and recommendations.

7.4.2.1.4.1 Training

All opinions of the training were positive, with staff enjoying the content, mainly the information concerning organ donation myths and theatre forum delivered by the SNOD. These opinions were echoed in all data collection time points.
“it was good to have the organ donation specialist there to tell of her experiences and the different approaches”
(Staff Online Survey)

“the training we had was the half a day session that was conducted...I thought that that was good”
(Focus Group – GP)

“the training session very very useful, bit of an eye opener in terms of erm definitely what ages and who they can and can’t use so that was really good.”
(Focus Group – Nurses and Healthcare Assistants)

Administrative and reception staff reported that attending the training gave them a positive boost as training of this kind is not something they would usually be involved in. The training also had an impact on staff registration behaviour with one administrative and reception staff member signing up to the register and discussing it with her family and another changing their views to include donating her eyes, which they discussed with their family also.

“Well I did go downstairs and put my name on the register ”
(Focus Group – Administrative and Reception Staff)

“I always used to say before this, I used to say my eyes, always...always I used to say that, its um, and then I said the only thing that made me change the way I think is I used to say not my eyes, but, they can have my eyes now, cos it’s not...I won’t need them you know,”
(Focus Group – Administrative and Reception Staff)

7.4.2.1.4.2 Prompted Choice

The prompted choice element was the central discussion in focus groups, and the following themes were found: lack of time, not appropriate for consultation, mostly acceptable to conduct, staff variation in when it was conducted, patient responses and the variation of these with patient demographics, and disagreement on how SystmONE should facilitate
prompted choice. Overall responses were mostly positive concerning prompted choice, and some staff described enjoying conducting it.

“The intervention itself, the subject was great, very interesting when I had the time to discuss it with patients”
(Focus Group – GP)

“I found when I had the conversation it was actually fun, because it was something we don’t do everyday and people sort of tend to have these really frank discussions about their beliefs”
(Focus Group – GP)

However, time constraints and the challenges of conducting prompted choice within time-restricted consultations was the topic discussed most often.

“Personally from my perspective I found.. It it was very time consuming”
(Focus Group – Nurses and Healthcare Assistants)

“the time was quite limited cos er, you know, like you said they’ve come in and they want to start telling you what’s wrong”
(Focus Group – Nurses and Healthcare Assistants)

“I think GPs would struggle to ask these questions in the 10 minutes we are given...because I struggled”
(Focus Group – GP)

The second most-often discussed theme was that prompted choice was not appropriate for some patients. However, this view was expressed more often by those who openly admitted not conducting prompted choice very much during the intervention period.

“Most of the feedback I had was they didn’t..they didn’t always feel that it was appropriate to ask”
(Focus Group – Administrative and Reception Staff)
“And sometimes I thought it wasn’t appropriate to ask.”
(Focus Group – GP)

“Erm, it depends on the patients really, erm because if they were really ill, I didn’t, I wouldn’t bring it up because I think that’s not appropriate”
(Focus Group – GP)

“when you see emergencies it might not be appropriate, when people are in pain or are depressed or whatever like that to just do that so, it takes away a lot of opportunity”
(Focus Group – GP)

A variation in how staff asked the question was present; some staff asked the question at the beginning of the consultation and some at the end.

“but I just literally just asked the question as soon as the walked through the door. Laughs Literally, BAM. *Laughs*”
(Focus Group – Nurses and Healthcare Assistants)

However, the SystmONE prompt did not facilitate asking patients at the end of consultations.

“I tried ok lets just suspend it and then you’ll talk to them after but that didn’t work either”
(Focus Group – Nurses and Healthcare Assistants)

Administrative staff believed that the prompt should not appear at the beginning of a consultation, GPs found the prompt satisfactory and straightforward and some nurses and healthcare assistants found the prompt satisfactory, and others stated that it was too complex.

“Erm it was, it was straightforward...yeah...it was easy to use...because you could pause it and then it wouldn’t come up and that was ok....”
(Focus Group – GP)
“it took me a couple of consultations to work out that I could pause it and it would come up at the end. And I used that quite a lot, but yeah, it was pretty easy after that”

(Focus Group – GP)

“I think because the prompt came up before the consultation had started, I think that’s wrong, I think it should be at the end. Because the doctor... really has to make the decision...when they first open the patients notes...About whether they’re going to be asking or not, but then they don’t necessarily know, what the consultation is about yet”

(Focus Group – Administrative & Reception Staff)

Further disagreement was found in this latter group of whether a ‘prompt’ should appear at all, with some finding it useful and others not so. Additionally, some staff reported forgetting to conduct prompted choice after the prompt has been paused, and others suggested that practice with the prompt and template was important.

“...you had to click one two three four five SIX times before you could get into the records to commence the consultation and I did find that quite tedious”

(Focus Group – Nurses and Healthcare Assistants)

“Sometimes you suspend it at the beginning, with the intention of going to it at the end, but then...the consultations done and they’re out the room really so..”

(Focus Group – Nurses and Healthcare Assistants)

“I just know that if I didn’t have some sort of prompt there, I might not remember”

(Focus Group – Nurses and Healthcare Assistants)

“I used to Umm, I’d call my patient, and I don’t go onto the screen until they’ve come through the door. So they’re actually sitting down and I’d say to them ‘oh this has popped up’ bla bla bla and I do it that way, so they can see that it’s on there so I’ve got to ask the question ”

(Focus Group – Nurses and Healthcare Assistants)

Overall the majority consensus on prompted choice is that acceptable and appropriate with responses that confirm this across all staff groups. A member of the nurse and healthcare focus group stated that prompted choice would give patients a better opportunity to seek
information concerning organ donation. However, some staff felt that due to time constraints, they could not provide enough time for patients to make an informed choice.

“... just a quick chat and reinforce that information or um queries that they have I think is better in this environment, than say just a poster on the wall”  
(Focus Group – Nurses and Healthcare Assistants)

“Well I do think it’s appropriate purely for the fact that the majority of the time it’s, it’s in this environment that patients are seen. So the access to patients for primary health is more, than in secondary health”  
(Focus Group – Nurses and Healthcare Assistants)

“I still think general practice would probably be the best place for these things to happen and it’s a real shame, if we cannot do this”  
(Focus Group – GP)

“It’s acceptable in that it is appropriate, it would be easy for us, it would be easier for the patient to have this discussion with us.”  
(Focus Group – GP)

“something that some tangible goal that we would have to reach would make it very challenging because this is not something you wanna just quickly go over, you really want to do it properly...It’s a big decision for people to make.”  
(Focus Group – GP)

Patient responses were discussed around the myths of organ donation. However, a difference of experiences according to patient age was discussed by staff, with some reporting younger people were more likely to say yes and others reporting they were more likely to say no.

“yeah I found that more young people who, were generally fit and well they weren’t interested.... At that point in their life”  
(Focus Group – Nurses and Healthcare Assistants)

“See I found my, my I’ll think about it’s were all, middle aged, like my age and upwards, I found that youngens were like ‘oh yeah I’ll go for it”
“I think sometimes...I found asking the elderly, it was a bit like, huh, are you only asking me because you think I’m gonna, die soon?”

“a lot of the older people, they were quite chuffed that we still wanted their organs”

“surprisingly I found a lot of people were worried about their eyes and their age, which I thought was a bit interesting”

Staff also discussed the differences in patient responses to prompted choice depending on ethnicity and religious beliefs.

“And there’s cultural differences as well, some patients, like...‘No! you can’t have my organs’”

7.4.2.1.4.3 Leaflets and Posters

Differing opinions were held concerning the usefulness of leaflets and posters.

Administrative and receptive staff did not view leaflets positively and believed patients rarely read them.

“I go somewhere I think oo that looks interesting, pick up a leaflet, put it in a handbag, and five years later it’s still in there”

The GPs, nurses and healthcare assistants had a more favourable view of these. GPs reported that patients mentioned the leaflets and posters, and they acted as an initiator to prompted choice, particularly as the patient is not caught unaware.
“Because definitely they come in handy, especially for those who want to think about it, or, as you said religious things that come up, it’s not just resting on our knowledge what we remember but actually you can give them information to go away with really”

(Focus Group – Nurses and Healthcare Assistants)

“Leaflets and posters are good, allowed patients to look at them whilst waiting and take them home, allowed clinicians to start the conversation and then give further information”

(Staff Online Survey)

Some nurses and healthcare assistants were not aware that the leaflets and posters were present or did not use them.

“I didn’t realise they were there to be honest, I’m not gonna lie”

(Focus Group – Nurses and Healthcare Assistants)

One staff member reported using the religious leaflets, specifically Muslim, Jewish and Hindu leaflets and that they supported conducting prompted choice.

“Well the religious ones, I did use the religious ones”

(Focus Group – Nurses and Healthcare Assistants)

7.4.2.1.4.4 Recommendations

The final section will discuss staff member reports of recommendations for the intervention split between each of the intervention components.

Training

Some suggestions for training were to record the session, provide more examples and to allow staff to practice prompted choice.
“Record the session”
(Training Evaluation Survey)

“More exampled may be useful”
(Training Evaluation Survey)

Recommendations for after the training were that a refresher training session would aid clinical staff members, one staff member suggested a week after the intervention began.

“maybe going through the questionnaires again, because we forget…”
(Focus Group – GP)

“Um I think maybe with um some clinical staff, it it, they might need perhaps a little refresher every now and again”
(Focus Group – Administrative and Reception Staff)

“I would have like to have had a refresher maybe a few weeks down the line, purely because some of the problems I encountered I had to ask other colleagues”
(Focus Group – GP)

One GP stated it should be made more transparent to staff at training that they would actually be registering patients during the intervention.

“No I thought that was pretty straightforward, what confused me for the first couple of patients I talked about was, if I click this button am I actually adding them to the donor register? Cos that wasn’t made very clear”
(Focus Group – GP)

Leaflets and Posters

Recommendations were minimal for leaflets and posters, with suggestions to include more posters in the practice, provide the leaflets for staff at training, and to give a leaflet to the patient after prompted choice has been conducted in the consultation.

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“Ummmm no, … probably more posters then everyone will know about it, like the patients…”
(Focus Group – GP)

“I know you said something about the leaflets but I never even saw them. So.. I think it’s probably… making sure the leaflets are there at the training, so that staff can umm… get some for themselves and keep, hopefully in their room”
(Focus Group – Nurses and Healthcare Assistants)

**Prompted Choice**

The majority of the recommendations were for the prompted choice element of the intervention and were varied; some staff believed it should be taken away from primary care, others believing it should stay. A target of asking one patient a day was suggested, and some staff recommended doing it at new patient health checks.

“P1: We could definitely do one a day,
P2: One a day should be fine”
(Focus Group – GP)

“P3: New patient health checks? So I think it could be good
P4: No
P3: I definitely think that yeah
P5: No we don’t get long enough to do it as it is ...”
(Focus Group – Nurses and Healthcare Assistants)

With regard to SystmONE, recommendations included having the prompt appear at the end of the consultation, to have an icon like patient health checks instead of the prompt, some staff wanted to remove the prompt however some staff wanted to keep it, that the prompt should be restricted at the upper age range for organ donation and that there are less clicks on the template.

“I think it should be asked at the end of the consultation”
(Focus Group – Administrative and Reception Staff)
“That’s what I’m thinking you know, how do you bring it to the attention of the clinician without it being sort of in your face, because for us it was about it’s something new. So I guess it had to come up at me otherwise I wouldn’t do it.”
(Focus Group – Nurses and Healthcare Assistants)

“Don’t have the annoying pop up *laughs* You know you couldn’t get past it. It was annoying, to me”
(Focus Group – Nurses and Healthcare Assistants)

“The prompt for Pts over the eligible age should not come up”
(Staff Online Survey)

The final recommendations do not concern any aspect of the intervention previously mentioned. These include changing the intervention so that it is a stall run by an independent person in reception, that something should be included on the patient screen in the waiting room, that patients are asked when booking an appointment at reception, that this should not be included in the QOF framework, that a separate clinic is introduced for this intervention, that additional staff provisions are included and that the results of the study are relayed to the practice after it has finished.

“I think that a little stall, at reception, with somebody advertising organ donation I think, I personally think that would be an easier way to approach it, because somebody who is interested will approach you, rather than us approaching them, when they’re sick.”
(Focus Group – Administrative and Reception)

“Participant 1: And then I think,... think it could be worthwhile putting it up on the screen, Participant 2: Yes! That’s what I was thinking yeah.”
(Focus Group – Nurses and Healthcare Assistants)
7.4.2.1.4.5 IIFF Model

The final findings from the staff focus group and online survey are those concerning the IIFF model of organ donation registration. Information provision was discussed by all staff and included providing information verbally as well as via the leaflets and posters. Particularly interesting was that staff were comfortable correcting myths patients held. However, again, the issue of time was raised that staff do not have enough time to provide as much information as they or the patients would like. Positive opinions were held about the training and providing staff with the information they needed to provide to patients.

Mixed views we held on whether an immediate opportunity to sign up is positive; with an administrative reception staff member suggesting that patients will want time to think. This staff member reported receiving two telephone calls from patients after being asked, both patients discussed this with their family one wanted to sign up, and another did not. This was supported by a GP who stated that few patients decided then and there if they wanted to join the NHS ODR.

“very few people made the decision then and there, quite a few people wanted to take away the information and think about it, whether they came back and did that or did that by themselves at home, I don’t know,”
(Focus Group – GP)

Fewer comments concerned focused engagement; however, the nurse and healthcare assistant focus group discussed how patients often want to come into their appointment and start talking about the reason they are there. When the appointment is finished, they want to leave with their prescription also which indicates patients may not be entirely
focused on the question of organ donation during consultations, regardless of whether the question is asked at the beginning or end.

Favorable activation was the second most discussed element after information. There were many references to concerns over whether it is appropriate to ask patients when they are unwell or if patients may be distressed by prompted choice in this setting. However, some staff believed that primary care is a non-emotional setting compared to secondary care when families are presented with donating the organs of a loved one. Also, some staff members reported having little issues with patient distress and reported most were okay with it.

“Many people are closed about the subject and by having a clinician bring up the topic for discussion in a non threatening way and at a non emotional time (as is often the case in hospital setting) started the thought process. In the future they may have found a different more considered answer rather than gut feeling.”

(Staff Online Survey)

7.5 Patient Online Survey Results

7.5.1 How feasible and suitable is the patient online survey as a data collection tool?

Out of the 743 text messages that were sent by the practice, only 48 responses were logged by patients (response rate 6.5%) (Table 35). Of those, only 12 visited the consent page, and when these were excluded, the response rate drops to 4.8%. Further, nine partial responses and 28 full responses (patients answered all questions) were recorded, equating to a 3.8% total response rate for completed questionnaires.
### Table 35: Patient online survey text message schedule and the number of patient responses.

<table>
<thead>
<tr>
<th>Prompted Choice Questionnaire Date</th>
<th>Total number of patients for whom Prompted Choice Questionnaire completed</th>
<th>Number of patients text sent to (with text message enabled)</th>
<th>Date Text Message Sent</th>
<th>Number of responses</th>
<th>Cumulative number of responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>25th June – 9th July</td>
<td>100</td>
<td>89</td>
<td>26th July</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>11th June – 24th June</td>
<td>126</td>
<td>116</td>
<td>2nd August</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>5th April – 10th June</td>
<td>599</td>
<td>538</td>
<td>9th August</td>
<td>39</td>
<td>48</td>
</tr>
<tr>
<td>Total</td>
<td>825</td>
<td>743</td>
<td></td>
<td>48</td>
<td></td>
</tr>
</tbody>
</table>

#### 7.5.2 How acceptable is the intervention patients?

Of the 36 patients who completed or partly completed the survey, 28 were asked to join the NHS ODR in their consultation, and eight were not. Twelve noticed the leaflets and posters, 22 did not, and two patients did not complete this question. Of those asked, 21 patients were asked by a nurse or healthcare assistant and seven were asked by a doctor or GP. Demographics of the patients who completed the survey are as follows: 22 patients were White - English/Welsh/Scottish/Northern Irish/British, 8 patients stated they were White – Other, 1 patient stated they were Asian/Asian British - Chinese, 1 Black - African, 1 Mixed - White & Black Caribbean, 1 Other - Any other ethnic group, 1 White – Irish and 1 patient preferred not to state their ethnicity. Eight patients were male, 28 patients were female with an average age of 43.4 (SD 15.7, Min 18, Max 81).

A separate qualitative analysis was conducted for patient responses to the online survey than from staff online survey. A preliminary descriptive analysis will be conducted on the responses given in this study in order to amend the intervention and data collection.
materials before the RCT. The descriptive analysis is organised by the questions asked in the online survey; experience of being asked, did being asked aid decision making, views of being asked (by those not asked), helpfulness of leaflets and posters, influence or leaflets and posters on decision, appropriateness and acceptability, recommendations.

7.5.2.1 Patient experiences of being asked

The majority of responses were positive regarding patient experiences of being asked to join the NHS ODR. Positive responses include references to staff asking in a polite, sensitive, professional manner without pressure, and some mentioned that they understood the importance of the issue of organ donation.

“The nurse was very sensitive and was aware that I may not want to talk about the issue. Once I assured I was fine with the topic she continued.”

One patient described being happy because they had wanted to register for a while. Some patients stated the experience felt routine, and several patients stated they were already on the NHS ODR when asked by staff in their consultation.

“I think she asked me at a blood test. I think I may have already been on the register but agreed again just in case”

“Experience was warm friendly unintrusiv and no pressure”

“I didn’t mind being asked as I know it is important”

“I went in to have my smear test and was asked at the end. I thought it was a great idea to ask me whilst in the room for a medical reason.”
Links to the IIFF model of organ donation registration were also briefly mentioned. One patient stated they had always considered joining the NHS ODR but had been postponing, because of this, they were positive about the intervention.

“I was happy to be asked about joining because I’ve considered joining but somehow I was postponing it”

This represents the previously discussed subset of patients who are ‘passive positives’ whom this intervention targets explicitly - those who want to join but have not got round to it yet. However, other responses included being surprised at being asked, not wanting to register at this time, and one patient felt forced to register.

“I was surprised. I never thought about it before”

“After gp had finished with sorting out my problem and as I stood up to leave I was asked my views on organ donation and wether I had or would consider it. I said I didn’t know how I felt about it personally and didn’t want to be put on any list at that time.”

“Forced in to it”

7.5.2.2 Did being asked aid patient decisions?

To the question, ‘did being asked aid the decision to join the NHS ODR?’, some patients stated that being asked did help them make a decision and consider joining, whereas others stated they were already on the register.

“Yes it did.....I had thought of it in passing
Nurse laid things out for clear understanding”

“Had always wanted to b a donor”

“I start thinking about it. All pros and cons of it.”
“Yes, I’ve always intended to join the register but always forgot to find out how”

“Yes, it prompted the thought and the response. The right professionals to discuss this with were also on hand to answer any questions.”

“No it didn’t help me make a decision as I feel it’s not something I wish to do”

Some expected staff to have access to the NHS ODR or knowledge that they were already on the register.

“I’m on it already, but for some reason that was not recorded on my file.”

7.5.2.3  Patient views of being asked by those not asked

The views of patients who were not asked were also captured, and the majority of their responses were positive that they would be happy to be asked and are already on the NHS ODR.

“Being asked would be fine. Maybe they have it on file that I’m a registered donor and no need to ask”

“I would be happy to be asked”

Some patients discussed the appropriateness of asking, the importance of a lack of pressure and that their parents would mind.

“There are times that it’s more appropriate”

“As long as asked once and not pressured I’m not bothered. I am already a donor.”

“I wouldn’t mind but I know that my parents would”
7.5.2.4 Were leaflets and posters helpful?

Those patients who stated they noticed the leaflets and posters, some responded that they were helpful, and some stated they were not.

“Didn’t look through them”

“Yes. They helped me make a decision.”

One patient stated that although they act as reminders, the most influential thing is having a conversation with someone.

“Useful as information reminders, but little influence on decision. The major influence for me on deciding this sort of thing is speaking with someone”

7.5.2.5 Did leaflets and posters influence patient decisions?

The majority of patients who noticed the leaflets and posters, reported that they did not influence their decision making, with only one stating they helped them make a decision.

“No already registered”

“Didn’t read any...I noticed them”

“Yes. They helped me make a decision.”

7.5.2.6 Appropriateness

Regarding the appropriateness of the intervention in their GP practice, the majority of patients stated they thought it was appropriate. Some patients stated they thought it was the best place to be asked, that it is needed because there is a lack of awareness of how to sign up.
“This is probably the most appropriate place to be approached”

“This is the best place for the conversation in my view”

“completely appropriate”

“Very ...i think that all eligible people should be asked”

“I think it’s needed as not everyone is aware how to sign up. Useful especially for those who came from countries where there is no donor register and your permission is assumed.”

“Very appropriate, as long as it’s done sensitively “

“Very important for patients to no bout this”

“It was very appropriate”

However, one patient believed it could be annoying to be asked in this manner.

“Ok. Its same as being bombarded with tv ads. Annoying.”

Some stated this was dependent on how the patient was asked or the reason for visit and others specified the importance of staff asking being able to provide information to patients.

“Appropriate as long as the patients reason for visit isn’t an organ illness”

“Depends on how your asked”

“It’s a bit surprising but I think GP should give all information and be able to answer different question( eg:how technically it’s look like to be a organ donor or how body looks like after)”

As in the staff focus groups and online survey, only one patient mentioned the opt-out consultation and shift towards presumed consent in England.
“Very appropriate although I think a bit late in the day as I understand that it will become automatic around 2021 unless people opt out”

7.5.2.7 Acceptability

As well as appropriateness, patients were also asked about acceptability, and the majority of patients believed a GP setting is an acceptable place.

“Absolutely”

“Yes, with the doctor is a great place to ask. Rather than doing it when redoing driving license.”

“Yes it far better than to wait until the decision has to be made by relatives”

“Yes. At the hospital when someone is on a ventilator it is hard for the family to make either a rational or informed decision”

Some patients believed the majority of people would sign up, that it is better than driving license, that it is better to ask now than before the decision has to be made by relatives and that it is a medical setting.

“Yes, I believe the majority of people would sign up if asked”

“Yes very much so”

“Yes it's a medical professional building”

“Yes I think it is an ideal place”

One patient stated that acceptability is dependent on the patient being asked.

“It's depend on situations. If someone is coming to get help with depression or terminal illness it's unacceptable but if coming to GP for some minor problems it's ok to do.”
The final question concerned recommendations, with most patients having no recommendations. Those that did suggested someone be situated in the waiting room to sign-up patients, to provide leaflets & posters, don’t force patients into it, on the patient call screen, for receptionists to mention it when booking appointments, using examples of people assisted by organ donation and offering other options such as donating the body to medical science.

“Have someone sat at a desk in the waiting room, talking to people as they wait and signing them up on the spot”

“Leaflets”

“Don’t force someone in to it”

“Perhaps hand out leaflets when you arrive for your appointment to give more information”

“Have more information available beforehand so people are more aware. On the TV screen in the waiting room for example”

“It may be helpful if by booking appointments receptionist could mention about it.”

“It could be helpful to get some leaflets or links regarding organ donation. Something that could encourage us to do it or at least discuss it with family members.”

“I have seen nurse once or twice since but no mention of organ register”

“Posters around with the positives of doing so”

“Just keep the conversation exactly as it was. I went in for a smear test and came out with a feel good feeling that I could make a real difference to someone’s life. Bingo!”

“Maybe by giving also a summary of other options, such as giving the body for science, medical research or schools of medicine”

“Use examples of people assisted.”
7.6 Summary

In summary, the results of the single practice feasibility study show that overall, the intervention was feasible and acceptable to conduct by some staff members and for some patients. The training was positively received, in particular the involvement of the SNOD and theatre forum sessions. Staff believed that prompted choice was a positive intervention overall. However, they expressed that time barriers and whether it was appropriate for all patients prevented them from conducting it in some circumstances. Mixed responses were had regarding the usefulness of the leaflets and posters, with some staff using them to initiate prompted choice; however, some staff and patients did not believe they were useful. The majority of patients believed the intervention was appropriate and acceptable. However, they also mentioned the importance of ensuring it was appropriate for the patient in their consultation. Differences in the rate of prompted choice performance were found between staff groups, with doctors less able to perform it than nurses and healthcare assistants. Finally, the intervention worked in the way it was intended as some patients took the opportunity to verbally join the NHS ODR during prompted choice.
8 Chapter 8: Intervention Refinement

This chapter fulfils the final part of objective two in this thesis (to refine a general practice intervention targeting NHS ODR sign-up), and discusses the results of the single practice feasibility study. Step four of Intervention Mapping (IM) is described, and the feasibility research questions described in chapter six revisited. Modifications to the intervention based on these findings are also discussed. This chapter then goes on to describe the feasibility randomised controlled trial (RCT) recruitment protocol, and details the challenges which resulted in the ultimate abandonment of stage two, the feasibility RCT.

8.1 Intervention Mapping Step 4: Pre-test Materials

This section discusses the single practice feasibility study findings and revisits IM step four. The aim of pretesting in IM is to examine how to adapt the intervention based on feedback from the targets of it. To do this, the authors of IM highlight that it is important to revisit the change methods for both the behavioural and environmental outcome, to determine whether these are adequately achieved. Table 36 outlines the change methods for both the behavioural and environmental outcomes, alongside whether these were met in the single practice feasibility study. Each intervention component is then discussed regarding how the change objectives were met and if they were perceived to be acceptable to staff and patients.
Table 36: Evaluation of change methods and their applications for both the behavioural and environmental outcomes, based on the single practice feasibility study results.

<table>
<thead>
<tr>
<th>Intervention Component</th>
<th>Behavioural Outcome</th>
<th>Determinants and Change Objectives</th>
<th>Method</th>
<th>Application</th>
<th>Was Change Objective Achieved?</th>
</tr>
</thead>
</table>
| Training               | GP Practice staff present existing patients with an opportunity to join the NHS ODR as well as new patients. | Information  
• In. 2. Staff can answer patients' questions directly following training or direct patients to leaflets. | Framing | Slides – Information concerning myths is presented in a positively framed manner, e.g., higher eligible age than most people expect, disease does not rule out donation. | Yes |
<p>|                        |                     |                                    | Planning coping responses | Slides and Q&amp;A – information on myths is presented, which helps guide staff in how to tackle difficult questions they may be fearful of. | Yes |
|                        | Immediate Sign-up   |                                    | Environmental re-evaluation | Slides – facts figures concerning organ donation, displays to staff importance of asking patients and increasing registration rates. | Yes |
|                        |                     |                                    | Modelling | SystmONE demonstration – showing staff how to register patients and complete data collection forms. | Partially |
|                        |                     |                                    | Theatre Forum – showing staff how to ask the question. | Yes |
|                        |                     |                                    | Environmental Re-evaluation | Slides – real-life organ donor stories will encourage staff to ask patients and realise the social good of asking. | Yes |
|                        |                     |                                    | Individualisation | SNOD Q&amp;A – staff, can ask SNOD open questions concerning organ donation, the intervention, and training content. | Yes |
|                        | Focused Engagement  |                                    | Modelling | Theatre Forum session – example patients could be dismissive, not engaged, shows an example to staff of how to deal with that. | Yes |
|                        |                     |                                    | Planning coping responses | Theatre forum session – For example, patients could be actively distressed or show signs they may become distressed at organ donation discussion. | Partially |
|                        | Favorable Activation |                                    | Modelling | Theatre Forum session – For example, patients, show how staff can cope with negative patient responses they could perceive as a barrier. | Yes |</p>
<table>
<thead>
<tr>
<th>Prompted Choice</th>
<th>Patients join the NHS ODR</th>
<th>Information</th>
<th>Individualisation</th>
<th>Final Decide</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• In.1. Patient gathers information about organ donation to help decide on joining the registry.</td>
<td>Clinical Staff member offers the opportunity for the patient to ask questions.</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Immediate Sign-up Opportunity</td>
<td></td>
<td>• Im.1. Patient has the opportunity to sign-up immediately in the GP practice.</td>
<td>Providing immediate and verbal opportunity for patients to register on NHS ODR.</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Favorable Activation</td>
<td></td>
<td>• Fa.1. Patient is in ‘favorable activation’ while sign-up opportunity is presented.</td>
<td>Clinical staff integrate new question into consultation flow how they see fit.</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Focused Engagement</td>
<td></td>
<td>• Fe.1. Patient has no other distractions during sign-up opportunity, and they are focused on the topic of organ donation.</td>
<td>Clinical staff only ask a patient if there is little risk of distress.</td>
<td></td>
<td>Partially</td>
</tr>
<tr>
<td>Leaflets and Posters</td>
<td></td>
<td>In.1. Patient gathers information about organ donation to help decide on joining the registry.</td>
<td>Leaflets and posters about organ donation are displayed in the practice.</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>
8.1.1.1 Training

Twenty four practice staff attended the training sessions, and responses were positive. All but two change objectives were achieved. The results indicate that the training was acceptable and feasible for staff, and prepared staff adequately to conduct prompted choice. Therefore, training was planned to remain mostly the same for the RCT – subject to minor amendments. Two elements required adaptation as they only partially met the change objectives – modelling, specifically the SystmONE demonstration, and the element of distress in the theatre forum session. During the intervention, some staff incorrectly used the Feasibility Questionnaire to record that patients did not want to join the NHS ODR, and a GP also reported that clarification was needed to ensure staff were aware that responding yes on the questionnaire results in the patient being added to the NHS ODR. Additionally, one patient reported they felt pressurised into join the NHS ODR. Modifications were planned therefore, with the importance of not pressuring patients emphasised and more time in training devoted to the SystmONE demonstration.

8.1.1.2 Prompted Choice

All but one change objective was fulfilled by prompted choice. Staff engagement with prompted choice was relatively high - in 12.4% of face to face consultations prompted choice took place. Four doctors (66.6% of those trained), two healthcare assistants (100% of those trained) and four nurses (100% of those trained) completed prompted choice on more than one occasion. Doctors only completed prompted choice in 1.6% of their face to face consultations, compared with 23.4% for nurses and 17.1% for healthcare assistants. Thirty-four per cent of Feasibility Questionnaires recorded that a lack of time was a barrier to
prompted choice, on 18.8% of occasions it was not appropriate to ask patients, and on 45.7% ‘Other’ was selected - with 82.1% of ‘other’ responses recorded that a telephone consultation was conducted. These results indicate that prompted choice is conducted by some staff groups (nurses and healthcare assistants) during face to face consultations, who have enough time, and for patients with whom organ donation discussion appears appropriate.

Prompted choice was found to be acceptable to conduct by the majority of staff; however, time and appropriateness for some patients were repeatedly reported as barriers. Consensus that it is a worthwhile intervention was found, particularly that it could impact positively on those on the transplant waiting list. The flexible non-prescriptive nature of how prompted choice was conducted helped accommodate barriers expressed. Some indications are that prompted choice could be restricted to only nurses and healthcare assistants who conduct practice nurse or phlebotomy sessions, as staff will know before the consultation commences the reason for the patient visit. Patient views on the intervention also highlight it is acceptable to the majority of patients. However, the change objective that only patients who were not at risk of distress were asked – via structural redesign was only partially fulfilled. As previously discussed, one patient felt negatively about prompted choice, that they were pressured into joining the NHS ODR. This indicates that although efforts were made to prevent distress, and only ask patients in a favourable affective state, this did not happen in all instances. As previously discussed, the training was adapted to better emphasise this element.
8.1.1.3 Leaflets and Posters

Leaflets and posters were displayed per-protocol throughout the three months, and this component fulfilled its change objective. However, only 100 leaflets were taken compared with 812 occasions when prompted choice was conducted. Both staff and patients expressed mixed views on the usefulness of these. Some staff members believed leaflets were not helpful and that patients do not read them, whereas some reported them to be a useful tool to start the prompted choice process. Twenty-two patients reported that they did not see the posters and leaflets, and twelve reported they did, which could support the assertion by some staff that patients do not read these. Further, the majority of patients reported that leaflets and posters did not influence their NHS ODR decision, and some suggested that they should be used in responses to the patient survey. This indicates that leaflets and posters may not be a necessary part of the intervention and could be removed. However, for the feasibility RCT, leaflets and posters were planned to remain the same as in the single practice feasibility study.

8.2 Revisiting the Feasibility Research Questions

As well as IM step four, it was also important to revisit the research questions concerning intervention feasibility. These include recruitment of staff to the training and intervention, the data collection materials, the resources required to run the study and intervention, and finally whether the intervention works in the way that it is intended (intervention promise).
8.2.1 Recruitment

Attendance at training sessions was a crucial element to the successful running of the intervention, due to only trained staff being allowed to conduct prompted choice. Only 12/24 of attendees were clinical staff, and challenges to clinical staff recruitment were that the training overlapped with clinic times and home visits, as it was conducted during the lunch break. Therefore it was important to explore other times to conduct the training, where these competing priorities were not present. Reflecting on the intervention, the Practice Manager suggested that it be included in Protected Learning Time (PLT), when practices are closed to patients for compulsory staff training. However, it is challenging to make training compulsory when the practice is taking part voluntarily. To counter this, financial incentives could be provided to encourage practice recruitment, and additional incentives could be used for those who achieve 100% training session attendance. Also, targeting clinicians' desire to increase their knowledge and to help patients could be integrated into training advertisements, as these have previously been found to be successful research incentives for GPs (Brodaty et al., 2013). Unfortunately, financial incentives could not be used in recruiting either practices or staff to the RCT, due to resource constraints. However, the training was planned to be conducted at PLT, subject to the agreement of the participating practices in the RCT. Additionally improved strategies for recruitment were planned, including emphasising the public good of the intervention to recruit both practices and doctors to training sessions.
8.2.2 Data Collection Materials

8.2.2.1 Training Evaluation Survey

The training evaluation survey findings align with the focus group and online survey findings regarding training – that it is acceptable to attend and generated a positive reaction. Fifteen out of twenty-four attendees completed the training evaluation survey, with the highest attrition rates from doctors and healthcare assistants. Previous studies support that it is challenging to recruit UK GPs to complete paper surveys (Cottrell et al., 2015), and in order to improve completion rates, more time could be given during training for survey completion. As a result, for the RCT it was planned to emphasise the importance of completing this survey during the training session, and to provide more time for staff to complete it at the end of the session. Few staff completed the open-ended survey questions, aligning with previous research that participants are more likely to complete open-ended questions if they are delivered online (Denscombe, 2009; Rada and Domínguez-Álvarez, 2014). However, based on the response rate to the staff online survey, changing the training survey to be online based could potentially increase attrition rates. Overall, the training evaluation survey was deemed to be a feasible way of collecting data on participant training reaction, despite the issues described (Kirkpatrick, 1996); therefore, it was planned to remain the same in the RCT.

8.2.2.2 SystmONE Questionnaires

Telephone consultations were recorded as the reason for non-completion of prompted choice on 36.2% of Feasibility Questionnaires completed. These findings demonstrate that it is challenging to conduct prompted choice during telephone consultations. Additionally, in
12.7% (N163) of Feasibility Questionnaires, administrative tasks were reported, and on two occasions (0.2%) home visits were reported as the reason prompted choice was not conducted. Unfortunately, SystmONE cannot determine whether a consultation is face to face, via the telephone, a home visit, or for administrative purposes. Therefore, telephone consultations, administrative tasks and home visits were planned to be excluded from questionnaire completion in the RCT.

The option ‘clinician personal beliefs’ was not selected on any Feasibility Questionnaire. This was included on the advice of the Lead GP who believed some staff would not conduct prompted choice due to personal beliefs. Conscientious objection is when clinicians refuse to perform some aspect of medical care due to moral or religious beliefs, and it has been discussed in the area of organ donation and transplantation (Savulescu and Schuklenk, 2017). The result, that no staff member selected this option, may indicate that this does not occur regarding prompted choice – however, two doctors did not complete a single Prompted Choice Questionnaire. The lack of participation and ignoring the prompt could be a form of conscientious objection; however, as clinicians did not select this response, it was planned to be removed for the RCT.

Finally, the length of the SystmONE questionnaires was discussed in the focus groups and online survey. They were described as ‘tedious’ and ‘annoying’ with staff recommending these be shorter. Constraints within SystmONE made this challenging, as some ‘clicks’ were the result of pop-ups which could not be edited or removed. However, merging Prompted Choice and Feasibility Questionnaires could help reduce the complexity of the questionnaire; therefore this was planned for the RCT.
8.2.2.3 Monitoring

The intervention was successfully monitored on all but two occasions during the three month prompted choice period. After week 4, leaflets ceased to be counted weekly, which reduced monitoring duration and staff consultations were counted manually from week five onwards. All issues raised with the monitor were during the initial few weeks of the intervention, and several reminders were sent to staff (via email from the Practice Manager) to rectify these. Therefore monitoring worked as intended by finding and rectifying issues in the first few weeks of the study. The inclusion of staff consultation counting did not increase monitoring time substantially, and as the monitor became more familiar with this process, monitoring time decreased. Restocking of leaflets was only required on one occasion for the Christianity leaflets written in Polish. As a result monitoring frequency was amended to fortnightly for the RCT.

8.2.2.4 Focus Groups

Several challenges occurred using focus groups, particularly regarding recruitment. On nine occasions, the PhD student was situated in the practice, and on only four of those occasions did staff attend focus groups. It was particularly challenging to recruit doctors, with only two GPs attending on two separate occasions who participated in prompted choice. This was despite an active recruitment strategy of an email sent one week prior, an email sent on the day, and the Practice Manager messaging staff 10 minutes before sessions were due to start. Four staff attended the administrative and reception staff focus group, and five the nurse and healthcare assistant group. Success in attendance for these was due to the
championing of these by a staff member within that group. The Practice Manager and Practice Nurse actively persuaded staff in person to attend and formed a group willing to participate.

A further issue was the short length of the administrative and GP focus groups. The latter could be due to the presence of only one or two staff members, making ‘discussion’ more challenging, and also limiting the capture of collective views. Additionally, staff were distracted by the time during these focus groups and expressed that they had competing priorities. This mirrors the findings that lack of time is a common reason for not conducting prompted choice – that time also impacts study-related data collection as well as the intervention.

The implications of this are that more resources than intended were used to run the focus groups; facilitator time, financial resources to purchase lunch, and Practice Manager time to organise sessions. Further, the quality of the focus group data was poor, due to the brevity of staff responses and lack of time they wished to devote to participating. Therefore due to these issues focus groups were not planned to be used in the RCT.

8.2.2.5 Staff Online survey

Poor response rates were also found in the staff online survey, which mirrors the focus group findings. This suggests that staff participation in study data collection is challenging generally, and not just isolated to focus groups. The lack of response could be due to staff already participating in focus groups and having no new views to express, alternatively lack
of time and competing resources could also impact response rates. Additionally, similar issues were found with the quality of the data found in the focus groups, namely, that responses were brief. These findings highlight the challenges facing researchers in recruiting staff in general practice. For the RCT, the focus group and staff survey data were planned to be used as the basis for a survey containing mostly closed questions in the RCT, as it was anticipated that closed questions may elicit higher response rates.

8.2.2.6 Patient Online Survey

The response rate for the patient online survey was low – 6.5%, dropping to 3.8% for full or partial responses. However, 28 responses were captured from patients which enabled some indications of patient acceptability to be established. A limitation of this survey was that only one recruitment text message was sent to patients, and no subsequent reminder text messages were sent. As in the staff survey, for the RCT, the patient online survey was planned to be converted into a survey containing predominantly closed questions, in an attempt to elicit higher response rates.

8.2.2.7 Field notes and reflective practice

Field notes and reflective practice indicated that a mixed methods training questionnaire could be developed for the RCT, where the training facilitator completes questions concerning fidelity and formally records attendance. This could also allow training barriers and facilitators to be detailed, as well as technological requirements and expertise.
8.2.3 Resources and Management

The resources required for the intervention centre around SystmONE. Access is crucial for the trial to run effectively, as is the expertise to implement the prompt, questionnaires, and test these. In order to do this, the practice provided the researcher with a chip card and password. SystmONE was vital for the study to run, and as a result, was included in the practice inclusion/exclusion criteria in the planned RCT. Few issues occurred and SystmONE worked as planned during the study period, with no patients asked who were under the age of the 18 and no untrained staff members conducting prompted choice.

To conduct the training, the practice were required to provide time and space for it when as many staff as possible could attend. Lunch proved a strong incentive for training session attendance, and it was also vital for the Practice Manager to aid in the scheduling of training sessions and advertising of these to practice staff. Critical to the success of the training found in the focus groups was the involvement of the Specialist Nurse in Organ Donation – specifically the theatre forum and Q&A session. Knowledge and the ability to train staff in the SystmONE data collection forms was also vital, as well as being comfortable with presenting organ donation information and answering questions on this. In future, it is possible a SNOD could conduct the entire training session if they are comfortable to present on these other elements.

NHSBT were required to provide the leaflets and posters for the study. In future, based on focus group feedback, it is important for NHSBT to provide a general information leaflet which was unavailable during the single practice study. The primary resource used for prompted choice was clinician time during consultations; however, few other resources
were required from the practice. Vital to the patient survey data collection was permission from the practice and administrator time to send recruitment text messages to patients. Additionally, the increase in NHS ODR registrations required the practice to provide more resources to add these to the Open Exeter database. Due to data protection issues, a researcher was unable to do this as they would view identifiable patient data (name, date of birth, address).

8.2.4 Intervention Promise

Finally, prompted choice worked in the way it was intended, 244 out of 812 patients joined the NHS ODR over three months (30.4%). An additional 112 people expressed they were already on the register and 110 of these re-registered on the NHS ODR (13.5%). In total, 43.9% of those asked joined for either the first or second time, indicating the intervention successfully provided a new access opportunity to the NHS ODR. Challenges were experienced, however, in validly capturing the number of BAME patients who registered, and unfortunately, ethnicity was not recorded for 318 patients who experienced prompted choice. Luton has a high percentage of BAME residents; therefore, more BAME patients may have experienced prompted choice than the data represent.

8.3 Multi-Practice Randomised Controlled Trial

The stop-go criteria, based on those by Thabane et al. (2010), were revisited following the results of the single practice feasibility study (Thabane et al., 2010). More than one staff member completed prompted choice for more than one patient during the three months. As a result, the intervention could progress to further testing through feasibility RCT. The
protocol for the stage two trial was developed using the pragmatic stance previously discussed. Sixteen months were available for this RCT, and this timespan drove the development of the protocol. The HRA were consulted on how to obtain approvals as quickly as possible, and recommended minimal adaptations to the single practice study in order to submit a Substantial Amendment for the RCT, as opposed to a new application. NHSBT kindly offered to fund the studentship for a fourth year to facilitate the conduct of the RCT, and the full protocol can be viewed in appendix 42.

8.3.1 Recruitment Protocol V1.0 15th February 2019

To fulfil the ‘Recruitment’ element of Orsmond and Cohn's objectives, data was collected on GP practice recruitment to the RCT (Orsmond and Cohn, 2015). A separate recruitment protocol was developed and submitted to the University of Bedfordshire Institute for Health Research Ethics Committee (IHREC) before submission of the substantial amendment to the Health Research Authority (HRA), NHS Research Ethics Committee (NHS REC) and Confidentiality Advisory Group (CAG). This enabled recruitment to commence while waiting for approval from these bodies. As recruitment did not involve patients within the NHS, an NHS ethics application was not required according to the HRA toolkit (NHS Health Research Authority, 2019c). The recruitment protocol was submitted to IHREC on 15th February 2019 and approved on 4th March 2019 (IHREC917). This protocol addressed the following research questions (Appendix 43):

- How many practices are eligible in the recruitment target area?
- How many practices were approached for participation?
- How many practices declined to take part in the study?
• How many practices did not respond to recruitment invitations?
• How many practices expressed an interest in participating in the study?
• How many practices formally enrolled in the study?
• How many practices were randomised?

Practices within Luton and Central Bedfordshire districts aimed to be contacted via telephone to confirm their eligibility for the study, according to the following practice inclusion and exclusion criteria:

Inclusion criteria

• The practice uses SystmONE computer software
• An organ donation intervention has not taken place within the practice in the previous year
• Located in either Luton or Central Bedfordshire district.

Exclusion criteria

• The practice does not use SystmONE computer software
• An organ donation intervention has taken place within the practice in the previous year
• Not located in either Luton or Central Bedfordshire district

Following this, eligible practices were sorted based on their list size and district to finalise stratification blocks. After which, two practices from each block, eight in total, were approached to be a part of the study (Table 37).
Table 37: Stratification and randomisation of practices in the multi-practice RCT

<table>
<thead>
<tr>
<th>District</th>
<th>Practice Size</th>
<th>Arm</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>Central Bedfordshire</td>
<td>Small</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Large</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Luton</td>
<td>Small</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Large</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

An email was sent to practices containing a letter of invitation to participate, advertisement sheet, and study information (Appendix 44). Practices were also contacted via telephone to discuss interest in participation. One week following this initial contact practices were contacted again to confirm interest or decline to participate. If a practice were undecided, this was recorded and the practice contacted at one-week intervals until a decision was made. Following this, if required, more practices were planned to be approached in the same way. Additionally, if recruitment through the initial email approach was poor, the practice who previously participated aimed to be contacted to aid recruitment via snowballing. Recruitment planned to cease on 30th June 2019, with all undecided practices contacted to confirm or decline participation. The intervention was then proposed to run from July – December 2019 with all practices who confirmed participation.

A recruitment diary consisting of ‘recruitment forms’ was used to collect data on recruitment (Appendix 45). The first form collected data on which practices were eligible to participate. Form two lists the eligible practices sorted by stratification blocks. Form three is the approach and expression of interest form, which collected information on how and how many times practices were contacted, whether they expressed an interest in participating and if this led to randomisation. All forms were completed digitally in one Microsoft excel password-protected spreadsheet.
8.4 Challenges to Multi-Practice Randomised Controlled Trial

8.4.1 Recruitment Results

Approval to commence recruitment data collection was received on Monday 4\textsuperscript{th} March 2019 and recruitment of practices to the RCT commenced on Tuesday 5\textsuperscript{th} March. Challenges to recruitment form completion were found, particularly with form one concerning eligibility. It was anticipated that all listed practices would be contacted by telephone to confirm their eligibility. However, the practice contact number available to the researcher was also used by patients, and these telephone lines had very long wait times. A decision was made to abandon this strategy and to investigate practice computer system use via the practice websites.

Additionally, once the SystmONE eligibility screening had been conducted, practices would be asked if they had conducted an organ donation intervention at the first point of contact for recruitment. This saved researcher time and avoided contacting 54 practices via telephone to establish this. All practices in central Bedfordshire (27/27) used SystmONE, and most of the practices in Luton used SystmONE (22/27) (Appendix 46). As a result, five practices in Luton were excluded and the 49 practices stratified according to their patient list size (Appendix 46 - list sizes retrieved from NHS Digital as of October 2017 (NHS Digital, 2017a)). Four practices from each district (2 small and two large) were then approached as per the recruitment protocol. Eight emails were sent on 13\textsuperscript{th} March 2019 to contact email addresses listed on the practice websites, and eight telephone calls were attempted to telephone contact numbers listed on the websites also. These calls were all unsuccessful.
and on no occasion was the researcher able to speak to the Practice Manager – who was either busy or not in the practice. Critically, due to accessing the general telephone lines, a wait of between 10 – 45 minutes was had before being able to speak to reception staff. None of the staff spoken to had read the recruitment email, and none could confirm whether the practice had partaken in an organ donation intervention in the previous year.

These difficulties speaking directly to practice managers led the researcher to attempt to obtain a direct email address and telephone number for Practice Managers (when not already listed as the practice general email address). These were not listed on any practice websites; therefore, freedom of information requests were sent to both Luton Clinical Commissioning Group (CCG) and Bedfordshire CCG (who cover Central Bedfordshire). The CCGs were unable to provide direct email or telephone numbers for the requested Practice Managers due to GDPR. After one week on 19th March 2019, no responses from all eight practices were received. On the advice of supervisors, the email was re-sent, this time cc’ing in the supervisory team. Again after one week on 26th March 2019, no responses from any practices had been received. Although recruitment was anticipated to be difficult, these results were unexpected. The lack of response from any practice indicated that more time than anticipated might be required to recruit eight practices.

8.4.2 Confidentiality Advisory Group Approval

NHS REC favourable opinion of the amendment took just over one month to receive (6th April 2019). However, CAG would not accept that the transition from single practice feasibility study to multi-practice feasibility RCT could be submitted as a substantial
amendment, despite NHS REC and HRA advice in this regard. A new CAG submission was produced and submitted on 12th March 2019. However, the application could not be reviewed until the end of April 2019 by CAG, and by the end of May 2019, the outcome would be received. This challenged the timeline of the research which required all approvals to be in place by the end of June 2019, including Information Governance (IG) Toolkit review of participating practices – ready for study set-up to commence. IG toolkit review caused a delay in obtaining study approval in the single practice study. The researcher examined the IG Toolkits of all practices in Luton and Central Bedfordshire, as the status of these is publicly available (NHS Digital, 2019). NHS Digital had reviewed no IG toolkit for any practice in these districts, and this is an essential part of obtaining CAG approval. On consultation with NHS Digital regarding this, they confirmed a backlog of these had occurred, and estimated approval would take between 2-3 months depending on the responsiveness of the practice. This element of approvals was entirely out of the research team control and required resources from the practice to be used.

Based on the challenges of the CAG approval process, lack of IG toolkit approval for all practices, and recruitment issues, consideration was required on whether to continue with the RCT. NHSBT had kindly offered to fund a fourth year of the study for the RCT to commence. However, if the study set up could not commence until August/September 2019 due to the IG toolkit review and lack of responsiveness of the practices, this would delay the start of the three month intervention period. If this delay occurred, it was anticipated the RCT would need to be abandoned in order for the thesis to be completed by the final deadline date. A risk assessment highlighted it was possible for NHSBT to fund a fourth year
and for the RCT not to be carried out. It was decided that due to this and to preserve NHSBT funds, it would be favourable to abandon the RCT.

8.5 Summary

In summary, the RCT was planned with the following modifications. The training was to remain mostly the same, with the importance of not pressuring patients and participating in post-intervention data collection emphasised. The training was planned to be conducted in PLT, and improved strategies for recruitment were planned e.g., emphasising the public good to recruit more doctors to the training session. The training evaluation survey was to remain the same; however, a new training assessment questionnaire was planned to assess training fidelity and resources required in a uniform manner. Prompted choice was also anticipated to remain mostly the same; however, adaptations to the prompt and questionnaire on SystmONE were planned – combining both Prompted Choice or Feasibility Questionnaires, removing the ‘clinician personal beliefs’ response, and excluding telephone consultations, home visits, and administrative tasks from questionnaire completion. Monitoring of the intervention was planned to be reduced to fortnightly. Counting the leaflets weekly during monitoring was also planned to be removed, and leaflets and posters were to remain the same and to be supplied by NHSBT (with the possible addition of a general information leaflet). Focus groups were removed, and only online surveys for both staff and patients containing mostly closed questions were proposed. Finally, practice recruitment inclusion criteria contained that practices use SystmONE, due to the preparation of the questionnaire and prompt in this software during stage one.
A recruitment protocol was developed and obtained ethical approval in March 2019. Recruitment was attempted, however challenges to this were found, specifically with access directly to discussions with Practice Managers. The HRA and NHS REC approved a substantial amendment to the stage one application to progress with stage two, however, CAG rejected this amendment and required a full application be submitted instead. This caused substantial delays to stage two, particularly regarding the necessary approval of IG Toolkits by NHS Digital. As a result of these delays and recruitment challenges, the feasibility RCT was not conducted.
Chapter 9: Discussion

9.1 Thesis Summary

This thesis aimed to design and refine a general practice intervention targeting NHS ODR registration and evaluate it for feasibility and acceptability. Three stages of research were conducted which fulfilled the three objectives; a literature, theoretical and systematic review, intervention design and refinement using intervention mapping, and a single practice feasibility study.

Objective one to collect, synthesise, and review literature that will inform an intervention designed targeting registration rates in UK general practice, was fulfilled by the literature review, systematic review and theoretical review. This review found a dearth of research in the area of general practice interventions targeting organ donation. The ten studies found in the systematic review indicated that interventions in this setting had promise if they used active techniques. The literature review found passive positives (i.e. those who wish to join but have not yet) are simpler to target than those who require a change to their attitude. However, barriers to implementation were found in this setting, including time and competing resources. Also found is that general practice is an untapped setting for organ donation interventions in the UK, as general practice is the only NHS location with the ability to add patients to the NHS ODR directly. These findings helped inform objective two, and an active intervention was developed, which accounted for potential barriers to implementation. The IIFF Model of Organ Donation Registration was used to underpin the intervention, following theoretical review, due to its specificity to target passive positives,
fulfilment of the intention-behaviour gap, practical guidance on intervention development and the iterative way in which it was developed.

Objective two to design, develop, and refine a general practice intervention targeting NHS ODR sign-up was achieved using Intervention Mapping and a single practice feasibility study. The intervention was underpinned by the IIFF model of organ donation registration and consisted of three components; prompted choice (staff asking patients in consultations if they would like to join the NHS ODR), staff training and leaflets and posters. These components were designed collaboratively with stakeholders from NHSBT, the participating practice, and the patient participation group. Lau et al.’s (2016) framework for primary care implementation was also used to guide the intervention, which focused on ease of use, simplicity, and adaptability between practices.

A single practice feasibility study was conducted in 2018 and addressed part of objective two, the refinement of the intervention, and objective three to assess the feasibility and acceptability of an NHS ODR sign-up intervention implemented in UK general practice. Overall the intervention was feasible to conduct and acceptable to some staff and patients. Only small refinements were required to the data collection forms and SystmONE prompt. Mixed findings were found for the usefulness of the leaflets, with staff finding them more helpful than patients. Training, however, was well-received by the majority of staff with few criticisms found. Key feasibility issues included time to conduct prompted choice during consultations and whether it was appropriate for all patients. However, 12.4% of patients for whom the practice conducted a face to face consultation with were exposed to
prompted choice, indicating that these barriers did not prevent prompted choice in all instances.

9.2 Overall Findings

The overall findings from this thesis are that it is feasible and acceptable to conduct the intervention in one practice in a primary care setting. The results support commentaries discussed in chapter two that suggest general practice is a promising setting to conduct organ donation interventions in (Neuberger and Keogh, 2013; Pradeep et al., 2018). The results also support those from the systematic review (Jones, Papadopoulos and Randhawa, 2017); Asghar and NHS Blood and Transplant (n.d.) and Faudree (2010), also investigated prompted choice type interventions and found a 39% and 21% sign-up rate respectively (Asghar and NHS Blood and Transplant, no date; Faudree, 2010). More surprising was the success of the intervention, particularly regarding how often staff were able to conduct prompted choice – in 12.4% of face to face consultations. Based on the challenges currently facing UK general practice discussed in chapter four, this rate could be viewed as higher than expected. During IM, the practice expressed concerns over time barriers and the resources the intervention would require, in line with those in the literature. Accordingly, the intervention was collaboratively designed with the practice, in order to minimise the impact on its day to day running. The successful performance of prompted choice on 812 occasions over three months could be due to this stakeholder involvement and focusing on simplicity and ease of use during development. Notably, the flexibility afforded to staff on how and when in consultations they conducted prompted choice, with no pressure to hit specific targets, is attributed to its success rate.
9.3 Intervention Techniques

The findings from the single practice feasibility study support the use of active techniques over passive techniques when designing organ donation interventions (Jones, Papadopoulos and Randhawa, 2017). Only 100 leaflets were taken during three months, whereas 214 patients signed up to the NHS ODR during prompted choice. Taking a leaflet does not necessarily result in patients registering on the NHS ODR, therefore the number of people who signed up just via leaflet exposure could be less than 100 patients. Additionally, the patient online survey findings support that patients may not notice passive interventions. Although this study did not explore this statistically, compared to the NHS ODR sign-up rates in Sallis, Harper and Sanders’ (2018) passive Driver and Vehicle Licensing Agency (DVLA) intervention (2.7% sign-up rate) prompted choice results in much higher rates of registration. It could be that prompted choice provides a more straightforward way for people to sign-up to the NHS ODR, i.e. just saying yes or no verbally, which results in more people using this opportunity due to the lesser effort they need to expend to do so.

Staff were positive about the training in all data collection methods (training evaluation survey, focus groups, and online survey). In particular, the staff were complimentary about the elements conducted by the SNOD, and the real stories she provided on organ donation practice in hospitals. This feedback demonstrates a strong level of buy-in by staff into training and could be attributed to the ‘forum theatre’ element based on focus group responses. Forum Theatre is a technique used in medical education where learners actively participate in demonstrations by actors, pausing them to interact with scenarios (Mcclimens and Scott, 2007). This technique has proven to be successful and well-received by learners in medical education settings (Crowshoe, Bickford and Decottignies, 2005; Mcclimens and
9.4 Acceptability

Staff views concerning acceptability were polarised. Some staff were very positive about the intervention – typically those who had conducted prompted choice on more occasions. Whereas those who conducted prompted choice less often were more neutral or negative about its acceptability, suggesting staff who find the intervention acceptable were more likely to conduct it. Interestingly staff views were not congruent with actual intervention performance and even staff who responded more positively to prompted choice discussed time barriers and whether it was appropriate to ask all patients. When compared to the results, however, asking 814 patients in three months does not reflect the strong emphasis on barriers to conducting it expressed by staff. This begs the question, are staff able to accurately assert whether something is feasible and acceptable to conduct in general practice? It is common in IM to conduct focus groups with intervention users before intervention development (Bartholomew Eldredge et al., 2016). Unfortunately, due to the time constraints for this research, these could not be conducted. Considering though the strong responses concerning barriers to conducting prompted choice expressed in focus groups post-intervention, if these had been expressed before intervention development prompted choice in the form employed in this intervention may not have been used. The results showing some staff can conduct it on some occasions contradict the strong responses by staff concerning barriers.
Important to consider, however, is that staff were not informed of the results of the study. It would be interesting to collect staff views after having informed them of the results.

Additionally, unlike the research team, staff may not perceive 12.4% to be a reasonable rate of prompted choice participation. The Quality Outcomes Framework (QOF) is a voluntary incentive program GP practices take part in (NHS Digital, 2017b). Practices receive payment if they achieve a certain percentage of patients in their practices for whom an indicator is recorded, and achievement thresholds for payment are between 30-90% of eligible patients (NHS Employers, 2014). The fidelity rate of prompted choice would not reach the threshold for payment according to the QOF. Staff, therefore, could be comparing the rate at which they performed prompted choice with the rate they perform QOF activities.

Another explanation of the strong expression of barriers comes from Cottrell et al. (2016). They explored survey recruitment rates of general practitioners in the UK and found that 93% stated too little time was the reason for non-completion. They suggest that ‘lack of time’ may not be the real reason for non-participation but is stated due to social desirability. Their lack of interest is more likely the reason for non-completion (Cottrell et al., 2015; Groenewegen, Greß and Schäfer, 2016). The caution and repeated mention of time may be a socially desirable response in this study, and one alternative for lack of prompted choice engagement could be due to personal barriers to organ donation. Vamvakopoulos, Melpmeni and Cockwell (2007) and Sque, Payne and Vlachonikolis (2000) found that healthcare professional views on organ donation are in line with those of the public, particularly concerning ambivalence and myths (Sque, Payne and Vlachonikolis, 2000; Vamvakopoulos, Melpmeni and Cockwell, 2007). Therefore perhaps barriers to donation prevent staff from conducting prompted choice. If organ donation is a topic which people
will avoid if possible (Siegel, Alvaro and Hohman, 2010), staff could be avoiding or acting in an ambivalent manner to conducting prompted choice due to its topic. Additionally, wishing to avoid organ donation could also result in not disclosing ‘true’ or more distressing reasons they did not conduct it, instead opting to mention time as a barrier because that is easier to discuss. The lack of engagement and ‘avoidance’ of participating in post-intervention data collection methods could also support this.

In contrast, the majority of patient views were positive. A theme repeatedly mentioned by staff was whether it is appropriate to conduct prompted choice as it could make patients distressed. Patient views of the intervention, however, were mostly positive and on only one occasion did a patient respond negatively. Further, one patient discussed that they had to reassure the staff member that they were happy to discuss organ donation. This example, in particular, supports that staff fears about appropriateness may not be founded in real reactions from patients, and may come from their own unconscious beliefs concerning organ donation. However, it could also be considered that the ‘avoidance’ of the topic could also have prevented patients from completing the questionnaire. Indeed, perhaps only those patients who were happy or comfortable with prompted choice and organ donation responded.

Likely, social desirability bias was also present due to the focus group facilitator being PhD student. Throughout the development and testing of the intervention, the PhD student was present in the practice and fulfilled many roles. Therefore staff responses may be biased in the training evaluation survey, focus groups, and online survey, to not offend or upset the PhD student. This bias could also have occurred with the patient online survey as patients
were sent a text message by the practice and may not want to offend or upset the practice by responding negatively (even though the role the impartiality of the survey was highlighted in the PIS). Some ways could be used to remove this bias; with staff, an independent focus group facilitator could be used, or the researcher should not be involved in training delivery. Thus, giving the impression that the researcher is independent from the intervention, with NHSBT delivering the training and seemingly developing the intervention. Social desirability bias is more challenging to overcome for patients; however, in-person surveys could be conducted using researchers wearing identification which highlights their separation from the practice. Alternatively, online focus groups could be used, which have previously been found to reduce social desirability bias compared to in-person focus groups when discussing sensitive death-related topics (Tates et al., 2009).

9.5 Patients Targeted by the Intervention

Only new patients are provided with the opportunity to register on the NHS ODR via the new patient registration form. As a result, in chapter two, GP practice registrations were predominantly found amongst younger age groups, in contrast to the number of older people who use GP practice (Appendix 1). The results of the single practice feasibility study show that by providing prompted choice to all existing patients, patients were targeted evenly across the age groups.

As previously mentioned, the intervention also supports the findings in chapter two for targeting passive positives. That 30.4% of patients signed up indicates these patients were passive positives. Also, staff discussed the lack of time they experienced to conduct the intervention and that it was brief for patients, providing further support to this (Siegel,
Alvaro and Hohman, 2010). However, only two components of the IIFF model were satisfactorily fulfilled by the intervention. Staff discussed in focus groups that they provided information to patients, either through directing them to leaflets or by providing information verbally – particularly concerning eligibility and myths. An immediate sign-up opportunity was also provided to patients with staff administrators putting all patients who signed up verbally onto the NHS ODR. Focused engagement however, may not have occurred for all patients. Staff discussed that some patients were distracted by the issue they were visiting for, and would start talking about it before the staff had an opportunity to conduct prompted choice. They also described that once patient issues were resolved, some wanted to leave and not engage in prompted choice. Therefore, some patients may not have been focused on prompted choice and could be preoccupied with their reason for visiting their surgery.

Similarly, staff expressed that patients on some occasions looked worried when asked about organ donation and that it was often not appropriate to ask them. However, the overall findings demonstrate that prompted choice still worked on some occasions despite potentially not fulfilling two components of the IIFF model. Alvaro, Siegel, and Jones (2011) found that when all components of the model were active in an intervention, a 50% registration rate could be found (approximately). Prompted choice caused 30.4% of patients to register in this study, indicating the assertions about focused engagement and favorable activation may be correct. It would be prudent, however not to disregard prompted choice in this setting completely, but make adaptations that can provide all four components, particularly by exploring alternate settings to maximise registration rates of passive positives in the UK.
The intervention was also found to successfully fulfil some recommendations made by Lau et al. (Lau et al., 2016). The first of these concerns the successful involvement of stakeholders throughout the process (external context). One of the strengths of this thesis is its collaborative approach with a variety of stakeholders - NHSBT, the participating practice staff – including partners and managers, the PPG of the practice, and patients. Engaging stakeholders in research is recommended in intervention development and testing (Absolom et al., 2015; Byrne, 2019) and was successfully conducted in this thesis.

Another external factor, according to Lau et al., (2016), is policy. One patient mentioned that prompted choice might no longer be required if the system changes and one GP mentioned opt-out as an alternative to prompted choice. These responses, however, were brief. It was surprising, therefore, that few patients or staff mentioned the public policy changes occurring during the intervention – opt-out (Wise, 2018). A consultation was open during intervention set up and had just closed before prompted choice commencement (Department of Health and Social Care, 2017). It could be that the staff or patients were unaware of the transition and consultation, that they did not understand it or did not make the link between opt-out and prompted choice.

At the organisational context, the intervention adhered to several recommendations - consider impact on workflows, foster collaboration, and engage internal and external staff. The latter recommendation was particularly pertinent as the championing of the intervention was critical to its success. The Practice Manager was involved in all aspects, design, set up, monitoring, and post-intervention data collection, and their time was used
without financial compensation. The nurse champion was also vital for intervention success and acted as an informal advisor for other staff. She also facilitated recruitment to the focus group, which resulted in nearly all nurses and healthcare assistants attending. Research champions have previously been found to positively impact patient recruitment to primary care research in the UK. (Oduola et al., 2017). The nurse and Practice Manager may have also positively impacted the likelihood that staff conducted prompted choice – although this would require further examination to determine definitively. Collaboration was fostered by allowing all staff to attend the training, which the administrative and reception staff responded to positively. The inclusion of all staff could have created a positive atmosphere in the practice regarding the intervention as all staff were aware of the need for more organs in the UK and may be motivated by this to encourage each others' participation. This could be developed further in future, with encouraging collaboration integrated into future intervention documentation – for example sending emails reporting back to the practice on the number of NHS ODR sign-ups they facilitate and how many lives this could save.

Regarding the professional contextual level, most staff believed prompted choice was congruent to their role, mainly that they can provide organ donation information. However, findings also highlight that some styles of clinical practice are less able to facilitate prompted choice. Clinics where the staff are unaware of what the patient is visiting for and are not routine, were more challenging for staff to conduct prompted choice whereas phlebotomy and practice nurse clinics were better suited to prompted choice. Staff also discussed their prioritisation of patient care over and above the intervention. This was a strong finding throughout all elements of this thesis that the participating practice had very high standards of patient care, and it was their primary priority. Which resulted in some
staff not conducting prompted choice in order not to jeopardise the patient-doctor relationship, but also resulted in staff conducting it because they believed they were providing a positive service for patients.

Finally, several recommendations regarding the intervention context were fulfilled. The intervention delivered the intended benefits to patients that it provided them with an opportunity to register. It also included mechanisms for patient safety with staff reporting not asking if they did not deem it appropriate, and adaptability for staff. This latter component, as previously discussed, could be responsible for the success of prompted choice with staff given the autonomy to conduct prompted choice how and when they wished during the intervention.

9.6 Challenges

The implementation challenges faced (SystmONE, NHS Ethical procedures, practice time) could explain why little research was found on organ donation interventions in the UK but also in general practice internationally (Chapter 2 and Chapter 3). Pradeep (2015) described barriers to conducting interventions in UK general practice, including lack of practice buy-in and recruitment challenges. Asghar et al. (n.d) found challenges to recruit practices and to encourage practice engagement in the intervention. In the wider literature challenges include lack of time, lack of incentives, workforce shortages, that research threatens meeting financial targets, increase in paperwork, impact on patient relationships, lack of interest in the research topic and not prioritising research (Yallop et al., 2006; Mason et al., 2007; Hummers-Pradier et al., 2008; Bower et al., 2009; Brodaty et al., 2013; Michalec, Fagan and Rahmer, 2014). These challenges could explain why general practice is not
explored as a setting for organ donation intervention and could also explain the recruitment challenges to the multi-practice feasibility study.

Another explanation for lack of engagement from practices in the multi-practice RCT could be the structural changes that were occurring in English primary care during this time. The NHS Long Term Plan introduced new primary care networks in 2019. These networks involve general practices grouping together to manage services within their area. Networks serve between 30,000-50,000 patients, and as of June 2019, every GP Practice was required to be a member of one (NHS England, 2019). This was introduced to practices in January 2019, and the previously discussed QOF deadline occurs at the end of the financial year (March 2019). The recruitment of practices for the RCT commenced from Monday 5\textsuperscript{th} March 2019 following ethical approval. Therefore it can be inferred that this time was busy for practices due to the QOF deadline, end of financial year and also due to the introduction of the new networks, and therefore may have impacted recruitment. Although the lack of response to recruitment attempts did impact the eventual abandonment of the trial, there were other challenges which collectively led to this decision being made.

Conducting research in the NHS with patients requires approval from specific bodies responsible for protecting their safety. Although essential for patient protection, many authors have highlighted the 'notorious' NHS REC process as lengthy and filled with unnecessary bureaucracy (Petrova and Barclay, 2019). As a PhD student new to it, this was one of the biggest challenges to conducting the research in this thesis. The single practice feasibility study approval took five months from submission to approval, which is short compared to some researchers' experiences (Petrova and Barclay, 2019). However,
particular issues were had with CAG who are responsible for providing favourable opinion regarding the use of patient data without informed consent. The CAG process requires data protection registration and completed IG toolkits for participating institutions. Although it is vital to approve the use of data in this manner, the system is built for large scale clinical trials being undertaken in hospitals with separate research and data governance departments. In general practice, this role falls to the Practice Manager who does not have the resources or expertise like a department dedicated to this purpose in a hospital would. Particularly the request of IG Toolkits to be approved by NHS Digital led to the eventual abandonment of the RCT. Through no fault of the practice or the research team, the delays caused by NHS Digital to approve these toolkits demonstrates the system is not fit for purpose for approving small scale student research projects which have tight timelines.

Additionally, it was frustrating for the research team that the NHS REC agreed that the ethical issues found by changing from a single practice study to multi-practice RCT remain the same; however CAG did not. Indeed, the procedures concerning collection and anonymisation of data without overt informed consent were more well defined than in the single practice study, as the possibility for incidental exposure to patient identifiers was now confirmed to be only restricted to NHS Number. This was debated with CAG; however they deemed the methodological change to RCT to be more than merely adding new sites to the intervention, and the knowledge that exposure to patient NHS Number for data linkage meant a separate application should be submitted. Many authors share the frustrations experienced, and there are calls for the process to be made more researcher friendly, be more consistent between committees, and more applicable particularly to researchers not conducting large scale pharmacological clinical trials (Jamrozik, 2004; Elwyn et al., 2005;
Stewart et al., 2008; McDonach, Barbour and Williams, 2009; Thompson and France, 2010; Braverman and Sidhu, 2011; Jonker, Cox and Marshall, 2011; Brown and Agius, 2012; Snooks et al., 2012; Kearney et al., 2014; Jansari et al., 2015; Dixon-Woods et al., 2016; Trace and Kolstoe, 2017). From the perspective of this research, more awareness is needed amongst staff in these organisations, of the time and resource-limited nature of student research. The provision of an expedited process in these instances could be considered as projects will most likely be smaller than more extensive studies led by multiple people.

SystmONE, the practice computer system, also proved to be a significant challenge for this research. TPP, the provider of this software to UK GP practices were contacted several times via telephone to discuss the possibilities of helping with the prompt questionnaire or directing to someone who could. TPP stated that SystmONE was built for practices to be able to make amendments themselves rather than needing external contractors. For research purposes, this increased the resource burden on the practices participating and relied on their skills and expertise in using SystmONE. Unfortunately, although the participating practice devoted a large amount of Practice Manager and administrator time to problem-solving this, they were not able to instruct the PhD student on how to construct a prompt or questionnaire. Luton CCG was contacted for advice on helping with this work, and the research team were informed that this would require a complicated application process to the CCG for their endorsement, before the provision of help. To go through another application and approval process was deemed unfeasible in the study timelines, mainly as the CCG could not provide estimates on how long this would take. They did, however, provide unofficial advice from their IT team on the creation of prompt and questionnaire. This advice incorrectly stated that read codes were not available relating to
organ donation, so a prompt could not be created. However, the CCG kindly provided contact information of external contractors who work on SystmONE related issues for them. This company was contacted and quoted a cost of £2507 for ten days work on the creation of the prompt and questionnaire. Resources for this research could not stretch to cover this cost; however, if the study were to progress, the use of external contractors for the prompt or questionnaire is recommended.

Although the PhD student successfully created a prompt and questionnaire, staff did not feel it was fit for purpose. In post-intervention data collection staff stated how the number of clicks and pop-ups involved in the prompt was too many, which was outside researcher control. Further, the prompt could only be triggered for specific activities; for example, if patients have a specific read code connected to their file, a prompt could be triggered to complete illness-specific tasks. The only option available to allow all patients in all consultations to receive a prompt was at the start of consultation. Staff expressed this was frustrating and caused them to exit the prompt and forget to ask on occasion. Additionally, the prompt appeared for non-patient facing events when staff were using patient files for administrative tasks. Relating to Lau et al.’s (2016) framework, these SystmONE issues did not make the intervention easy to use and integrate with workflows in this regard. Mainly as prompts in this manner are not used as standard practice. However, no recommendations on how to improve this can be suggested due to lack of expertise, and it is recommended that for future trials substantial financial resources are budgeted for to employ experts in SystmONE who may be able to overcome this. These experts will also be required to perform the SystmONE related tasks in multiple practices as these would be challenging for researchers to perform in a larger trial. Additionally, more time should be allowed for
prototype and usability testing of this system with a variety of staff types before the intervention.

9.7 Limitations

As well as challenges to this thesis, there are limitations to it also. The first of these is the challenge of obtaining grey literature in the systematic review. Only four studies were found through peer-reviewed journals, and six studies could be considered grey literature. In the UK, NHSBT is the body responsible for organ donation, including interventions and promotional activities. One of the studies obtained for the review came from NHSBT. Internationally, other organisations similar to this may have conducted primary care or general practice studies aiming to increase organ donation. Therefore conclusions made within this thesis that there is a dearth of literature on this topic can only refer to peer-reviewed journal articles. In the USA, for example, states take ownership of registries, and there could be an abundance of unpublished research in this area which is inaccessible to researchers. On reflection, a search for results on interventions conducted by these bodies could have been undertaken through contacting these organisations.

A further limitation concerns the use of theory and intervention mapping (IM). The authors of IM suggest that important gaps in the literature should be identified and research to fill these conducted to inform development (Bartholomew Eldredge et al., 2016). The theoretical review in chapter four highlights that there is a lack of consensus on the theoretical predictors of organ donation registration and evaluates three of the main models tested to explain this. However, it was found that the IIFF Model has not been evaluated for its predictive utility in enough studies or the UK population. Based on IM
guidance, this should have been explored prior to intervention development to ensure the IIFF model was applicable for a UK context. As previously stated, this research was funded by NHSBT to explore and test an intervention to increase organ donation registration in general practice. In order to fulfil this requirement, preparatory theoretical work on the IIFF model could not be conducted due to the limited time available. As a result, a pragmatic approach was taken in the design of this research to fulfil these requirements. However, the single practice feasibility results show that not all components of the IIFF model were fulfilled, supporting the need for more testing of this model. It is important to state, however, the authors of IM do not want developers to be put off using this method due to limited resources. They dedicate a section of the book (Bartholomew Eldredge et al., 2016, p.32) to outline that previous critique of IM, its complexity and resource-intensive nature, can be overcome by using it with the resources available to developers, however small these may be.

The stop-go criteria can also be seen as a limitation of the work in this thesis. The criteria for progression from the single practice feasibility study to RCT was minimal that only one staff member completed prompted choice once during the intervention period. Selecting this criteria was complex due to the funded nature of this work by NHSBT. It is challenging to define stop-go criteria based on the single practice findings, as NHSBT will ultimately decide whether the study should go ahead. Although academically stop-go criteria require definition, it is only NHSBT who can determine acceptable thresholds for resources the intervention uses, indications of success, and which rate of prompted choice completion by practices is successful. Ideally, consultation would have been held with NHSBT to discuss this, particularly with those staff members who are decision-makers. However, this was not
deemed appropriate before any intervention testing, due to the relatively small scale of this research compared to the managerial role these decision-makers play in NHSBT. It is recommended that NHSBT consult on the stop-go criteria of any future larger-scale trial.

Another factor to consider, however, is the challenge of which outcomes to use to determine stop-go criteria. Although NHS ODR registration is a vitally important part of the family consent process, family discussion is also of equal priority to NHSBT. Therefore registration rates alone may not be enough for them to conclude whether the intervention is feasible to conduct. For example, the 812 patients who visited the practice during the three months could have discussed organ donation with their family, and some members of their families decided to register as a donor. If people registered in any other manner except during prompted choice, there is no record that it was due to the intervention they experienced in GP practices. This element is particularly important as prompted choice could influence organ donation discussion in underrepresented areas on the NHS ODR – low Socioeconomic Status (SES) or Black, Asian and Minority Ethnic (BAME) groups, for example, if GP practices in these areas were conducting it. In the future, to examine intervention impact in this context, a large scale roll-out should be conducted in a large area of the UK, and pre-post intervention registration rates from this area examined by NHSBT.

Another limitation of the intervention is its applicability once England moves to an opt-out system of consent. As previously described, the aims and objectives of this thesis were defined before the opt-out consultation and subsequent adoption of it. Therefore, the intervention was designed for opt-in systems of consent, where prompting can allow people to opt-in to organ donation. There is the potential for the intervention to change to allow
patients to both opt-in and opt-out of organ donation via prompted choice; however, the infrastructure through which practices could register patients on the opt-out register would need to be in place to facilitate this. It is also possible that prompted choice could be used at the same time as a transition to opt-out and act as an educational tool as well as merely a prompt. However, this would require IM to be revisited to facilitate this, and the training adapted also. The introduction of opt-out also impacts the stop-go criteria, as the strategic objectives of NHSBT may change – for example, resources may be prioritised for opt-out educational marketing over opt-in registration interventions. Therefore the resources required to test it further and implement it could have been acceptable before opt-out; however, while NHSBT resources are focused on opt-out the intervention may no longer be a priority.

Methodologically there are also some limitations to the findings from the single practice feasibility study. During this study, baseline rates of NHS ODR registration by new patients were planned to be collected alongside registration rates from prompted choice. This data aimed to compare if the intervention targets more patients than usual care and to examine how baseline data could be collected for the future RCT. Unfortunately, the practice informed us that before and during the intervention period, the registration of new patients was significantly lower than usual. Therefore any data collected from new patient registration forms would not be an accurate representation of those patients who are typically exposed to a registration opportunity. Critically, the resources and methods to collect this data – either by researcher or practice administrators, could not be established. This is an essential element of the RCT, as control arm practices will only provide data from registrations obtained in this way. In the future, it is recommended that data collection pilot
studies are conducted with practices to examine how best this data is collected before any feasibility RCT.

Fidelity data on how staff conduct prompted choice could not be captured. Craig et al. (2008) state that examining fidelity in complex interventions is challenging, as some interventions may have strict standardisation guidelines whereas others, like prompted choice, may be more adaptable to local conditions (Craig et al., 2008). The only method of capturing prompted choice fidelity concerned whether it was conducted, not how it was conducted. It could be considered ethically important to examine whether staff adhere to the recommendations in training not to coerce and not to ask patients who may be distressed. However, how to examine this presents its own challenges ethically. Typically fidelity would be obtained through observations (video or in-person) of consultations with patients, or via self-report from staff (Breitenstein et al., 2010). These, however, have operationalisation problems. Video or in-person observations would require the patient to express their informed consent for this to occur during their consultation. Not only is this a sensitive time for patients, but would add additional time to an already stretched consultation. Self-report, on the other hand, may lack the validity of observation, with staff likely to respond in a socially desirable manner that they conducted prompted choice without coercion or with distressed patients. The challenge of how to capture the fidelity of prompted choice, particularly regarding ethics, should be revisited before the conduct of a future study.

Two oversights during the study design occurred, which resulted in amendments being submitted to the Health Research Authority (HRA) – the number of staff consultations held...
during the prompted choice period, and the removal of patient focus groups. It was important to understand how often prompted choice was conducted, compared with how often staff had consultations. This issue was only discussed however, once the intervention had started. In order to rectify this oversight, solutions were sought, which would allow for this data to be collected. On discussion with the Practice Manager and administrator however, they did not believe SystmONE could provide this data for specific staff members, only for the whole practice. Additionally, SystmONE would not distinguish between telephone and face to face consultations. Therefore it was concluded that manually counting these via an appointment screen, where no patient details are visible, was the only viable option. Although this was viable for the single practice feasibility study, if the intervention were to be tested in multiple practices in future, consideration would be required on whether it is feasible to collect data in this manner. The researchers would have to decide whether resources could stretch to do this, or if practice-wide consultation numbers could be used - in the knowledge that these may not validly represent the number of consultations had by only staff who had attended the training, nor whether these were via telephone or face to face.

Patient focus groups were initially planned to capture patient views on intervention acceptability. Recruitment to these was to be via text message, with those willing to participate contacting the researcher to schedule this. No system for screening these patients was introduced however, and this was only discussed whilst the intervention was running. As a result, concerns were had over researcher safety as the focus groups would be conducted in the practice with only one person facilitating them. The focus groups, therefore, were changed to an online survey to prevent risk to the researcher in this
manner. However, as the ethical approval for the study had already been obtained, the focus group topic guide was converted to this method and only minimally edited, to prevent further delays from the NHS ethical approval process occurring. These questions were very open in nature, and may not have been best suited to the online survey method. Indeed, the result that patient responses using this method were too brief to enable framework analysis to be conducted could indicate this was the case. In future, it is important that either patient focus groups are conducted with adequate researcher safety precautions, or the patient online survey is redesigned using closed questions, in order to better establish patient acceptability of the prompted choice intervention.

The final limitation of the work in this thesis regards distress and coercion. Extensive efforts were made during training to limit the impact of these on patients. Staff were instructed that the intervention was not to ‘persuade’ patients, merely offer them a sign-up opportunity to the NHS ODR. They were also instructed to use their professional discretion and only ask patients whom they believed would not be distressed by the topic. However, it is not possible to state that this completely mitigated these issues, and no patient was distressed by the topic or felt coerced. Indeed, one patient stated they felt pressured into signing up to the NHS ODR. It is important to recognise that the power dynamics present in healthcare settings, particularly between doctors and patients, could influence this intervention (Donetto, 2010). The traditionally paternalistic style of healthcare practice, where the clinician ‘knows best’, lends itself to potentially coercing patients to join the NHS ODR (Coulter, 1999). In this scenario, patients may be influenced by the status of a healthcare professional asking them if they would like to join – like the patient stated in their response to the survey. It could be that the patient who felt ‘pressured’ had an
appointment with a more traditional paternalistic healthcare professional. It is important, however, to examine the transition of clinical practice away from paternalism and towards patient-centred decision making (Coulter, 1999). Over the last 50 years, healthcare has strived to change from a ‘doctor decision making' model to a collaborative one where patients make informed choices about their healthcare with their doctors (Taylor, 2009). This makes coercion in the manner described less likely to occur as staff are routinely trained in the importance of patient-centred care (Taylor, 2009).

An important consideration when discussing this is the need to balance the ethical issues with the potential the intervention has to change and save lives. Although coercion and distress are very important to prevent, these should be weighed against the potential for public good of the intervention (The British Psychological Society, 2014). If the intervention were able to increase sign-up and public discussion of organ donation, this could result in an increase in the number of families consenting to donation and organs ultimately donated. Throughout the design of the intervention, the stakeholder group prioritised limiting the effect of coercion and distress. However, they were also mindful of the positive effect on organ donation the intervention could have. The group believed that although organ donation may be a distressing topic to discuss, the training provided in the intervention and the training clinicians receive in medical or nursing school was a strong enough strategy to mitigate against this. Further, registration on the NHS ODR was considered to be reversible if patients changed their mind after their consultation – unlike other medical interventions. It was also discussed that asking a patient to join the NHS ODR is supplementary to the consultation, like health markers used in the QOF. Therefore it can be considered standard
practice for clinicians in general practice to discuss unrelated clinical issues with patients under the guise of checking on general health or performing an administrative function.

9.8 Recommendations

The first recommendation is to investigate further the applicability of the IIFF Model of organ donation registration in general practice and the UK. A study by Siegel et al. (2016) investigated favorable activation in the DMV. Participants were recruited to complete an online survey which activated either the emotions present in the DMV or a control condition, and examined the impact of these on registration likelihood (Siegel et al., 2016). This study could be replicated in the UK about general practice and would be simple to operationalise due to its lack of involvement directly within NHS settings. Another alternative to this could examine patient emotions pre/during/post GP practice appointments in a variety of consultations (e.g., routine blood pressure testing, phlebotomy, test results) and examine the impact of these on prompted choice outcomes. However, this latter study would be challenging to conduct in the complex UK general practice environment.

The next recommendations relate to the intervention. Training, although very positively received in this intervention needs to be adaptable. If this intervention were to be made standard practice, this would require a trained and experience SNOD to conduct sessions in practices nationally. The practicalities of this could be complicated and resource-intensive. An alternative to face to face training could be to develop an online training program (Degenholtz et al., 2019). By changing the mode of delivery from face to face to online, this could greatly reduce the NHSBT resources required to deliver the training. Additionally, a
critical factor to study success is that as many staff as possible complete the training and ultimately conduct prompted choice. Online training could help reduce the recruitment issues found for training, and more staff could complete it due to its flexibility. However, it would be important to assess whether the positive views held for the in-person training can translate to online training. For prompted choice, a further avenue for investigation is how it could be implemented after Spring 2020, and the introduction of the opt-out system. An examination of NHSBT stakeholder views on the priorities of this, particularly whether opt-out registrations should also be facilitated could be conducted alongside patient views.

A feasibility RCT was planned as part of this research; however, several barriers prevented this from being conducted. This study was pragmatically designed to fit within the three year PhD period and to facilitate it being run by one person. Based on the findings in this thesis, a future feasibility RCT should be run as part of a future larger study run by more than one person. During the development of the methodology of this thesis, the expected design for general practice studies (cluster randomised controlled trial) was found to be not appropriate. Therefore each practice acts as an individual data point or as a ‘person’ within a traditional RCT. There are issues with this design, namely that if each practice is acting as a data point (the unit of analysis and randomisation) then a larger number of practices are required to conduct it than would be required in a cluster RCT. Due to this, it is recommended that an extensive program of research is conducted, which has the appropriate funding. A series of studies are required before a feasibility RCT. To pilot the data collection materials for the control arm (including CAG approval process) and to pilot an amended SystmONE prompt and questionnaire and its transition between practices by
an external organisation, to establish stop-go criteria as defined by NHSBT requirements and to develop and test a method to assess prompted choice fidelity.

Additionally, the intervention should be piloted in several other practices for feasibility before the conduct of an RCT; to examine transferability new feasibility issues that may occur and assess acceptability further with patients. Following this refinement of the intervention and data collection materials, it is proposed that an adapted study design using a nested pilot trial is used to establish the figures required for a future sample size calculation (Graffy et al., 2010). This involves embedding within a full RCT for effectiveness/efficacy a pilot trial used to determine sample size (Graffy et al., 2010). Thabane et al. (2010) state that several feasibility issues such as sample size estimation and protocol elements concerning randomisation cannot be examined until the intervention is tested in a full trial. If the procedures and sample size are defined during an embedded trial this allows for randomisation and blinding procedures to be preserved in a full trial – allowing for those practices recruited for the embedded pilot to be potentially used in a full scale trial (Lancaster, Dodd and Williamson, 2004; Thabane et al., 2010).

Recruitment was a critical issue for the single practice and multi-practice feasibility studies in this thesis. Future studies (both feasibility and full RCT) should be registered on the National Institute of Health Research (NIHR) Clinical Research Network Portfolio during the NHS Ethics Application, to overcome these issues. As this PhD studentship is match-funded by the University of Bedfordshire, it was not eligible for adoption to the portfolio (National Institute for Health Research, 2019b). Being adopted in this portfolio allows researchers to access several additional resources and support, particularly from R&D departments.
Discussions were held with the R&D department responsible for supporting this research project as part of the NHS Ethics application, and they stated that adopted studies could have practice recruitment facilitated by them using their network. Therefore portfolio adoption is recommended for a future RCT looking to recruit practices. It is also crucial in future RCTs to factor in the possibility of recruitment delays, mainly as these are commonplace in primary care research (Fernald et al., 2018). Additionally incentives should be considered for both the practice as a whole for their participation as well as for staff members participating in feasibility data collection forms such as surveys or focus groups to help improve recruitment compared to that in the single practice feasibility study (Pit, Vo and Pyakurel, 2014; Parkinson et al., 2015; Fernald et al., 2018).

9.9 Conclusions

The main aim fulfilled by this thesis was to develop and evaluate the feasibility of a general practice intervention designed to increase NHS ODR sign-up. Previously discussed is the lack of literature investigating interventions in this area; therefore, this thesis adds to this literature base as well as that on feasibility studies in UK general practice. The findings suggest that despite some feasibility issues, an intervention based on asking patients verbally if they wish to join the NHS ODR in general practice can be conducted and is perceived as acceptable by some staff and patients. This is the second study to the authors' knowledge, which uses IM to design and refine an organ donation intervention. Therefore, that steps one to four of this technique can be successfully used to create an intervention that aids registration as an organ donor, could help guide further organ donation
intervention develops to use it. This thesis also helps add to the literature on the IIFF model regarding developing organ donations.

It was also found to target an underrepresented group on the UK NHS ODR, older people and can facilitate sign-up of this group of people. The evidence found regarding SystmONE barriers to intervention development, to the best of the authors' knowledge, has never been reported before academically, which can help guide researchers to develop techniques and strategies to overcome these barriers before the implementation of interventions in this setting. Finally, this is one of the first interventions using the technique prompted choice conducted general practice internationally, and at the time of writing, nowhere in the UK currently provides the public with the opportunity to sign-up verbally to the NHS ODR. This technique mimics that of the Department of Motor Vehicles (DMV) in the USA, and the results of this study have wide-reaching implications for interventions targeting systems of UK NHS ODR registrations. It could ultimately help increase rates of organ donation in the UK through facilitating family consent to donation because more people have formally expressed their wish to be a donor.

Word Count: 76,548
10 References


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10.1080/13548501003623922.


Available at: http://10.0.3.248/S0277-9536(99)00325-1.


10.1016/j.transproceed.2008.03.060.
11 Appendices

Appendix 1: How do people sign up to the NHS Organ Donor Register? An exploratory analysis of sources of registration.

Removed to maintain confidentiality.
Appendix 2: GP Practice New Patient Registration Form (GMS1 Form)
**Appendix 3: Completed PRISMA Checklist for Systematic Review**

Table 38: PRISMA Checklist completed prior to systematic review publication in Transplantation Reviews.

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist item</th>
<th>Reported on section</th>
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<td></td>
<td></td>
<td></td>
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<tr>
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<td><strong>ABSTRACT</strong></td>
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<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
<td>3.2</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
<td>3.3</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
<td>3.4</td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
<td>3.4.1</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
<td>3.4.2</td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
<td>3.4.3</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
<td>3.4.3</td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
<td>3.4.4</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td>3.4.4</td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</td>
<td>N/A</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
<td>3.4.5</td>
</tr>
<tr>
<td>Summary measures</td>
<td>13</td>
<td>State the principal summary measures (e.g., risk ratio, difference in means).</td>
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<td>Section</td>
<td>Item</td>
<td>Description</td>
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<tr>
<td><strong>Synthesis of results</strong></td>
<td>14</td>
<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$) for each meta-analysis.</td>
<td>N/A</td>
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<tr>
<td><strong>Risk of bias across studies</strong></td>
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<td>Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
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<tr>
<td><strong>Additional analyses</strong></td>
<td>16</td>
<td>Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
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<tr>
<td><strong>RESULTS</strong></td>
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<td></td>
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<tr>
<td>Study selection</td>
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<td>Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.</td>
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<tr>
<td>Study characteristics</td>
<td>18</td>
<td>For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.</td>
<td>3.5.2</td>
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<tr>
<td>Risk of bias within studies</td>
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<td>Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).</td>
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<tr>
<td>Results of individual studies</td>
<td>20</td>
<td>For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.</td>
<td>3.5.4, 3.5.5, 3.5.6</td>
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<tr>
<td>Synthesis of results</td>
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<td>Present results of each meta-analysis done, including confidence intervals and measures of consistency.</td>
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<tr>
<td>Risk of bias across studies</td>
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<td>Present results of any assessment of risk of bias across studies (see item 15).</td>
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<tr>
<td>Additional analysis</td>
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<td>Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).</td>
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<td><strong>DISCUSSION</strong></td>
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<td></td>
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<tr>
<td>Summary of evidence</td>
<td>24</td>
<td>Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).</td>
<td>3.6.1</td>
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<tr>
<td>Limitations</td>
<td>25</td>
<td>Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).</td>
<td>3.6.4</td>
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<tr>
<td>Conclusions</td>
<td>26</td>
<td>Provide a general interpretation of the results in the context of other evidence, and implications for future research.</td>
<td>3.7</td>
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<td>Funding</td>
<td>27</td>
<td>Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.</td>
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*For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org)*.
Appendix 4: Systematic Review Protocol

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<th>Title:</th>
<th>Primary care interventions to encourage organ donation registration and familial discussion: a systematic review</th>
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<tr>
<td>Authors:</td>
<td>Pedder Jones, C. Institute of Health Research, University of Bedfordshire. <a href="mailto:catrinpedder.jones@beds.ac.uk">catrinpedder.jones@beds.ac.uk</a></td>
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<tr>
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<td>Papadopoulos, C. Institute of Health Research, University of Bedfordshire <a href="mailto:chris.papadopoulos@beds.ac.uk">chris.papadopoulos@beds.ac.uk</a></td>
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<td>Randhawa, G. Institute of Health Research, University of Bedfordshire <a href="mailto:gurch.randhawa@beds.ac.uk">gurch.randhawa@beds.ac.uk</a></td>
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<td>Asghar, Z. NHS Blood and Transplant. <a href="mailto:zeeshan.asghar@nhsbt.nhs.uk">zeeshan.asghar@nhsbt.nhs.uk</a></td>
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<td>Support:</td>
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Background and Rationale

In the UK between 1st April 2016 and 8th November 2016 6518 people were in need of an organ, however only 2022 transplants were carried out in that period (1). A similar pattern is present worldwide (2) with a disparity present between available organs and number needed. Organ donation can be either from a deceased or living person, the former has reduced over the past 10 years in the U.K (3). Improvements in car safety, medical treatment and a shift to lifestyle change to decrease certain diseases have been proposed to explain this reduction in donor rates (4). Although positive changes for society and mortality rates, these have negatively impacted the number of organs available for transplant after death, particularly brain stem death.

In opt-in countries, where consent for donation is not assumed, donation wishes of the deceased are acknowledged either by registry in life and/or by family consent after death. For example in the U.K. this occurs through registration as an organ donor on the Organ Donation Register (ODR). The ODR currently contains 22.5 million people, equating to 35% of the U.K. population (5). Being a member of a registry gives an official method for acknowledgement wishes and increases the likelihood of family consent (6). However, due to the importance of family consent within the donation process, registration alone is not enough to guarantee donation will take place (6).

Several interventions have been developed to improve rates of organ donation and reduce the disparity between need and actual transplant (3). These focus on targeting registration and/or discussing organ donation wishes with family members. Internationally these have been implemented using numerous techniques and settings, for example; health care professional training (7), hospital process improvement (8), mass media campaigns (9), school education (10), workplace (11), church (12), community (13) and primary care based interventions (14). Many systematic reviews on interventions in these areas have been carried out (e.g. school based interventions (10), healthcare professionals (7), ethnic minority focused interventions (15)). No review however has yet
been published focusing solely on interventions in the primary care setting. Numerous studies exist in this area and by reviewing these the most effective methods, strategies and theory can be used to base primary care studies and interventions in future. Finally, in the U.K. at present asking patients to join the ODR only occurs at registration, responsible for 14% of the total registrations (5). By developing a new U.K. primary care intervention based on the results of this review, it is anticipated that recruitment to the register can be boosted.

Research Questions

1. What interventions have previously been conducted in a primary care setting to increase deceased organ donation rates?

2. How successful were these interventions in improving both primary and secondary outcomes?

Inclusion Criteria

- Organ Donation Interventions
- Interventions set in a Primary Care Setting
- Primary Studies with experimental designs
- Reports one or more of the following outcomes:
  - Actual Behaviour: sign-up, conversations with family
  - Intention: to donate, to sign up to a register, to discuss with family
  - Cognitive: knowledge improvement, attitude change, barrier & facilitator improvement or identification.
- Published in the English language
- Published in the year 2000 or after

Exclusion Criteria

- Intervention not conducted in a Primary Care Setting
- Not an Organ Donation Intervention
- Non-experimental study design

Search Methods

Electronic Databases


Other Methods

Websites: Search engines - Google
Hand Searching: References of papers meeting eligibility criteria and relevant journals. Dissertations & theses, contact experts regarding potential studies.

Proposed Search Terms

((((Organ OR transplant)) AND intervention*) AND (GP OR "general pract*" OR "family medicine" OR physician* OR "primary care")

Scoping Reviews

Scoping reviews were carried out using the following search strings:

TI organ donation AND intervention AND primary care
TI organ donation AND TI ("primary care" OR GP OR doctor)
TI organ donation register AND (systematic review OR meta-analysis OR review OR meta)
TI organ donation AND TI (systematic review OR meta-analysis OR review OR meta)
TI (organ donor OR organ donation) AND TI ("primary care" OR GP OR doctor)
AB organ donation register.
Limiters: Academic Journals, duplicates removed.
Databases: The entirety of the DISCOVER EBSCO search system.

This identified no previous systematic review carried out on this topic.

### Review Methods

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<tr>
<th>Selection Process</th>
<th>Abstracts and full texts will be screened by one reviewer (CPJ). The former viewed to initially examine if exclusion criteria are met, if so, the full text will be subsequently viewed for eligibility by CPJ and one additional reviewer (CP or GR).</th>
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<tr>
<td>Data Extraction</td>
<td>Records will be managed using Endnote and a centralised Excel spreadsheet.</td>
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<tr>
<td></td>
<td>Primary Outcomes: Changes to actual behaviour e.g. actual registration, actual family conversation.</td>
</tr>
<tr>
<td></td>
<td>Secondary Outcomes: Changes to intention, changes to knowledge, attitudes, barriers and facilitators, changes to primary care practice.</td>
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<tr>
<td></td>
<td>Data will be collected using the following column headings in excel: title, author, date of publication, language, aims, hypotheses, design, sample details (size, method), intervention design &amp; timescale, intervention theory, intervention target group (patients/staff), intervention target gender, intervention target participant age, intervention target participant ethnicity, intervention target participant SES (if applicable; patient gender, patient age, patient ethnicity, patient SES), attrition, outcome, outcome measures, analysis method, outcome results, other results, limitations, other comments.</td>
</tr>
<tr>
<td>Bias assessment</td>
<td>Quality assessment will be examined using the Cochrane recommended ‘Assessment Tool for Quantitative Studies’. This tool is public health specific and examines; selection bias, design, confounders, blinding, data collection methods, withdrawals/dropouts, intervention integrity and analysis. It will be used alongside it’s accompanying manual which provides full instructions for use.</td>
</tr>
<tr>
<td>Data Synthesis</td>
<td>An Interpretative, thematic analysis and (if data allows) a meta-analysis may be conducted. This will examine the nature and delivery of interventions, outcomes assessed.</td>
</tr>
</tbody>
</table>

**Estimated Timeline**
<table>
<thead>
<tr>
<th>Protocol</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature Search</td>
<td>1 month</td>
</tr>
<tr>
<td>Quality Appraisal</td>
<td>2 months</td>
</tr>
<tr>
<td>Data Extraction</td>
<td></td>
</tr>
<tr>
<td>Synthesis</td>
<td></td>
</tr>
<tr>
<td>Writing Up</td>
<td>2 months</td>
</tr>
</tbody>
</table>

**References**

### Appendix 5: Recommendations for Intervention Development and Implementation Planning (Lau et al., 2016).

Table 39: Lau et al. (2016) recommendations for developing and implementing interventions in primary care.

<table>
<thead>
<tr>
<th>Contextual Level</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| **External Context** | Consider how your proposed intervention or change fits with current policy and the legislative framework as well as the organisation’s goals and objectives.  
Consider the economic climate nationally and locally. How will this affect resource allocation and your proposed intervention and implementation?  
Consider whether your intervention is congruent with dominant paradigms nationally and locally (e.g. NICE, professional leaders, media/public values).  
Identify, communicate and actively engage with key stakeholders about the benefits of the interventions and involve them in the process of implementation and decision making as early as possible. |
| **Organisation Context** | Devise a strategic implementation plan with realistic and measurable goals and milestones prior to implementation  
Clarify and widely disseminate expected benefits (e.g. improved patient health outcomes, streamlined care, more efficient work processes).  
Determine the necessary resources for all the stages of implementation (e.g. funding, adequate staff with appropriate skills, training and ongoing support) and consider how to provide these. Costs and resource needs may vary according to the phase of implementation – e.g. smaller (pilot) vs. larger (scaling) deployment phase.  
Consider how the intervention will impact on existing workflows and structures within the organisation, and respond appropriately.  
Identify and engage key internal and external leaders to promote the intervention.  
Identify and engage key staff to lead and coordinate the implementation.  
Actively involve all relevant personnel and foster collaboration between team members and management. |
| **Professional Context** | Consider how the new intervention influences or fits with the following:  
Professional role (e.g. will health care professionals see use of the intervention as congruent with their perceived role)  
Style of clinical practice – how different tasks are normally carried out  
Personal interest  
Consultation/ current workflow: a. Time; b. Relationship between health care professionals and patients |
| **Intervention Context** | Intervention characteristics that promote implementation include:  
Ease of use, good integration with existing systems and workflow, adaptable to local conditions  
Evidence that the intervention delivers intended benefits  
Established mechanisms for protecting patient safety, privacy and confidentiality |

Table 40: An examination of the active methods proposed by the planning group according to Lau et al.’s (2016) recommendations for implementation of primary care interventions.

<table>
<thead>
<tr>
<th>Suggestion</th>
<th>Intervention Implementation Recommendations (Lau et al., 2016)</th>
<th>Established mechanisms for protecting patient safety, privacy and confidentiality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patients are asked if they would like to join NHS ODR during consultations and information can be provided if required</td>
<td>Ease of use – May be challenging for all clinicians and patient dependent. However they have adequate expertise to answer questions</td>
<td>Consultations are private environments. Clinicians are trained in discussing challenging topics with patients as well as patient confidentiality. Clinicians would be able to use their discretion to determine whether patients should be asked or not; e.g. if patient has received bad news or is suffering from a severe mental health problem</td>
</tr>
<tr>
<td></td>
<td>Integration in workflow – May put pressure on consultation times. However clinicians undertake QOF health promotion activities which are similar to this suggestion.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adaptability – Could easily be transferred and adapted to all general practices.</td>
<td></td>
</tr>
<tr>
<td>2. Receptionists ask patients when they come up to the desk and offer information</td>
<td>Ease of use – receptionists may struggle to answer questions concerning organ donation compared with clinicians in consultations. However receptionists are used to carrying out ‘administrative’ tasks such as this, so could mirror the DMV in the USA and treat it as an administrative task.</td>
<td>Reception environments are not private, conversations could be overheard. In addition, organ donation could be a distressing topic and receptionists will be unable to determine whether a patient is suitable to be asked – this could cause ethical issues.</td>
</tr>
<tr>
<td></td>
<td>Integration in workflow- In some practices, receptionists do not have direct contact with every patient as screens are used for check-in.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adaptability - Most practices have receptionists. However receptionists are busy on the telephone as well as in person and have limited interaction time with patients.</td>
<td></td>
</tr>
<tr>
<td>3. Receptionists give people a paper form</td>
<td>Ease of use – More complex for receptionists to use, as they would need to provide a facility for collection of the forms and pens for all patients.</td>
<td>Receptionists will not be able to determine which patients it is appropriate to give the forms to and who could be distressed by the topic. Additionally, confidentiality issues arise as paper forms need to be collected containing sensitive data (patient name, age,</td>
</tr>
<tr>
<td>Integration in workflow – New patient registration forms are already given in this manner with pens, however the number of additional pens and interactions required to provide this for all patients would greatly increase workload for receptionists. Adaptability - Most practices have receptionists. However receptionists are busy on the telephone as well as in person and have limited interaction time with patients.</td>
<td>address, gender etc.). Mechanisms to privately store these forms would need to be in place.</td>
<td></td>
</tr>
<tr>
<td>---</td>
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<td></td>
</tr>
<tr>
<td><strong>4. Using electronic sign-in screens to ask patients</strong> Ease of use – The practice were unaware if SystmONE had the facility to add questions into patient sign-in screens. This would require external consultation on software and/or development of this with TPP SystmONE provider. Integration in workflow – Patients may not be expecting to be asked to respond to questions on digital check-in screens. However it would integrate well for practice as it would require little resources from them to conduct. Adaptability – Not all practices have the screen sign-in facility or use SystmONE. Other computer systems are used in UK general practice such as EMIS. Therefore this may not be as adaptable to all practices if they do not have the facility or use different software providers who may not be able to implement this.</td>
<td></td>
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</tr>
<tr>
<td>This is more private than being asked verbally in reception, however patients may be taken by surprise as it is not usual practice to be asked questions on sign-in screens. It is also ethically questionable as patients may not be making fully informed decisions and could press a button incorrectly indicating they wish to register.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>5. Including a sign-up stall run by the patient participation group in the waiting room</strong> Ease of use – This is challenging to use and involves voluntary participation by the PPG. It would require a large investment of time and requires an organised PPG member to facilitate this. Integration in workflow – For the practice the impact on workflow would be minimal, apart from providing a table and area where this stall could be run from. Adaptability – The stall is easily adaptable between practices as NHSBT already provide resources for this purpose to a number of organisations. However, it is dependent on how active the PPG are in each practice.</td>
<td>The PPG are not clinical professionals or practice professionals. It is unknown if they are trained in the same principles of patient privacy, confidentiality and safety. Volunteers will be unable to establish whether patients in the waiting room should be approached and there is potential for people in distress to be approached about a topic which is inappropriate i.e. death.</td>
<td></td>
</tr>
</tbody>
</table>
Table 41: An examination of the active methods proposed by the planning group and the findings from the literature review (Chapter 2) and systematic review (Chapter 3).

<table>
<thead>
<tr>
<th>Suggestion</th>
<th>Active or Passive Technique (Section 3.8)</th>
<th>Intervention Implementation Recommendations (Lau et al., 2016)</th>
<th>Literature Findings Method Fulfils</th>
<th>Literature Findings - Chapter Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Patients are asked if they would like to join NHS ODR during consultations and information can be provided if required</td>
<td>Active</td>
<td>This method would increase access to NHS ODR sign-up opportunities and explicitly to existing patients as well as new patients. The DMV in USA provides promising evidence that offering a verbal opportunity to join an organ donor registries is a successful intervention. IIFF model underpinning suggests this could be successful. Includes all four elements – Information, Favorable Activation, Immediate sign up opportunity and Focused engagement.</td>
<td>IMPROVE ACCESS</td>
<td>2.3.3. 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>VERBAL SIGN-UP</td>
<td>2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>IIFF MODEL</td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>INTERPERSONAL EDUCATIONAL</td>
<td>2.3.3  2.2.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TARGETS PASSIVE POSITIVES</td>
<td>2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ACCESS TO MOST PATIENTS</td>
<td>2.3.3.</td>
</tr>
</tbody>
</table>
12. **Receptionists ask patients when they come up to the desk and offer information**

   **Active**

   This method would increase access to NHS ODR sign-up opportunities and explicitly to existing patients as well as new patients.

   **IMPROVE ACCESS** 2.3.3. 2.2.3.

   The DMV in USA provides promising evidence that offering a verbal opportunity to join an organ donor registries is a successful intervention.

   **VERBAL SIGN-UP** 2.2.3.

   IIFF model underpinning suggests this could be successful – however receptionists will not be able to determine whether patients are in favorable activation as well as clinicians in a consultation.

   **IIFF MODEL – NOT FAVORABLE ACTIVATION** 4.2.

   This is an interpersonal intervention however it does not have the ability to provide education by qualified professional.

   **INTERPERSONAL** 2.3.3 2.2.3.

   Would help target passive positives as they would only have to respond yes or no if they wished to sign-up. Rather than fill in and submit a form themselves.

   **TARGETS PASSIVE POSITIVES** 2.2.3.

   This is a relatively simple intervention with one core component.

   **SIMPLICITY** 3.8.

13. **Receptionists give people a paper form**

   **Active**

   This method would increase access to NHS ODR sign-up opportunities and explicitly to existing patients as well as new patients.

   **IMPROVE ACCESS** 2.3.3. 2.2.3.

   IIFF model underpinning suggests this could be successful – however receptionists will not be able to determine whether patients are in favorable activation as well as clinicians in a consultation.

   **IIFF MODEL – NOT FAVORABLE ACTIVATION** 4.2.
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>14. Using electronic sign-in screens to ask patients</strong></td>
<td><strong>Active</strong></td>
<td>This method would increase access to NHS ODR sign-up opportunities and explicitly to existing patients as well as new patients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IMPROVE ACCESS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.3.3. 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IIFF model only adheres to one component – Immediate Sign-Up Opportunity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IIFF MODEL – NOT INFORMATION, FAVORABLE ACTIVATION OR FOCUSED ENGAGEMENT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This is a relatively simple intervention with one core component.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SIMPLICITY</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.8.</td>
</tr>
<tr>
<td><strong>15. Including a sign-up stall run by the patient participation group in the waiting room</strong></td>
<td><strong>Active</strong></td>
<td>This method would increase access to NHS ODR sign-up opportunities and explicitly to existing patients as well as new patients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IMPROVE ACCESS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.3.3. 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IIFF model underpinning suggests this could be successful – however volunteers will not be able to determine whether patients are in favorable activation as well as clinicians in a consultation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IIFF MODEL – NOT FAVORABLE ACTIVATION</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This is an interpersonal intervention however it does not have the ability to provide education by qualified professional.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>INTERPERSONAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.3.3. 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Access to most patients visiting the surgery would be achieved through this method as pass through the waiting area.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACCESS TO MOST PATIENTS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.3.3.</td>
</tr>
</tbody>
</table>
Table 42: An examination of the passive methods proposed by the planning group according to Lau et al.’s (2016) recommendations for implementation of primary care interventions.

<table>
<thead>
<tr>
<th>Suggestion</th>
<th>Intervention Implementation Recommendations (Lau et al., 2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ease of use, good integration with existing systems and workflow, adaptable to local conditions</td>
</tr>
<tr>
<td></td>
<td>Established mechanisms for protecting patient safety, privacy and confidentiality</td>
</tr>
<tr>
<td>1. Leaflets with registration forms are provided in the practice</td>
<td>Ease of use – Simple and easy to use.</td>
</tr>
<tr>
<td></td>
<td>Integration in workflow – Leaflets are already displayed in all practices as standard.</td>
</tr>
<tr>
<td></td>
<td>Adaptability – Very adaptable to practices.</td>
</tr>
<tr>
<td>2. Adding a message to the ‘news’ section of the website with link to</td>
<td>Ease of use – Simple and easy to use.</td>
</tr>
<tr>
<td>NHSBT sign-up page</td>
<td>Integration in workflow – Would integrate well if the practice have a news site and patients use it.</td>
</tr>
<tr>
<td></td>
<td>Adaptability – All practices have a website, however they may not have a ‘news’ section or keep this updated as often as the participating practice.</td>
</tr>
<tr>
<td>3. Adding a message on the text message appointment reminder service</td>
<td>Ease of use – Fairly simple to use for the practice as text message reminders can be edited on SystmONE simply.</td>
</tr>
<tr>
<td></td>
<td>Integration in workflow – Would integrate well into workflows as text message appointment reminders are sent out routinely as standard in the participating practice.</td>
</tr>
<tr>
<td></td>
<td>Patients may be in distress when they receive a text message concerning organ donation. This could be problematic for patient safety as there is no facility to control for this using this technique.</td>
</tr>
<tr>
<td>4. The use of television screens to display content regarding organ donation</td>
<td>Ease of use – Simple to use, however the design of the content would have to be created from scratch and approved by NHSBT.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Integration in workflow – Would integrate well into existing workflows as information screens are used within the practice.</td>
</tr>
<tr>
<td></td>
<td>Adaptability – Not all practices display information in this manner, however if they do it is relatively easily adaptable.</td>
</tr>
<tr>
<td>5. Adding hold messages to the telephone appointment line</td>
<td>Ease of use – Relatively simple to use, however material would have to be recorded from scratch with NHSBT approval.</td>
</tr>
<tr>
<td></td>
<td>Integration in workflow – Would integrate well into existing workflow as information is often provided to patients in this manner.</td>
</tr>
<tr>
<td></td>
<td>Adaptability – Would adapt well to different practices all of whom have telephone hold messages. However the software used to provide this may differ between practices.</td>
</tr>
</tbody>
</table>
Table 43: Examination of the passive methods proposed by the planning group and the findings from the literature review (Chapter 2) and systematic review (Chapter 3).

<table>
<thead>
<tr>
<th>Suggestion</th>
<th>Active or Passive Technique (Section 3.8)</th>
<th>Intervention Implementation Recommendations (Lau et al., 2016) Evidence that the intervention delivers intended benefits</th>
<th>Literature Findings Method Fulfils</th>
<th>Literature Findings - Chapter Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Leaflets with registration forms are provided in the practice</td>
<td>Passive</td>
<td>This method would increase access to NHS ODR sign-up opportunities and explicitly to existing patients as well as new patients.</td>
<td>IMPROVE ACCESS</td>
<td>2.3.3. 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IIFF model only adheres to two components – Information and Immediate Sign-up Opportunity.</td>
<td>IIFF MODEL – NOT FAVORABLE ACTIVATION OR FOCUSED ENGAGEMENT</td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Access to most patients visiting the surgery would be achieved through this method as pass through the waiting area.</td>
<td>ACCESS TO MOST PATIENTS</td>
<td>2.3.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This is a relatively simple intervention with one core component.</td>
<td>SIMPLICITY</td>
<td>3.8.</td>
</tr>
<tr>
<td>2. Adding a message to the ‘news’ section of the website with link to NHSBT Sign-up page</td>
<td>Passive</td>
<td>This method would increase access to NHS ODR sign-up opportunities and explicitly to existing patients as well as new patients.</td>
<td>IMPROVE ACCESS</td>
<td>2.3.3. 2.2.3.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IIFF model only adheres to one component – Information</td>
<td>IIFF MODEL – NOT IMMEDIATE SIGN-UP, FAVORABLE ACTIVATION OR FOCUSED ENGAGEMENT</td>
<td>4.2.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This is a relatively simple intervention with one core component.</td>
<td>SIMPLICITY</td>
<td>3.8.</td>
</tr>
<tr>
<td>3. Adding a message on the text message appointment reminder service</td>
<td>Passive</td>
<td>This method would increase access to NHS ODR sign-up opportunities and explicitly to existing patients as well as new patients.</td>
<td>IMPROVE ACCESS</td>
<td>2.3.3. 2.2.3.</td>
</tr>
<tr>
<td></td>
<td>4. The use of television screens to display content regarding organ donation</td>
<td>Passive</td>
<td>IIFF model only adheres to one component – Information</td>
<td>IIFF MODEL – NOT IMMEDIATE SIGN-UP, FAVORABLE ACTIVATION OR FOCUSED ENGAGEMENT</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>This is a relatively simple intervention with one core component.</td>
<td>SIMPLICITY</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Access to most patients visiting the surgery would be achieved through this method as pass through the waiting area.</td>
<td>ACCESS TO MOST PATIENTS</td>
</tr>
<tr>
<td></td>
<td>5. Adding hold messages to the telephone appointment line</td>
<td>Passive</td>
<td>IIFF model only adheres to one component – Information</td>
<td>IIFF MODEL – NOT IMMEDIATE SIGN-UP, FAVORABLE ACTIVATION OR FOCUSED ENGAGEMENT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>This is a relatively simple intervention with one core component.</td>
<td>SIMPLICITY</td>
</tr>
</tbody>
</table>
Appendix 7: Final Training Slides

Appendix 8: Training Theatre Forum Case Studies

Appendix 9: Training Manual

Appendices 7-9 removed to maintain practice anonymity.
### Appendix 10: SPIRIT Checklist for Published Protocol – March 2018

Table 44: “SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents”

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Addressed on page number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Administrative information</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
<td>1</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td>N/A</td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
<td>1</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
<td>24</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1, 25</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Introduction
## Background and rationale

6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

6b Explanation for choice of comparators

## Objectives

7 Specific objectives or hypotheses

## Trial design

8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

## Methods: Participants, interventions, and outcomes

### Study setting

9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

### Eligibility criteria

10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

### Interventions

11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

### Outcomes

12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

### Participant timeline

13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
<table>
<thead>
<tr>
<th>Sample size</th>
<th>14</th>
<th>Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment</td>
<td>15</td>
<td>Strategies for achieving adequate participant enrolment to reach target sample size</td>
<td>12</td>
</tr>
</tbody>
</table>

**Methods: Assignment of interventions (for controlled trials)**

**Allocation:**

<table>
<thead>
<tr>
<th>Sequence generation</th>
<th>16a</th>
<th>Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment mechanism</td>
<td>16b</td>
<td>Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned</td>
<td>N/A</td>
</tr>
<tr>
<td>Implementation</td>
<td>16c</td>
<td>Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions</td>
<td>N/A</td>
</tr>
<tr>
<td>Blinding (masking)</td>
<td>17a</td>
<td>Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>17b</td>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Methods: Data collection, management, and analysis**

<table>
<thead>
<tr>
<th>Data collection methods</th>
<th>18a</th>
<th>Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol</th>
<th>7-17</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18b</td>
<td>Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols</td>
<td>N/A</td>
</tr>
<tr>
<td>Section</td>
<td>Item</td>
<td>Description</td>
<td>Page(s)</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Data management</td>
<td>19</td>
<td>Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol</td>
<td>17-18</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>20a</td>
<td>Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>20b</td>
<td>Methods for any additional analyses (eg, subgroup and adjusted analyses)</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)</td>
<td>N/A</td>
</tr>
<tr>
<td>Methods: Monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>21b</td>
<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
<td>N/A</td>
</tr>
<tr>
<td>Harms</td>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
<td>13</td>
</tr>
<tr>
<td>Auditing</td>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
<td>13</td>
</tr>
<tr>
<td>Ethics and dissemination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research ethics approval</td>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
<td>19, 24</td>
</tr>
<tr>
<td>Protocol amendments</td>
<td>25</td>
<td>Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)</td>
<td>24</td>
</tr>
<tr>
<td>Consent or assent</td>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>19</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------</td>
<td></td>
</tr>
<tr>
<td>Confidentiality</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
<td>19-20</td>
<td></td>
</tr>
<tr>
<td>Declaration of interests</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Access to data</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Ancillary and post-trial care</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Dissemination policy</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Appendices</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Biological specimens</td>
<td>Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons Attribution-NonCommercial-NoDerivs 3.0 Unported license.*
**Appendix 11: Study Monitoring Form V1 and V2**

**Study 1 – Single Practice Feasibility Monitoring Form V2 April 2018**

<table>
<thead>
<tr>
<th>Monitoring Visit Date</th>
<th>Monitoring Visit Time</th>
<th>Monitoring Visit Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Who study discussed with?</th>
<th>Practice Manager/Office Manager/Other (specify other)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Practice Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitor Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Posters</th>
</tr>
</thead>
</table>
| Are study posters informing patients about organ donation study in place? (non-NHSBT) | Yes/No  
Expand on No:  
Were posters replaced if not in positions: Yes/No |
| Are study posters for staff helplines & support in place? (non-NHSBT) | Yes/No  
Expand on No:  
Were posters replaced if not in positions: Yes/No |
| Are NHSBT posters displayed in key locations? | Waiting room – Yes/No  
Upstairs waiting room – Yes/No  
Were posters replaced if not in positions: Yes/No |
|                                                 |
### English Leaflets

<table>
<thead>
<tr>
<th>Leaflet Type</th>
<th>Number of leaflets remaining on display</th>
<th>Were leaflets restocked to original number?</th>
<th>Total no. of leaflets displayed after visit.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Check 1</td>
<td>Check 2</td>
<td></td>
</tr>
<tr>
<td>Religious perspectives</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buddhism</td>
<td></td>
<td>Y/N</td>
<td></td>
</tr>
<tr>
<td>Christianity</td>
<td></td>
<td>Y/N</td>
<td></td>
</tr>
<tr>
<td>Hinduism</td>
<td></td>
<td>Y/N</td>
<td></td>
</tr>
<tr>
<td>Islam</td>
<td></td>
<td>Y/N</td>
<td></td>
</tr>
<tr>
<td>Judaism</td>
<td></td>
<td>Y/N</td>
<td></td>
</tr>
<tr>
<td>Sikhism</td>
<td></td>
<td>Y/N</td>
<td></td>
</tr>
<tr>
<td>Questions Answered</td>
<td></td>
<td>Y/N</td>
<td></td>
</tr>
<tr>
<td>3 Fold Yes I donate</td>
<td></td>
<td>Y/N</td>
<td></td>
</tr>
</tbody>
</table>

### Language Specific Religious Leaflets

<table>
<thead>
<tr>
<th>Language</th>
<th>Religion</th>
<th>Were leaflets restocked?</th>
<th>Total no. of leaflets displayed after visit.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hindi</td>
<td>Hinduism</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Tamil</td>
<td>Hinduism</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Gujarati</td>
<td>Hinduism</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Punjabi</td>
<td>Hinduism</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Polish</td>
<td>Christianity</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Arabic</td>
<td>Islam</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Punjabi</td>
<td>Islam</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Somali</td>
<td>Islam</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Bengali</td>
<td>Islam</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Gujarati</td>
<td>Islam</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Urdu</td>
<td>Islam</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Punjabi</td>
<td>Sikhism</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

### Data Summary Checklist

- Has yes questionnaire data been anonymised and exported onto study memory stick?
- Has no questionnaire data been anonymised and exported onto study memory stick?
- Have demographic variables been inputted into yes and no export data on study memory stick?
- Have any export files apart from those on memory stick been deleted from practice computers?
- Have staff consultations been counted?
### Step 2

**No Questionnaire**

<table>
<thead>
<tr>
<th>Data Date Range</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Data File Name</td>
<td></td>
</tr>
<tr>
<td>Was raw data saved onto practice computer?</td>
<td></td>
</tr>
<tr>
<td>Was raw data password protected?</td>
<td></td>
</tr>
<tr>
<td>On eyeballing the data, were any untrained staff completing the questionnaire?</td>
<td>If yes, have staff been informed? Y/N</td>
</tr>
</tbody>
</table>

### Step 3

**Demographic Information – Yes Questionnaire**

<table>
<thead>
<tr>
<th>Data Date Range</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Data File Name</td>
<td></td>
</tr>
<tr>
<td>Was raw data saved onto practice computer?</td>
<td></td>
</tr>
<tr>
<td>Was raw data password protected?</td>
<td></td>
</tr>
<tr>
<td>Has age been inputted into Yes Questionnaire Spreadsheet?</td>
<td></td>
</tr>
<tr>
<td>Has gender been inputted into Yes Questionnaire Spreadsheet?</td>
<td></td>
</tr>
<tr>
<td>Has ethnicity been inputted into Yes Questionnaire Spreadsheet?</td>
<td></td>
</tr>
<tr>
<td>Have duplicate patients been recorded?</td>
<td></td>
</tr>
</tbody>
</table>

### Step 4

**Demographic Information – No Questionnaire**

<table>
<thead>
<tr>
<th>Data Export Date Range</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Export File Name</td>
<td></td>
</tr>
<tr>
<td>Was raw data saved onto practice computer?</td>
<td></td>
</tr>
<tr>
<td>Was raw data password protected?</td>
<td></td>
</tr>
<tr>
<td>Has age been inputted into No Questionnaire Spreadsheet?</td>
<td></td>
</tr>
<tr>
<td>Has gender been inputted into No Questionnaire Spreadsheet?</td>
<td></td>
</tr>
<tr>
<td>Has ethnicity been inputted into No Questionnaire Spreadsheet?</td>
<td></td>
</tr>
<tr>
<td>Have duplicate patients been recorded?</td>
<td></td>
</tr>
</tbody>
</table>

### Step 5

**Anonymisation & Export**

<table>
<thead>
<tr>
<th>Have all patient identifiers been removed from the Yes Questionnaire spreadsheet containing demographic information?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Have all patient identifiers been removed from the No Questionnaire spreadsheet containing demographic information?</td>
<td></td>
</tr>
<tr>
<td>Has completed anonymised Yes Questionnaire data been moved onto memory stick?</td>
<td></td>
</tr>
<tr>
<td>Has completed anonymised No Questionnaire data been moved onto memory stick?</td>
<td></td>
</tr>
<tr>
<td>Have all other identifiable export files been deleted off practice computer?</td>
<td></td>
</tr>
</tbody>
</table>
Monitoring Notes
Appendix 12: Training Evaluation Survey Participant Information Sheet

TRAINING PARTICIPANT INFORMATION SHEET

Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
IRAS ID: 230702

Introduction
I am Catrin Pedder Jones, a PhD Student working with the University of Bedfordshire and NHS Blood and Transplant. I am conducting research on the feasibility of organ donation interventions in a U.K. primary care setting. I am going to give you some information and invite you to be part of this research project. Before you decide to take part, you can ask any questions you like and take some time to think about your decision. If you do not understand elements of this consent form, please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me.

Purpose of the research
The NHS Organ Donor Register is a database which keeps a record of everyone who wants to donate their organs after death. However, only 35% of the U.K. population are on the NHS Organ Donor Register. To help increase this, we have developed an intervention in partnership with *practice name*.

As you are aware, an intervention will be conducted in *practice name* for the next three months and the training session is the first part of this. We now wish to see what staff thought of the training session.

This research will involve your participation in a survey that will take approximately five minutes.

You have been invited to take part because we feel you could give us valuable information about our training and are a staff member at *practice name*.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

Procedures
We require you to complete the attached consent form and evaluation questionnaire. Once completed please hand this to the researcher Catrin P Jones.

Risks & Benefits
There are few risks identified in taking part in this survey. However, the training content will concern organ donation and some may find this distressing. Telephone numbers for support services are supplied on the last page of this PIS. There will be no direct benefit to you, but
your participation is likely to help us adapt our training and help us increase membership of the NHS Organ Donor Register in other GP Practices.

**Reimbursements**
You will not be provided any incentive to take part in the research and will not receive reimbursements for expenses.

**Confidentiality**
We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone. Your Consent form will not be stored with your evaluation responses. Only your participant identification number will be used on your responses.

**Sharing the Results**
Nothing that you write in the survey will be attributed to you by name. It may however be attributed to *practice name*. The knowledge that we get from this research may be published in academic journals or distributed by the media. This is so that others may benefit from our findings in this research project. Additionally, we may quote parts of what you say in these publications and responses may be traceable back to *practice name* in publication. However, these will be anonymous and not include your name.

**Right to Refuse or Withdraw**
You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the survey at any time that you wish without your job being affected. You also may withdraw your responses following the evaluation period. However, please bear in mind that if data has been analysed it will no longer be possible for you to withdraw your responses.

**Ethical Approval**
This proposal has all been reviewed and approved by the Heath Research Authority and Brent Research Ethics Committee whose task it is to make sure that research participants are protected from harm. This proposal has also been reviewed and approved by the University of Bedfordshire Research Ethics Committee who are part-funding the study.

**Who to Contact**
If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

**Catrin Pedder Jones, PhD Student.**
Telephone:
Email: catrin.jones1@study.beds.ac.uk

Dr. Chris Papadopoulos, Supervisor
Email: chris.papadopoulos@beds.ac.uk
If you feel affected in any way by the topic of organ donation, please see below for some local support services who may be able to help.

Samaritans: 116 123  
Cruse Bedfordshire, Bereavement Counselling: 01582 595300  
Keech Hospice Care Bereavement Service: 01582 492339
Appendix 13: Training Evaluation Survey Consent Form

TRAINING EVALUATION SURVEY CONSENT FORM

Title of Project: Organ donation intervention in primary care: A feasibility study.

Name of Researcher: Catrin Pedder Jones

- I confirm that I have read the information sheet dated September 2017 (V2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

- I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

- I agree to take part in the above study.

Name of Participant __________________________ Date __________ Signature ______________

Name of Person taking consent __________________________ Date __________ Signature ______________

IRAS ID: 230702
Centre Number: 001
Study Number: 001
Participant Identification Number:
Appendix 14: Training Evaluation Survey Questions

ORGAN DONATION TRAINING EVALUATION FORM V2 September 2017
Please indicate your level of agreement with the following statements on a scale of 1 – 10 (agree):

Overall the training successfully prepared me to implement the organ donation intervention.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Agree</td>
</tr>
</tbody>
</table>

The training was worth attending.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Agree</td>
</tr>
</tbody>
</table>

The time taken to attend this training was acceptable.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Agree</td>
</tr>
</tbody>
</table>

The training successfully prepared me to conduct organ donation discussions with patients.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Agree</td>
</tr>
</tbody>
</table>

The training successfully prepared me to answer questions about organ donation.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disagree</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Agree</td>
</tr>
</tbody>
</table>

The training content was too basic.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
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The training has increased my knowledge of organ donation.

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The training has improved my confidence in conducting organ donation conversations with patients.

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Please rate your satisfaction levels with the following between 1 – 10.

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The use of slides and other resources.

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Please provide comments on the following:

Strengths of the training

Weaknesses of the training

374
To help us improve our training package for this intervention, please provide any additional comments below.

Finally, please tick the box which most closely describes your staff group.

| Clinical - Doctor                         |
| Clinical – Nurse                        |
| Clinical – Other                        |
| Administrative – with clinical training |
| Administrative – with no clinical training |
FOCUS GROUP PARTICIPANT INFORMATION SHEET – Staff

Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
IRAS ID: 230702

Introduction

I am Catrin Pedder Jones, a PhD Student working with the University of Bedfordshire and NHS Blood and Transplant. I am conducting research on the feasibility of organ donation interventions in a U.K. primary care setting. I am going to give you some information and invite you to be part of this research project. Before you decide to take part, you can ask any questions you like and take some time to think about your decision. If you do not understand elements of this consent form, please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me.

Purpose of the research

The NHS Organ Donor Register is a database which keeps a record of everyone who wants to donate their organs after death. However, only 35% of the U.K. population are on the NHS Organ Donor Register. To help increase this, we have developed an intervention in partnership with *practice name*.

As you are aware, the intervention has been conducted in *practice name* for the past three months and is over. We now wish to see what staff thought of the intervention. This research will involve your participation in a group discussion that will take approximately 30 minutes to 1 hour.

You have been invited to take part because we feel you could give us valuable information about our intervention, are a staff member at *practice name*.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

Procedures

We are asking you to help us learn about how you, the staff, found the intervention. If you accept, a date and time will be arranged for you to meet and discuss it. There will be 6 – 8 other people invited who will all be of the same staff grouping as yourself (Administrative, Clinical – GP or Clinical – Other), and it will be conducted in a private room at *practice name*. You will be invited to sit down and we will make sure you are comfortable before we begin. An opportunity will be provided to address questions you may have before we begin.

In this discussion, I, the researcher, will ask the group questions about the intervention. I will also guide your conversation to make sure we stay on topic. The discussion will be
recorded using a Dictaphone (recording device) and I will take notes occasionally while you are talking.

You will be asked questions about the organ donation intervention. For example, if you liked it, disliked it, noticed it and what impact it had on you and your work. We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.

No one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept in a locked filing cabinet at the University of Bedfordshire. The information recorded is confidential, and no one else except Catrin P Jones will have access to the tapes. The tapes will be destroyed after 5 years.

**Duration**

After the group discussion, your participation in the research will be over. You will be able to contact me, the researcher or my supervisors if you have concerns or questions. Following the focus group an online survey will be distributed to all staff. More information about this will be given in the email accompanying the circulation of this.

**Risks**

There are few risks to taking part in the research. However, discussions may involve the topic of organ donation and death, which some people might find difficult. Telephone numbers of support services can be found at the end of this PIS.

You do not have to answer any question or take part in the discussion if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview.

**Benefits**

There will be no direct benefit to you, but your participation is likely to help us adapt our intervention and help us increase membership of the NHS Organ Donor Register in other GP Practices.

**Reimbursements**

You will not be provided any incentive to take part in the research and will not receive reimbursements for expenses.

**Confidentiality**

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the
group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.

**Sharing the Results**
Nothing that you tell us today will be attributed to you by name. It may however be attributed to *practice name*. The knowledge that we get from this research may be published in academic journals or distributed by the media. This is so that others may benefit from our findings in this research project. Additionally, we may quote parts of what you say in these publications and responses may be traceable back to *practice name* in publication. However, these will be anonymous and not include your name.

**Right to Refuse or Withdraw**
You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the discussion at any time that you wish without your job being affected.

**Ethical Approval**
This proposal has all been reviewed and approved by the Heath Research Authority and London Brent Research Ethics Committee which is a committee whose task it is to make sure that research participants are protected from harm. This proposal has also been reviewed and approved by the University of Bedfordshire Research Ethics Committee who are part-funding the study.

**GDPR Statement**
The University of Bedfordshire is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bedfordshire will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Catrin Jones, catrinpedder.jones@beds.ac.uk.

**Who to Contact**
If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Catrin Pedder Jones, PhD Student.
Telephone:
Email: [catrin.jones1@study.beds.ac.uk](mailto:catrin.jones1@study.beds.ac.uk)
Dr. Chris Papadopoulous, Supervisor  
Email: chris.papadopoulous@beds.ac.uk

Prof. Gurch Randhawa, Supervisor  
Email: gurch.randhawa@beds.ac.uk

If you feel affected in any way by these discussions, please see below for some local support services who may be able to help.

Samaritans: 116 123  
Cruse Bedfordshire, Bereavement Counselling: 01582 595300  
Keech Hospice Care Bereavement Service: 01582 492339
Appendix 16: Focus Group Consent Form

CONSENT FORM - Version 1. 13 July 2017
Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
Study Element: Focus Group

- I confirm that I have read the information sheet dated.................... (version............) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

- I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

- I agree to take part in the above study.

____________________________  __________________________  _______________________
Name of Participant       Date                     Signature

____________________________  __________________________  _______________________
Name of Person            Date                     Signature
taking consent

IRAS ID: 230702
Centre Number:
Study Number:
Participant Identification Number:
Appendix 17: Clinical Staff Focus Group Topic Guide

Version 1. 13 July 2017

FOCUS GROUP TOPIC GUIDE – Clinical Staff

Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
IRAS ID:

Welcome & Introduction
- Participants will be welcomed into the room and offered refreshments.
- Once all participants are seated, introduce self and thank participants for agreeing to take part.
- Give brief background to the project.
  o University of Bedfordshire & NHSBT funded.
  o We want to capture experiences of the intervention
- After this introduction we will talk about your experiences of the intervention, the data collection procedures, how well it fits within the practice and if you have any recommendations.
- Emphasise that the project is assessing feasibility and that honest views are really important. Even if they are negative.

Anonymity
- The focus group is being taped, however this discussion will be anonymous when transcribed.
- Please try not to use names in our discussion. Numbers will be allocated to each person and placed in front of you. Try and use these instead.
- If you do use names however, don’t worry, these will be anonymised later.
- It is important to remember that your responses may be associated with *practice name* in publication even though they are anonymous.
- Please do not discuss the content of this focus group outside of this room.

PIS & Consent Forms
- The patient information sheet and consent forms will be distributed.
- Participants will be instructed to read through these and the key content will be explained by the facilitator.
- Questions will be invited.
- Participants will be instructed to sign the consent form if they consent.
- Participant ID numbers will be cross referenced to training forms.

Ground Rules
- The most important rule is that only one person speaks at a time. There may be a temptation to jump in when someone is talking but please wait until they have finished.
- There are no right or wrong answers
- You do not have to speak in any particular order
- When you do have something to say, please do so. There are many of you in the group and it is important that I obtain the views of each of you
- You do not have to agree with the views of other people in the group
- Does anyone have any questions? (answers).
- OK, let’s begin

**Introductory Question**
- Can you briefly talk about your experience of the intervention overall?
  - Prompts: Was it positive or negative overall and why? Easy or difficult and why?

**Prompted Choice**
- Can you talk about your experience with the prompted choice element or having the conversations with patients?
  - Prompt: Was it easy, difficult and why? How confident were you in having these and why? How did the conversation impact your relationship with your patients and why?

  - What were the barriers and facilitators to having the conversation?
  - Prompt: What made it easier and harder, and why?

**Professional Role**
- Can you talk about how you feel the intervention fits with your professional role?
  - Prompt: Does it fit well or poorly for you to be having organ donation discussion?

**Data Collection – SystmONE**
- Can you talk about your opinion on the SystmONE prompt?

  - Can you talk about your opinion on the SystmONE registration collection form?
    - Prompt: Did you use it at all?

**Leaflets and posters**
- Do you think the leaflets and posters in the waiting room were helpful?
  - Prompt: Did patients mention them?

**Training**
- Can you talk about how the training prepared you to conduct the intervention and why?
  - Prompt: Did it prepare you? How could the training be improved?

**Acceptability**
- Overall how appropriate do you think primary care is for this intervention and why?
  - Prompts: Emotional impact, burden, any ethical issues, cost v benefit

**Resources**
- Can you talk about whether you believe you had the resources to conduct the intervention? For example, time or money?
How much, if at all, did the intervention impact the existing practice workflows and systems and why?

Recommendations
- Do you have any recommendations for us on how we can improve the intervention?

Concluding Questions
- Is there anything else that anyone feels that we should have talked about but didn’t?

Conclusion
- Thank you for participating. This has been a very successful discussion.
- Your opinions will be a valuable asset to the study.
- We hope you have found the discussion interesting.
- If there is anything you are unhappy with or wish to complain about, please contact me or my supervisors.
Appendix 18: Administrative and Reception Staff Focus Group Topic Guide

Version 1. 13 July 2017

FOCUS GROUP TOPIC GUIDE – Administrative Staff
Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
IRAS ID:

Welcome & Introduction
• Participants will be welcomed into the room and offered refreshments.
• Once all participants are seated, introduce self and thank participants for agreeing to take part.
• Give brief background to the project.
  o University of Bedfordshire & NHSBT funded.
  o We want to capture experiences of the intervention
• After this introduction we will talk about your experiences of the intervention, the data collection procedures, how well it fits within the practice and if you have any recommendations.
• It is key that we want your honest opinions, there are no right or wrong answers.

Anonymity
• The focus group is being taped, however this discussion will be anonymous when transcribed.
• Please try not to use names in our discussion. Numbers will be allocated to each person and placed in front of you. Try and use these instead.
• If you do use names however, don’t worry, these will be anonymised later.
• Please do not discuss the sensitive content of this focus group outside of this room.

PIS & Consent Forms
• The patient information sheet and consent forms will be distributed.
• Participants will be instructed to read through these and the key content will be explained by the facilitator.
• Questions will be invited.
• Participants will be instructed to sign the consent form if they consent.
• Participant ID numbers will be cross referenced to training forms.

Ground Rules
• The most important rule is that only one person speaks at a time. There may be a temptation to jump in when someone is talking but please wait until they have finished.
• There are no right or wrong answers
• You do not have to speak in any particular order
• When you do have something to say, please do so. There are many of you in the group and it is important that I obtain the views of each of you
• You do not have to agree with the views of other people in the group
• Does anyone have any questions? (answers).
• OK, let’s begin
**Introductory Question**
- Can you briefly talk about your experience of the intervention overall?
  - Prompts: Was it positive or negative overall and why? Easy or difficult, and why?

**Prompted Choice**
- Can you talk about your experience with the prompted choice element of the intervention?
  - Prompt: Was it easy, difficult and why? How confident were you in having these, and why?
- Did staff or patients express any opinions about the prompted choice element to you?

**Data Collection – SystmONE**
- Can you talk about your opinion on the SystmONE prompt?
- Can you talk about your opinion on the SystmONE registration collection form?
  - Prompt: Did you use it at all?

**Leaflets and posters**
- Do you think the leaflets and posters in the waiting room were helpful and why?
  - Prompt: Did patients mention them?

**Training**
- Can you talk about how the training prepared you to conduct the intervention and why?
  - Prompt: Did it prepare you? How could the training be improved?

**Acceptability**
- Overall how appropriate do you think primary care is for this intervention and why?
  - Prompts: Emotional impact, burden, any ethical issues, cost v benefit, current NHS environment

**Resources**
- Can you talk about whether you believe you had the resources to conduct the intervention? For example, time or money?
- How much, if at all, did the intervention impact the existing practice workflows and systems and why?

**Recommendations**
- Do you have any recommendations for us on how we can improve the intervention?

**Concluding Questions**
Is there anything else that anyone feels that we should have talked about but didn’t?

Conclusion

- Thank you for participating. This has been a very useful discussion.
- Your opinions will be a valuable asset to the study.
- I hope you have found the discussion interesting.
- If there is anything you are unhappy with or wish to complain about, please contact me or my supervisors.
Appendix 19: Staff Online Survey Recruitment Email

Dear *practice name*Staff,

Thank you once again for your participation and commitment to our research study.

We now wish to commence the final stage of evaluation of the intervention and invite you to take part in an online survey. The survey can be reached by clicking the link below and should take only 10 minutes to complete:

{INSERT LINK}

The aim of this survey is to capture views that you may not have felt comfortable sharing during the focus group. Or those which you thought of following group discussions.

Your participation is entirely voluntary, however, it would be helpful for us to hear your views and experiences of our intervention.

If you have any questions or queries regarding the research, please feel free to email me.

Kind Regards and Best Wishes,

Catrin
Appendix 20: Staff Online Survey Participant Information Sheet

Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
IRAS ID:

Participant Information
I am Catrin Pedder Jones, a PhD Student working with the University of Bedfordshire and NHS Blood and Transplant. I am conducting research on the feasibility of organ donation interventions in a U.K. primary care setting.

Purpose of the research
The NHS Organ Donor Register is a database which keeps a record of everyone who wants to donate their organs after death. However, only 35% of the U.K. population are on the NHS Organ Donor Register. To help increase this, we have developed an intervention in partnership with *practice name*.

As you are aware, the intervention has been conducted in *practice name* for the past three months and is over. We now wish to see what staff thought of the intervention.

This research will involve your participation in an online survey, which will take approximately 10 – 15 minutes.

You will be presented with 13 open ended questions, which we would like you to complete to help us refine our intervention for use in the future.

The aim of this online survey is to capture any individual views on the organ donation intervention that may not have wished to share in group discussion.

You have been invited to take part because we feel you could give us valuable information about our intervention and are a staff member at *practice name*.

Voluntary Participation
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

Risks
There are few risks to taking part in the research. However, discussions may involve the topic of organ donation and death, which some people might find difficult. Telephone numbers of support services can be found at the end of this PIS.
You do not have to answer any question or take part in the discussion if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview.
**Benefits**
There will be no direct benefit to you, but your participation is likely to help us adapt our intervention and help us increase membership of the NHS Organ Donor Register in other GP Practices.

**Reimbursements**
You will not be provided any incentive to take part in the research and will not receive reimbursements for expenses.

**Confidentiality**
We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

**Sharing the Results**
Nothing that you tell us today will be attributed to you by name. It may however be attributed to *practice name*. The knowledge that we get from this research may be published in academic journals or distributed by the media. This is so that others may benefit from our findings in this research project.

Additionally, we may quote parts of what you say in these publications and responses may be traceable back to *practice name* in publication. However, these will be anonymous and not include your name.

**Right to Refuse or Withdraw**
You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the discussion at any time that you wish without your job being affected.

**Ethical Approval**
This proposal has all been reviewed and approved by the Heath Research Authority and Brent Research Ethics Committee which is a committee whose task it is to make sure that research participants are protected from harm. This proposal has also been reviewed and approved by the University of Bedfordshire Research Ethics Committee who are part-funding the study.

IF YOU WISH TO TAKE PART IN THE STUDY, PLEASE CLICK NEXT.
Appendix 21: Staff Online Survey Consent Page

CONSENT FORM
Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
Study Element: Online Survey

Please tick box

• I confirm that I have read the information sheet dated for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

• I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

• I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

• I agree to take part in the above study.
Appendix 22: Staff Online Survey Questions

Thank you for agreeing to participate in this research. We shall ask you 13 open questions and request you give us as much detail as possible in your responses.

1. Firstly, in your own words, please describe your overall experience of all elements of the intervention (patient discussions, training and leaflets and posters). Imagine you are reviewing the intervention for other practices. For example, were your experiences positive or negative overall and why.

2. Did the training adequately prepare you for the intervention? If so/not why?

3. Now the 3 month intervention period has passed, do you have any recommendations for us on how to modify the training element of the intervention in future?

4. Now, please can you tell us about your experience with patient discussions about organ donations.

5. Did you face any barriers or facilitators to discussing organ donation with patients? Please explain these in detail.

6. Do you have any recommendations for us on how to modify the prompted choice element of the intervention in future?

7. Please can you describe your experiences in using the new SystmONE organ donation form and prompt. For example, is it fit for purpose? Are any elements positive or negative?

8. Do you have any recommendations for us on how to modify the SystmONE organ donation form and prompt in the future?

9. Please can you tell us about your experiences of the leaflets and posters placed around the practice.

10. Do you have any recommendations for us on how to modify the leaflet and poster element of the intervention in future?

11. Do you believe the intervention is acceptable for you to conduct? Please give context to your answers. For example, acceptability is defined through emotional impact, burden of the intervention, ethical issues, use of resources (money, time), costs versus benefits and perceived effectiveness.

12. Please describe any other experiences, issues, thoughts or recommendations that have not already been mentioned.
13. Finally, we would like your thoughts on this intervention being rolled out to other primary care practices as a way to increase membership of the NHS Organ Donor Register.

END PAGE

Thank you. You have now completed the online survey element. We appreciate the time you have taken to do this.

Who to Contact
If you wish to ask questions about this research, you may contact any of the following:

Catrin Pedder Jones, PhD Student.
Telephone:
Email: catrin.jones1@study.beds.ac.uk

Dr. Chris Papadopoulos, Supervisor
Email: chris.papadopoulos@beds.ac.uk

Prof. Gurch Randhawa, Supervisor
Email: gurch.randhawa@beds.ac.uk

If you feel affected in any way by these discussions, please see below for some local support services who may be able to help.

Samaritans: 116 123
Cruse Bedfordshire, Bereavement Counselling: 01582 595300
Keech Hospice Care Bereavement Service: 01582 492339
Appendix 23: Original Patient Focus Group Topic Guide

Version 1. 13 July 2017

FOCUS GROUP TOPIC GUIDE – Patients

Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
IRAS ID:

Welcome & Introduction

- Participants will be welcomed into the room and offered refreshments.
- Once all participants are seated, introduce self and thank participants for agreeing to take part.
- Give brief background to the project.
  - University of Bedfordshire & NHSBT funded.
  - We want to capture experiences of the specific organ donation intervention that was conducted in *practice name* over the past 3 months.
- After this introduction we will talk about your experiences of the intervention, the data collection procedures, how well it fits within the practice and if you have any recommendations.
- Emphasise that the project is assessing feasibility and that honest views are really important. Even if they are negative.
- Can we go around the group and introduce ourselves before I go over the ground rules of the discussion?

Anonymity

- The focus group is being taped, however this discussion will be anonymous when transcribed.
- Please try not to use names in our discussion. Numbers will be allocated to each person and placed in front of you. Try and use these instead.
- If you do use names however, don’t worry, these will be anonymised later.
- Please do not discuss the content of this focus group outside of this room.

PIS & Consent Forms

- The patient information sheet and consent forms will be distributed.
- Participants will be instructed to read through these and the key content will be explained by the facilitator.
- Questions will be invited.
- Participants will be instructed to sign the consent form if they consent.
- Participant ID numbers will be cross referenced to training forms.

Ground Rules

- The most important rule is that only one person speaks at a time. There may be a temptation to jump in when someone is talking but please wait until they have finished.
- There are no right or wrong answers
- You do not have to speak in any particular order
• When you do have something to say, please do so. There are many of you in the group and it is important that I obtain the views of each of you.
• You do not have to agree with the views of other people in the group.
• Does anyone have any questions? (answers).
• OK, let’s begin.

**Introductory Question**
- Can you briefly talk about your experience of the organ donation intervention overall?
  - Prompts: Did you notice it? Were you asked?

**Prompted Choice**
- Can you talk about your experience of being asked if you would like to join the organ donor register?
  - Prompt: Was it an easy conversation? Were you comfortable? Were your experiences positive or negative? Did you understand what you were being asked? Do you feel any pressure to sign-up because it was your doctor asking you?
  - Did being asked help you make a decision on whether to register or not, and why?

**Leaflets and posters**
- Did you notice the leaflets and posters in the waiting room?
- Were these leaflets and posters helpful for you and why?
- Did these help you make a decision on whether to register or not?

**Acceptability**
- Overall how appropriate to you think this intervention is in your GP practice?
- Do you think this is an acceptable place to have any organ donation intervention?
- How appropriate to others do you think this intervention is in your GP practice?

**Recommendations**
- Do you have any recommendations for us on how we can improve the intervention?

**Concluding Questions**
- Is there anything else that anyone feels that we should have talked about but didn’t?

**Conclusion**
- Thank you for participating. This has been a very successful discussion.
- Your opinions will be a valuable asset to the study.
- We hope you have found the discussion interesting.
- If there is anything you are unhappy with or wish to complain about, please contact me or my supervisors.
Appendix 24: Patient Recruitment Text Message

The University of Bedfordshire and NHS Blood and Transplant have been conducting organ donation research in *practice name* for the past 3 months. As a patient who visited the practice during this time we would like to invite you to complete an anonymous online survey about your views on this. To do this, please click on the following link. Thank you.

{INSERT LINK}
Appendix 25: Patient Online Survey Participant Information Sheet and Consent Form Adapted From Focus Group Participant Information Sheet and Consent Form

*Highlighted areas show adaptations

ONLINE SURVEY – Patients

Title of Project: Organ donation intervention in primary care: A feasibility study.
Name of Researcher: Catrin Pedder Jones
IRAS ID:

I am Catrin Pedder Jones, a PhD Student working with the University of Bedfordshire and NHS Blood and Transplant. I am conducting research on the feasibility of organ donation interventions in a U.K. primary care setting.

Summary
The NHS Organ Donor Register is a database which keeps a record of everyone who wants to donate their organs after death. However, only 35% of the U.K. population are on the NHS Organ Donor Register. To help increase this, we have developed an intervention in partnership with a GP practice. The intervention has been conducted in your GP surgery for the past three months and is over. We now wish to see what patients thought of our intervention.

This research will involve your participation in a short online survey that will take approximately 15 minutes.

You have been invited to take part because we feel you could give us valuable information about our intervention, are a patient at *practice name* and have visited your practice within the 3-month intervention period.

Voluntary Participation
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at your GP Practice will continue and nothing will change.

Procedures
We are asking you to help us learn about how you, the patients, found the intervention. You will be presented with three questions about you (your age, gender and ethnicity) followed by 12 questions about the intervention. These questions are open and you can write as little or as much as you like in response.

The questions will be about the organ donation intervention. For example, if you liked it, disliked it, noticed it and what impact it had on you. We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.

Risks
There are few risks to taking part in the research. However, questions involve the topic of organ donation and death, which some people might find difficult. Telephone numbers of support services can be found at the end of this form and again at the end of the survey. You do not have to answer any question if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question.

**Benefits**
There will be no direct benefit to you, but your participation is likely to help us adapt our intervention and help us increase membership of the NHS Organ Donor Register in other GP Practices.

**Reimbursements**
You will not be provided any incentive to take part in the research.

**Confidentiality**
We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private.

**Sharing the Results**
Nothing that you tell us today will be attributed to you by name and at no point will we ask your name. It may however be attributed to *practice name*. The knowledge that we get from this research may be published in academic journals or distributed by the media. This is so that others may benefit from our findings in this research project.

Additionally, we may quote parts of what you say in these publications and responses may be traceable back to *practice name* in publication. However, these will be anonymous and not include your name.

**Right to Refuse or Withdraw**
You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your treatment at *practice name* in any way. You may stop participating in the discussion at any time that you wish.

**Ethical Approval**
This proposal has all been reviewed and approved by the Heath Research Authority and London Brent Research Ethics Committee which is a committee whose task it is to make sure that research participants are protected from harm. This proposal has also been reviewed and approved by the University of Bedfordshire Research Ethics Committee who are part-funding the study.

**GDPR Statement**
The University of Bedfordshire is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bedfordshire will keep identifiable information about you for 5 years after the study has finished.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Catrin Jones, catrinpedder.jones@beds.ac.uk.

Who to Contact
If you wish to ask questions about this research, you may contact any of the following:

Catrin Pedder Jones, PhD Student.
Telephone: 
Email: catrin.jones1@study.beds.ac.uk

Dr. Chris Papadopoulos, Supervisor
Email: chris.papadopoulos@beds.ac.uk

Prof. Gurch Randhawa, Supervisor
Email: gurch.randhawa@beds.ac.uk

If you feel affected in any way by these discussions, please see below for some local support services who may be able to help.

Samaritans: 116 123
Cruse Bedfordshire, Bereavement Counselling: 01582 595300
Keech Hospice Care Bereavement Service: 01582 492339

IF YOU WISH TO TAKE PART IN THE STUDY, PLEASE CLICK NEXT.

CONSENT FORM

Title of Project: **Organ donation intervention in primary care: A feasibility study.**
Name of Researcher: Catrin Pedder Jones
Study Element: Online Survey - Patient

• I confirm that I have read the information for the above study. I have had the opportunity to consider the information.

• I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

• I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.
• I agree to take part in the above study.
**Appendix 26: Patient Online Survey Questions Adapted from Focus Group Topic Guide**

*Highlighted areas show adaptations*

**DEMOGRAPHIC AND SCREENING QUESTIONS**
Thank you for agreeing to participate in this research, first we will ask you 3 demographic questions.

1. **How old are you in years? .....**

2. **What is your gender?**
   a. Male
   b. Female
   c. Other
   d. Prefer not to say

3. **What is your ethnicity?**
   a. White – English/Welsh/Scottish/Northern Irish/British
   b. White – Irish
   c. White – Gypsy or Irish Traveller
   d. White – Other
   e. Mixed – White & Black Caribbean
   f. Mixed – White & Black African
   g. Mixed – Other
   h. Asian/Asian British – Indian
   i. Asian/Asian British – Pakistani
   j. Asian/Asian British – Bangladeshi
   k. Asian/Asian British – Chinese
   l. Asian/Asian British – Other
   m. Black – African
   n. Black – Caribbean
   o. Black – Other
   p. Other – Arab
   q. Other – Any other ethnic group

**INTERVENTION QUESTIONS.**
Thank you, we will now ask you a maximum of 11 questions about your experience of the intervention.

4. **Were you asked during a consultation at *practice name* if you would like to join the NHS Organ Donor Register?**
   a. Yes (questions 5, 6 & 7 will open)
   b. No (question 8 will open)

5. **If yes, do you remember which type of staff member asked you this question?**
   a. Doctor/GP
6.  **(If yes)** can you write about your experience of being asked if you would like to join the organ donor register?
   - **For example:**
     - Was it an easy conversation?
     - Were you comfortable?
     - Were your experiences positive or negative?
     - Did you understand what you were being asked?

7.  **(If yes)** Did being asked help you make a decision on whether to register or not, and why?

8.  **(If no)** can you write about your views on being asked if you would like to join the organ donor register by staff at your GP Practice?

9.  **Did you notice the leaflets and posters in the waiting room?**
   - a.  **Yes** (questions 10&11 open)
   - b.  **No** (goes straight to question 12)

10. Were these leaflets and posters helpful for you and why?

11. Did these help you make a decision on whether to register or not?

12. Overall how appropriate do you think this intervention is in your GP practice?

13. Do you think this is an acceptable place to have any organ donation intervention?

14. Do you have any recommendations for us on how we can improve the intervention?

15. Is there anything else that you would like to tell us about our intervention?

END PAGE

Thank you. You have now completed the online survey element. We appreciate the time you have taken to do this.

**Who to Contact**
If you wish to ask questions about this research, you may contact any of the following:

Catrin Pedder Jones, PhD Student.
Telephone:  
Email:  [catrin.jones1@study.beds.ac.uk](mailto:catrin.jones1@study.beds.ac.uk)
Dr. Chris Papadopoulos, Supervisor
Email: chris.papadopoulos@beds.ac.uk

Prof. Gurch Randhawa, Supervisor
Email: gurch.randhawa@beds.ac.uk

If you feel affected in any way by these discussions, please see below for some local support services who may be able to help.

Samaritans: 116 123
Cruse Bedfordshire, Bereavement Counselling: 01582 595300
Keech Hospice Care Bereavement Service: 01582 492339
**Appendix 27: Conversion of SystmONE Ethnic Categories to ONS Categories**

**Table 45: Categorisation of SystmONE ethnic groups into ONS Categories (Office for National Statistics, 2011).**

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>ONS Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>(XaFwD) White British</td>
<td>1 White - English/Welsh/Scottish/Northern Irish/British</td>
</tr>
<tr>
<td>(Xaluh) White Scottish</td>
<td></td>
</tr>
<tr>
<td>(XaJRC) English - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaQEa) White British - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(Y9930) Race - British</td>
<td></td>
</tr>
<tr>
<td>(9SA9.) Irish (NMO)</td>
<td>2 White - Irish</td>
</tr>
<tr>
<td>(9SA9.) Irish (NMO)</td>
<td></td>
</tr>
<tr>
<td>(XaFwE) White Irish</td>
<td></td>
</tr>
<tr>
<td>(XaJQw) Irish - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaQEb) White Irish - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJSD) Gypsy/Romany - ethnic category 2001 census</td>
<td>3 White - Gypsy or Irish Traveller</td>
</tr>
<tr>
<td>(9S1..) White - ethnic group</td>
<td></td>
</tr>
<tr>
<td>(9SAC.) Other European (NMO)</td>
<td></td>
</tr>
<tr>
<td>(XaedS) Hungarian Roma</td>
<td></td>
</tr>
<tr>
<td>(XaFwF) Other white ethnic group</td>
<td></td>
</tr>
<tr>
<td>(Xalui) Other white British ethnic group</td>
<td></td>
</tr>
<tr>
<td>(XaJQx) Other White background - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJRI) Greek - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJRm) Italian - ethnic category 2001 census</td>
<td>4 White - Any other White background</td>
</tr>
<tr>
<td>(XaJSE) Polish - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJSF) Baltic Estonian/Latvian/Lithuanian - ethn categ 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJSI) Albanian - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJSK) Croatian - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJSP) Oth White European/European unsp/Mixed European 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJSQ) Other White or White unspecified ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(Xar4o) Romanian</td>
<td></td>
</tr>
<tr>
<td>(Xar4p) Bulgarian</td>
<td></td>
</tr>
<tr>
<td>(XaW8w) Portuguese</td>
<td></td>
</tr>
<tr>
<td>(XacuS) Mixed: White and Black Caribbean - NI ethnic cat 2011 census</td>
<td>5 Mixed/Multiple ethnic groups - White and Black Caribbean</td>
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<td>(XaJQy) White and Black Caribbean - ethnic category 2001 census</td>
<td></td>
</tr>
<tr>
<td>(XaJQz) White and Black African - ethnic category 2001 census</td>
<td>6 Mixed/Multiple ethnic groups - White and Black African</td>
</tr>
<tr>
<td>(XaJR0) White and Asian - ethnic category 2001 census</td>
<td>7 Mixed/Multiple ethnic groups - White and Asian</td>
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<td>(134I.) Race: Mixed</td>
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<td>404</td>
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<tr>
<td>9S47.</td>
<td>Black - other Asian</td>
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<td>9S5..</td>
<td>Black - other, mixed</td>
</tr>
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<td>9S51.</td>
<td>Other Black - Black/White orig</td>
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<td>9S81.</td>
<td>Other ethnic, Black/White orig</td>
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<td>(XaJQw)</td>
<td>British or mixed British - ethnic category 2001 census</td>
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<tr>
<td>(XaJR1)</td>
<td>Other Mixed background - ethnic category 2001 census</td>
</tr>
<tr>
<td>(XaJRL)</td>
<td>Asian and Chinese - ethnic category 2001 census</td>
</tr>
<tr>
<td>(XaJSO)</td>
<td>Other mixed White - ethnic category 2001 census</td>
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<td>9S6..</td>
<td>Indian</td>
</tr>
<tr>
<td>(Xacuc)</td>
<td>Asian or Asian British: Indian - NI ethnic cat 2011 census</td>
</tr>
<tr>
<td>(XaJR2)</td>
<td>Indian or British Indian - ethnic category 2001 census</td>
</tr>
<tr>
<td>9S7..</td>
<td>Pakistani</td>
</tr>
<tr>
<td>(Xacui)</td>
<td>Asian/Asian British: Pakistani - NI ethnic cat 2011 census</td>
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<tr>
<td>(Xacv0)</td>
<td>Asian: Pakistani/Pakistani Scot/Pakistani Brit- Scot 2011</td>
</tr>
<tr>
<td>(XaJR3)</td>
<td>Pakistan or British Pakistani - ethnic category 2001 census</td>
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<td>9S8..</td>
<td>Bangladeshi</td>
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<td>(Xacti)</td>
<td>Asian/Asian Brit: Bangladeshi- Eng+Wales eth cat 2011</td>
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<tr>
<td>(XaJR4)</td>
<td>Bangladeshi or British Bangladeshi - ethn categ 2001 census</td>
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<td>9T1C.</td>
<td>Chinese</td>
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<td>(XaJR9)</td>
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<td>Other Asian (NMO)</td>
</tr>
<tr>
<td>9T1E.</td>
<td>Other Asian</td>
</tr>
<tr>
<td>(XaE4A)</td>
<td>Vietnamese</td>
</tr>
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<td>(Xafwz)</td>
<td>Asian - ethnic group</td>
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<td>(Xafx0)</td>
<td>Other Asian ethnic group</td>
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<td>(XaJR5)</td>
<td>Other Asian background - ethnic category 2001 census</td>
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<td>(XaJRR)</td>
<td>Sri Lankan - ethnic category 2001 census</td>
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<td>(XaJRT)</td>
<td>Sinhalese - ethnic category 2001 census</td>
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<td>Black African</td>
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<td>Description</td>
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<td>----------</td>
<td>-----------------------------------------------------------------------------</td>
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<td>XE2Nv</td>
<td>Black East African Asian/Indo-Caribbean</td>
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<td>XM1S7</td>
<td>Black Indo-Caribbean</td>
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<td>Brit. ethnic minor. unsp (NMO)</td>
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<td>XaJrk</td>
<td>Turkish - ethnic category 2001 census</td>
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<tr>
<td>XaJsa</td>
<td>South and Central American - ethnic category 2001 census</td>
</tr>
<tr>
<td>XaJrb</td>
<td>Ethnic category not stated - 2001 census</td>
</tr>
<tr>
<td>XaJQu</td>
<td>Ethnic category - 2001 census</td>
</tr>
<tr>
<td>XaJSU</td>
<td>Mid East (excl Israeli, Iranian &amp; Arab) - eth cat 2001 cens</td>
</tr>
<tr>
<td>XaJSY</td>
<td>Moroccan - ethnic category 2001 census</td>
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<td>XaJSZ</td>
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<td>Ethnicity and other related nationality data</td>
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<td>XEOocc</td>
<td>Race: Not stated</td>
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<td>XaJSd</td>
<td>Hindu - ethnic category 2001 census</td>
</tr>
<tr>
<td>XaJSe</td>
<td>Muslim - ethnic category 2001 census</td>
</tr>
</tbody>
</table>
Appendix 28: Preliminary Notes and Codes From Familiarisation In Framework Analysis

- Repeated references to time as a barrier to prompted choice in all staff groups
- Great variation in responses – some staff very positive whilst others more neutral, including in reporting patient reactions.
- Great variation in recommendations and suggestions, sometimes polarizing – some want prompt removed, some want to leave it as it is, some want to remove intervention altogether other want to keep it.
- Mostly positive reactions to the training session, particularly the SNOD.
- Concerns about whether it’s appropriate for patients voiced by some staff.
- Leaflets were used by some staff but general opinion of leaflets in waiting rooms is negative.
- Common myths were suggested as responses by patients including age, eye donation and concerns over continuation of care if a donor.
- Overall positive opinions of needing intervention, sometimes contrasting with staff members negative responses concerning individual components.
- Reports that conducting the intervention is patient dependent.
- Repeated recommendation for putting information on the patient call screen.

- External Context
  - Policy and Legislation
    - Opt-out
- Intervention Context
  - Recommendations
    - Prompted Choice
      - Examples
      - Leaflets
      - Incentives
      - Move away from consultation
      - Specialized clinic
      - Role dependent
      - SystmONE
    - Training
      - More examples
      - Leaflets
      - Refresher training
  - Implementability
    - Receptionist or administrator involvement
  - Nature
    - Prompted Choice
      - Barriers to asking
        - Clinic Type
        - Consultation flow
        - Forgetting
        - Lack of knowledge or confidence
        - Language barrier
        - Not appropriate
- Patient needs
- SystmONE
- Time

- Facilitators to asking
  - Colleague support or champion
  - Confidence
  - Patient body language
  - Perceived benefit of asking
  - Positive patient feedback
  - Practice
  - Previous training
  - SystmONE
  - Timing of asking
  - Training

- Patient responses
  - Age
  - Death procedures
  - Ethnicity & religion
  - Eyes
  - Family views
  - Myths
  - Previous experience of organ donation

- Staff experiences
  - Asking spouses
  - Little involvement
  - Negative experiences
  - Positive experiences
  - Staff personal experiences of organ donation
  - Telephone consultations
  - How to ask

  - Training

  - Strengths
    - Confidence
    - Ideas on how to ask
    - Information provided
    - Manual and materials
    - Normalises organ donation discussion
    - Registration of staff
    - Roleplay
    - Specialist nurse

  - Weaknesses
    - Experience will tell
    - Missed part of session
    - None
    - Practice & Confidence

- Safety & data privacy
  - Incorrect knowledge
Appendix 29: A Thematic Map Of The Lau et al. Framework Combined With IIFF Model.

Figure 41: Map of Lau et al. Conceptual Framework and IIFF Model (Lau et al., 2016; Siegel et al., 2010).
Appendix 30: A Map of Other Themes Found During Framework Analysis

Figure 42: Map of other themes found during framework analysis.
Appendix 31: Final Framework

Figure 43: Combined and refined map of themes found during framework analysis.
### Appendix 32: Invivo Coding Examples

<table>
<thead>
<tr>
<th>Parent Node</th>
<th>Node</th>
<th>Quote</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External Context</strong></td>
<td>Dominant Paradigm</td>
<td>“Well normally it’s a no no, you don’t talk about things like that do you, no”</td>
<td>Admin &amp; Reception Focus Group</td>
</tr>
<tr>
<td></td>
<td>Economic Climate</td>
<td>“And that goes for everything in general practice, because we do have issues with staff and time”</td>
<td>GP Focus Group</td>
</tr>
<tr>
<td></td>
<td>Incentives</td>
<td>“…if there was a goal to say you need to hit 95% by the end of the year we’d probably hate our lives by the end of it”</td>
<td>GP Focus Group</td>
</tr>
<tr>
<td></td>
<td>Infrastructure</td>
<td>“Um a lot of the young um adults had already sort of done it through their driving license, so I was getting that a lot”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
<tr>
<td></td>
<td>Policy and Legislation</td>
<td>“say the person who was born in wales and didn’t know because she was born in wales whether or not she was still opted, opted out”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
<tr>
<td></td>
<td>Public Awareness</td>
<td>“Most were positive but for some it was the first time they had even thought of the subject”</td>
<td>Staff Survey</td>
</tr>
<tr>
<td></td>
<td>Stakeholder Buy-in</td>
<td>“I didn’t find any problems asking the questions, because I think it is a good idea”</td>
<td>GP Focus Group</td>
</tr>
<tr>
<td></td>
<td>Technological Advances</td>
<td>“I think it could be worthwhile putting it up on the screen”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
<tr>
<td><strong>Organisational Context</strong></td>
<td>Culture</td>
<td>“It’s just, we’re in the position that we can then, if we had that knowledge impart that to patients for them to make a more informed decision”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
<tr>
<td></td>
<td>Involvement</td>
<td>“Especially one of our nurses, I don’t know if I should mention her name or not, but one of our nurses was heavily involved in this and really keen to participate”</td>
<td>GP Focus Group</td>
</tr>
<tr>
<td></td>
<td>Processes and Systems</td>
<td>“I think because the prompt came up before the consultation had started, I think that’s wrong, I think it should be at the end. Because the doctor really has to make the decision when they first open the patients notes”</td>
<td>Admin &amp; Reception Focus Group</td>
</tr>
<tr>
<td></td>
<td>Relationship</td>
<td>“…you know I don’t want the patient doctor relationship to be tarnished you know”</td>
<td>GP Focus Group</td>
</tr>
<tr>
<td></td>
<td>Resources</td>
<td>“positive overall...but difficult subject to broach in such a short conversation”</td>
<td>Staff Survey</td>
</tr>
<tr>
<td></td>
<td>Skill Mix</td>
<td>“maybe it’s different for the for the patients who are pre-booked, so you know what they’re coming in for”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
<tr>
<td><strong>Professional Context</strong></td>
<td>Attitudes to change</td>
<td>“because we have greater access for patients I think it is a great place to do it”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
<tr>
<td></td>
<td>Competency</td>
<td>“Will need to look at template in further details to familiarize myself before I feel confident to have conversation with patients”</td>
<td>Training Evaluation Form</td>
</tr>
<tr>
<td></td>
<td>Philosophy of care</td>
<td>“because if not here then where?!?!”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
<tr>
<td></td>
<td>Professional role</td>
<td>“I think it’s probably easier for us, especially because most of the patients we already know”</td>
<td>GP Focus Group</td>
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<td>Node</td>
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<td>------</td>
<td>------</td>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td>Nature</td>
<td>Recommendations</td>
<td>Leaflets and Posters</td>
<td>“I know you said something about the leaflets but I never even saw them. So I think it’s probably making sure the leaflets are there at the training”</td>
</tr>
<tr>
<td>Prompted Choice</td>
<td></td>
<td></td>
<td>“So if this had to be provided by us, there would need to be provisions, staff or money or incentives or something, and I mean even if there were monitor incentives, physically I don’t think we would have the capacity to do it as things are now”</td>
</tr>
<tr>
<td>Training</td>
<td></td>
<td></td>
<td>“I think maybe with um some clinical staff they might need perhaps a little refresher every now and again”</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td>“get something on the patient call screen you’ve got more chance of them reading that than the leaflet”</td>
</tr>
<tr>
<td>Leaflets and Posters</td>
<td></td>
<td>Staff Awareness &amp; Use</td>
<td>“leaflets and posters are good, allowed patients to look at them whilst waiting and take them home, allowed clinicians to start the conversation and then give further information”</td>
</tr>
<tr>
<td>Training</td>
<td></td>
<td>Strengths</td>
<td>“It was good to have the organ donation specialist there to tell of her experiences and the different approaches”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Weaknesses</td>
<td>“None”</td>
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<tr>
<td>Prompted Choice</td>
<td></td>
<td>Acceptability</td>
<td>“Well I do think it’s appropriate purely for the fact that the majority of the time it’s it’s in this environment that patients are seen”</td>
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<tr>
<td></td>
<td></td>
<td>Barriers to asking</td>
<td>“Um it was difficult, mainly because of time constraints because we only have 10 minute slots”</td>
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<tr>
<td></td>
<td></td>
<td>Facilitators to asking</td>
<td>“I learnt a lot about the process myself and felt I could give good quality/accurate information so patients could make an informed decision at that point or enable patients to go away and think about registering or discussing with relatives”</td>
</tr>
<tr>
<td>Patient Responses</td>
<td></td>
<td></td>
<td>“Um, actually asking patients…um I had mixed feedback, some were...you know// up for it others were like no what are you talking to me about that for I don’t wanna know”</td>
</tr>
<tr>
<td>Staff Experiences</td>
<td></td>
<td></td>
<td>“I didn’t as a receptionist have a lot of involvement in it, but I did have two conversations with patients one on the telephone and one face to face”</td>
</tr>
<tr>
<td>Safety &amp; Data Privacy</td>
<td></td>
<td></td>
<td>“what confused me for the first couple of patients I talked about was, if I click this button am I actually adding them to the donor register?”</td>
</tr>
<tr>
<td>Implementability</td>
<td></td>
<td></td>
<td>“I think I certainly got into the swing of how I introduced that and once I was happy with what I, how I introduced it to the patient and the feedback that I got that wasn’t particularly upsetting to the patient or um”</td>
</tr>
<tr>
<td>IIFF Model</td>
<td>Information</td>
<td>“But that was also the biggie actually, about age, because most people from say from about 70 thought they were too old, and then obviously introduced that actually you can get on the register till about 87”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
<tr>
<td>---</td>
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<tr>
<td>Immediate Sign-up Opportunity</td>
<td></td>
<td>“I don’t want to make my mind up there and then”</td>
<td>Admin &amp; Reception Focus Group</td>
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<tr>
<td>Focused Engagement</td>
<td></td>
<td>“cos patients come in and they wanna just start talking about what’s wrong with them and sometimes it was difficult sort of, hold on a minute, I wanna, we’re doing a study here”</td>
<td>Nurse &amp; HCA Focus Group</td>
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<tr>
<td>Favorable Activation</td>
<td></td>
<td>“yeah when someone’s coming in you know, they’re obviously unwell, the last thing they wanna talk about is, I think, is organ donation, you know they just wanna get sorted”</td>
<td>Nurse &amp; HCA Focus Group</td>
</tr>
</tbody>
</table>
Appendix 33: Populated frameworks

Appendix 34: Health Research Authority Request for Clarification 11th August 2017

Appendix 35: NHS Research Ethics Committee Letter Requesting Further Information 30th August 2017

Appendix 36: NHS Research Ethics Committee Favourable Opinion Letter 3rd November 2017

Appendix 37: Confidentiality Advisory Group Favourable Opinion Letter 8th December 2017

Appendix 38: Health Research Authority Approval 11th December 2017

Appendix 39: University of Bedfordshire Institute for Health Research Ethics Committee Approval 20th November 2017

Appendix 40: Non-Substantial Amendment Approvals in 2018

Appendices 33-40 removed due to maintain practice anonymity.
## Appendix 41: Leaflets Taken During Prompted Choice Period.

Table 48: Leaflet details from monitoring visits during the three month prompted choice period.

<table>
<thead>
<tr>
<th>Leaflet Type</th>
<th>Language</th>
<th>Number of Leaflets Displayed at setup</th>
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<th>Visit 1 Number of Leaflets restocked</th>
<th>Visit 2 - Number of Leaflets displayed</th>
<th>Visit 2 Number of Leaflets restocked</th>
<th>Visit 3 - Number of Leaflets displayed</th>
<th>Visit 3 Number of Leaflets restocked</th>
<th>Visit 4 - Number of Leaflets displayed</th>
<th>Visit 4 Number of Leaflets restocked</th>
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<td>Questions Answered</td>
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</tbody>
</table>
Appendix 42: Multi-Practice RCT Protocol February 2019

*Highlighted sections refer to those which were changed in single practice protocol V3.3


Research Protocol
Version 4 21 February 2019
Catrin Pedder Jones

## Protocol Amendments

<table>
<thead>
<tr>
<th>Reason</th>
<th>Details</th>
<th>Page Number</th>
<th>Date</th>
<th>New Version</th>
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</thead>
<tbody>
<tr>
<td>NHS REC Amendment</td>
<td>Inclusion of information warning patients that study is taking place during prompted choice element.</td>
<td>12</td>
<td>20/09/17</td>
<td>V2.0</td>
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<tr>
<td>NHS REC Amendment</td>
<td>Clearly detail the risks of taking part in the research under the heading ‘Risks’ in the PIS</td>
<td>33, 41, 53, 59</td>
<td>20/09/17</td>
<td>V2.0</td>
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<tr>
<td>NHS REC Amendment</td>
<td>Remove NHS England from the ‘Ethical Approval’ section of the PIS.</td>
<td>34, 42, 54, 60</td>
<td>20/09/17</td>
<td>V2.0</td>
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<tr>
<td>NHS REC Amendment</td>
<td>Include the name of the Brent Research Ethics Committee in the section ‘Ethical Approval’ of the PIS.</td>
<td>34, 42, 54, 60</td>
<td>20/09/17</td>
<td>V2.0</td>
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<tr>
<td>NHS REC Amendment</td>
<td>Clearly state under the header ‘Reimbursements’, in the PIS, that participants will not receive reimbursements for expenses.</td>
<td>33, 42, 53, 60</td>
<td>20/09/17</td>
<td>V2.0</td>
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<tr>
<td>HRA Amendment</td>
<td>Clarify who will be responsible for the study focus group transcriptions.</td>
<td>17</td>
<td>20/09/17</td>
<td>V2.0</td>
</tr>
<tr>
<td>HRA Amendment</td>
<td>Detail in the focus group PIS documents that identifiable data collected will be stored at the University of Bedfordshire.</td>
<td>41, 59</td>
<td>20/09/17</td>
<td>V2.0</td>
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<tr>
<td>HRA Amendment</td>
<td>Participants focus group and questionnaire responses will be anonymised but ‘responses may be traceable back to the practice in publication’. Please can you detail this in the relevant PIS documents.</td>
<td>33, 42, 53, 60</td>
<td>20/09/17</td>
<td>V2.0</td>
</tr>
<tr>
<td>Non-Substantial Amendment</td>
<td>Following development of questionnaire in practice computer system, minor alteration to data collection items.</td>
<td>12-15</td>
<td>19/02/2018</td>
<td>V3.0</td>
</tr>
<tr>
<td>Non-Substantial Amendment</td>
<td>Updates from NHSBT caused minor changes to the questionnaire. Altering “No” response to “Do not ask patient again”. Also including the option to ask the patient if they wish to</td>
<td>12-15</td>
<td>22/02/2018</td>
<td>V3.1</td>
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re-register if they believe they’re already on the register.

<table>
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<tr>
<th>Amendment Type</th>
<th>Description</th>
<th>Page Numbers</th>
<th>Date</th>
<th>Version</th>
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<tbody>
<tr>
<td>Non-Substantial</td>
<td>Addition of collecting number of staff consultations had.</td>
<td>16</td>
<td>21/04/2018</td>
<td>V3.2</td>
</tr>
<tr>
<td>Non-Substantial</td>
<td>Adaptation of patient focus group to online survey. Minor alterations to PIS &amp; consent, focus group topic guide converted to online survey content.</td>
<td>17-18, 20, 64-71</td>
<td>27/06/2018</td>
<td>V3.3</td>
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</table>
| Substantial    | Method change from single practice feasibility study to multi-practice feasibility study:  
• Removal of focus groups  
• Removal of mention of practice who previously participated  
• Addition of recruitment section  
• Addition of randomization & stratification section  
• Amendment of patient survey to include quantitative questions  
• Removal of staff data collection – training evaluation & online survey, not within NHS REC & HRA remit  
• Change to staff consultation numbers – only counting face to face consultations  
• Addition of website link for patient recruitment | 1-3, 5-6, 7 11-21, 26-28, 30-33, 36-38 | 21/02/2019 | V4.0    |

1.0 Title

2.0 Purpose and design
2.1 Research question
Can an intervention targeting organ donation rates be feasibly implemented in a U.K. primary care setting?

2.2 Aim
To develop and evaluate the feasibility of a GP practice-based intervention designed to increase organ donation rates in ethnically diverse locations.

2.3 Objective
To assess the feasibility and acceptability of an organ donation intervention implemented in U.K. primary care.

3.0 Background
3.1 Organ Donation in the U.K.

Thirty-five percent of the U.K. population are on the organ donation register (NHS Blood and Transplant, 2017a); this represents an increase of 6.6% since 2014-2015, the highest increase since 2010. Despite this, the U.K. is still affected by a shortage of organs for transplant. In 2015-16, 6,462 were people awaiting transplant but only 3,529 deceased donation transplants and 970 living donation transplants carried out in the same period (NHS Blood and Transplant, 2017a). Out of the 570,000 U.K. deaths only 5,603 people were eligible to be deceased organ donors between 2015-2016 (where eligible donors are those with no medical contraindications to donation) (NHS Blood and Transplant, 2017a). Only 1,364 people, 24.3% of those eligible, actually became donors however and only 43% of those who eventually donated their organs were signed up to the ODR (NHS Blood and Transplant, 2017a).

A focus to increase the number of transplants and donations is therefore emphasised by recent guidelines and policy in the U.K. The Taking Transplant to 2020 strategy aimed to identify barriers to organ donation and produce recommendations to improve these (NHS Blood and Transplant, 2008). The strategy aims to increase consent levels to 80%, matching the best performing countries for donation. Recommendations for how to achieve this focus on increasing positive decisions to consent through NHS ODR sign-up, addressing family consent issues and the importance of preference discussion (NHS Blood and Transplant, 2008).

Family consent is an important and necessary as part of the organ donation pathway, yet it represents a significant barrier to donation in the U.K (Hulme et al., 2016) with refusal rates higher than mainland Europe (Hulme et al., 2016). Over an 18-month period (April 2012 – September 2013) a 31% refusal rate was observed (Hulme et al., 2016). After investigation, prior knowledge of patients wishes were key in these decisions. The results support the findings from an integrative review that registration as an organ donor is an important factor in decision making (de Groot et al., 2015). This review, a thematic synthesis of qualitative studies, found that honouring the wishes of the deceased is an important factor for families consulted (de Groot et al., 2015). Of particular interest is the theme ‘respecting the donor’ where wishes are important to be taken into account, and when wishes were not specified by the patient, families felt hesitant and indecisive (Ralph et al., 2014). These studies highlight the complexity of family consent, but membership of the NHS ODR could facilitate decision making for families at a distressing and difficult time (Ralph et al., 2014; de Groot et al., 2015; Hulme et al., 2016).

Interventions targeting family consent through organ donation register sign up have been conducted. Strategies include educational interventions for adolescents (Li et al., 2013), college students (D’Alessandro, Peltier and Dahl, 2012) and medical and nursing students (Kurz, 2014; Ramadurg and Gupta, 2014), mass media campaigns (Feeley and Moon, 2009), healthcare professional training (Douville, Godin and Vézina-Im, 2014), community based (Salim et al., 2012), and training gatekeepers of sign-up methods (Harrison et al., 2008; Zaramo et al., 2008; Rodrigue et al., 2012). These have had mixed success, although promising results have been found in some areas, particularly the Driving License Authority in the U.S.A. (Harrison et al., 2008). The need to develop and implement successful interventions remains substantial in the U.K. to improve NHS ODR sign up rates and family
consent. Where to implement interventions in the U.K. is also important as setting for interventions is a vital part of their success.

3.1 U.K. Primary Care Context

General Practitioners are responsible for consulting with patients regarding health issues, providing treatment, referring patients to other healthcare professionals, providing screening, immunisation, diagnostic services and preventative health behaviour advice (Baird et al., 2016). Ninety percent of all contact with the NHS occurs in general practice (Hippisley-Cox and Vinogradova, 2009) and primary care has a high footfall of patients who often return regularly for follow-up appointments (Lock et al., 2009). Overall, high patient satisfaction levels are found (Baird et al., 2016) and patients trust and value advice given by their GP (Boyce et al., 2010). For these reasons, many health behaviour interventions have been conducted in primary care with successful results. For example, healthy diet programs (Bhattarai et al., 2013), alcohol interventions (O’donnell et al., 2014) and smoking cessation programs (Stead, Bergson and Lancaster, 2008).

In the USA, an intervention to increase sign-up to the organ donor register was successfully conducted in primary care (Degenholtz et al., no date). Physicians and office staff were trained using either an in-person training session or online training program to encourage sign-up and patients were given a donor form complete with return envelope. One hundred and twenty-one clinics were recruited across Pennsylvania and West Virginia and enrolled into the three arm randomised controlled trial (in person training, online training or control of posters and brochures). Zero new donors were recruited in the control arm, whereas 536 and 225 new donors were recruited in the training arms respectively, equating to 8.6% and 7.1% of non-donors visiting the practices respectively. As well as increasing registration rates, the authors report that the intervention did not impact on the patient flow or workflow in the practice. This RCT provides promising evidence to support primary care as an effective location for organ donation intervention.

The results of this study may not be generalisable to primary care in the U.K. however. In the USA healthcare is privatised with patients claiming for treatment via insurance companies or through self-funding (Ham, 2005). In contrast the UK’s National Health Service (NHS) provides free healthcare for all and is funded by the taxpayer (Ham, 2005). The USA also has higher spending on healthcare as a percentage of GDP than the U.K. (Reeves et al., 2014) and crucially 48% of the population of the USA are registered as organ donors in comparison with 35% of the U.K. population (U.S Department of Health and Human Services, 2016). These differences do not mean that primary care interventions to increase organ donation should not be conducted in the U.K; what they do suggest is that thorough investigation of whether U.K. primary care is an acceptable setting for an organ donation intervention should be conducted prior to examining the efficacy of such an intervention.

3.2 A Feasibility Approach

To assess whether U.K. primary care is appropriate for an organ donation intervention, a feasibility study will be conducted. Feasibility studies provide the foundations for full randomised controlled trials. They tackle the question; can the full trial be conducted? As opposed to; is the intervention effective? (Tickle-Degnen, 2013). Traditional experimental studies in healthcare intervention aim to assess whether an intervention is effective through
hypothesis testing. A key feature of feasibility studies is that they do not test hypotheses, but rather examine whether the intervention and full experimental trial can be conducted in the setting of interest (Tickle-Degnen, 2013).

A feasibility study investigating organ donation interventions in U.K. primary care has yet to be conducted. Previous studies have examined intervention efficacy, however, Asghar et al. (Asghar and NHS Blood and Transplant, no date, Appendix b) implemented a prompted choice intervention in Enfield, where GPs were trained by NHS Blood and Transplant and asked patients during their visit if they wanted to join the NHS Organ Donor Register. Although promising, issues were expressed by practice staff about resources and time required to ask patients in an already stretched consultation. These issues were echoed in an intervention by Pradeep (Pradeep, 2014) where GPs were initially approached to speak to patients. The author stated that the practices refused to implement an intervention of this type due to resource limitations and put up posters and brochures instead, resulting in no new registrations.

The barriers expressed in these two studies are currently widespread in primary care in the U.K. GPs are under increasing pressure as the rate of recruitment to the profession does not match the growing population (Baird et al., 2016). They experience the lowest morale amongst doctors in the NHS (Croxson, Ashdown and Hobbs, 2017), low job satisfaction (Croxson, Ashdown and Hobbs, 2017), experience high rates of alcohol addiction (Brooks, Gerada and Chalder, 2011) and stress related burn-out rates are higher than in other European countries (Brooks, Gerada and Chalder, 2011; May, Johnson and Finch, 2016). The effects of increasing pressure are also felt by the patients, with demand for consultations up 51% between 2007-2008 and 2014-2015 (Hobbs et al., 2016). Further, the impact of this is felt by other staff members with practice managers perceiving themselves as professionally isolated and lacking support in their complex day-to-day activities (Baird et al., 2016). Reasons for the increase in demand include an increasing ageing population with high numbers of co-morbidities, the increase in complexity of conditions being seen in practice, focus on health prevention services and the change in policy to move treatment from hospitals to the community to alleviate pressure (May, Johnson and Finch, 2016). These potential barriers to organ donation intervention highlight the need for thorough investigation of primary care feasibility. Although successful results may be found for the intervention method, for example training (Degenholtz et al., no date), resources could limit the practically applicability of it.

### 3.3 Rationale
The rationale for the present study is based on the discrepancy between the number of people awaiting transplant in the U.K. and the current number of organ donors (NHS Blood and Transplant, 2017a). In an attempt to combat this discrepancy, intervention is required to increase the number of people donating their organs after death (NHS Blood and Transplant, 2008). The Taking Transplant to 2020 strategy was created to increase donation rates and propose increasing membership to the NHS Organ Donor Register. Primary care interventions have previously proved to be successful in recruitment to the organ donor registry in the U.S.A (Bidigare and Ellis, 2000; Salim et al., 2014; Thornton et al., 2016) and U.K. (Asghar and NHS Blood and Transplant, no date; Pradeep, 2014) however, more research is required to form clear conclusions. Further, barriers to implementation and
acceptability of these were expressed by General Practitioners and primary care staff in the U.K. (Asghar and NHS Blood and Transplant, no date; Pradeep, 2014). Prior to the development and evaluation of intervention efficacy in this setting, the feasibility of primary care needs to be established based on the barriers expressed. Feasibility studies investigate if the setting for the intervention is appropriate, through assessment of patient views, staff views and resources required to implement it (Tickle-Degnen, 2013). In this study, we need to examine if primary care is a suitable place to run an intervention, if U.K. wide resource constraints can allow the intervention to be run successfully, consistently and acceptably for both patients and GP practice staff. Additionally, this study aims to add to the evidence base in this area, informing future research into feasibility and organ donation interventions.

4.0 Design and methodology
4.1 Study design
A stratified feasibility randomised controlled trial using a mixed experimental design (both between-groups and within-groups) will be used to test the intervention. Eight practices from Luton and Central Bedfordshire districts aim to be recruited, 4 practices randomised to the intervention arm and 4 practices randomised to the control arm. Practices will be stratified based on district and practice list size and the intervention will commence for a 3-month period. Following this evaluation of the intervention will occur. This evaluation will use mixed methods design, combining both quantitative and qualitative data collection techniques. Quantitative data includes registration information and acceptability investigation using online surveys patients. Qualitative data will also be captured using these online surveys. By combining these, both breadth and depth of intervention feasibility and acceptability can be examined. Those practices randomised to the control arm will not receive training or conduct the prompted choice intervention, only data on the number of registrations to the NHS ODR collected via new patient registration form will be collected in the control arm.

4.2 The Intervention Arm
The intervention was developed using Intervention Mapping, and is guided by both organisational and behaviour change theory (Bartholomew Eldredge et al., 2016). A Luton based practice participated in stage 1 of this feasibility research and co-designed the intervention alongside the research team and funders, NHS Blood and Transplant and the University of Bedfordshire. A letter of approval from NHS Blood and Transplant can be seen in Appendix 12.

The intervention consists of three parts; Staff Training, Leaflets and Posters, and a Prompted Choice element. The central intervention component is a question asked by clinical staff to patients, if they would like to join the NHS ODR (Prompted Choice). The training will focus on how best to ask this question and the leaflets and posters will be available if patients require more information. These individual components will be discussed in more detail in the next section of this protocol.

4.2.1 Training
Training will be conducted at practices randomised into the intervention arm prior to the intervention commencement. It will consist of two parts; NHS BT training and Intervention Data Collection Training.
The NHSBT training will be provided by the funder and involve the NHSBT specialist organ donation nurse training division. Clinical staff, experienced in having organ donation conversations with grieving families will train practice staff in how discuss the organ donor register with patients. The specific training content will be provided by NHS BT and include the importance that joining the NHS ODR is a choice to be made by patients. The ethical issues of coercion will also be addressed and staff will be provided with suggestions on how to phrase these conversations.

Training in adaptations made to the computer system (SystmONE) will be provided by the investigator and will outline the new computer based elements surrounding the prompted choice conversation.

4.2.2 Leaflets and posters
Existing NHS BT leaflets and posters will be displayed in practices randomised to the intervention arm in a dedicated display area to be determined by the practice. Examples of these leaflets and posters can be seen in Appendix 2. These will help prompt patients to think about organ donation prior to the question being asked in their consultation. Additionally, staff can direct patients to the leaflets which contain organ donation information for those undecided.

The provision of leaflets concerning religious beliefs in various languages will aid access to information to those who require more information on this topic. The leaflets, posters and languages specified are those available to the research team and already published by NHS BT. Finally, the recruitment leaflet contains a sign-up form. Patients who complete this in the practice will be directed via signage to hand in these completed forms to reception. These will be stored in a lockable metal box behind the reception area, access to the key will only be available to the CI.

4.2.3 NHS ODR Discussion
All clinical staff members working in intervention arm practices will ask patients during their consultation if they wish to join the NHS ODR, subject to attending the training session. Staff must inform the patient that the question is being asked as part of a research study, a scripted question is provided to guide staff. Patient responses will be recorded on SystmONE, the clinical data system used by the staff member. The development of the questionnaire on SystmONE was conducted with the practice manager, practice administrator and SystmONE trainer in the single practice study, to ensure the practice were happy with the content their clinicians will view. Amendments to the SystmOnE questionnaire have also been made based on the results from the single practice feasibility study. The following describes the process of prompting staff and recording patient responses.

Prompt appears on screen for staff member to ask patient if they wish to join the NHS ODR and will contain the following options.

Prompt Text
“Organ Donation Study”
Please click ‘Ok’.

If you would like to ask the patient after the consultation please press Pause.
When you are ready to ask please press ‘Save’ then ‘Resume Protocol’ or ‘Patient -> Resume’

If you are undertaking a telephone consultation, home visit or using the patient record for administrative purposes please click the red x.”

When the staff member presses ‘Ok’ on the prompt the following text will appear.

“Eligibility
Does the patient have capacity to consent?
Yes
No (Staff member will be unable to complete the questionnaire if they answer no to this question)

Tell the following to the patient:

"As part of a research study, I am going to ask you some questions about organ donation."

Patient preferences on joining NHS ODR:
Yes – Any of organs and tissues (prompt will be turned off)
Yes – Selected Organs (prompt will be turned off)
Yes - Heart
Yes - Liver
Yes - Kidneys
Yes - Corneas
Yes - Lungs
Yes – Pancreas
Unsure - Patient will think about it (prompt will appear again at next appointment)
Do not ask patient again (prompt will be turned off)
Patient believes they are already on the register (prompt will be turned off)
Would the patient like to re-register?
Yes - All organs and Tissues
Yes - Selected organs and Tissues
Yes - Heart
Yes - Liver
Yes - Kidneys
Yes - Corneas
Yes - Lungs
Yes – Pancreas
No - Patient would not like to re-register
Patient was not asked. Reason why patient was not asked:
Not appropriate for consultation
Lack of time
It was highlighted that locum GPs may not have received training in organ donation discussions. To ensure no untrained staff member will ask patients about organ donation, the prompt will only appear to those staff members who have received training. Further to ensure adherence to the eligibility criteria the prompt will be restricted to only those patients who are aged 18 or over. The responses were taken from the GMS1 form which is completed by new patients to a GP practice (appendix 3) and includes the option to register on the NHS ODR. The response “Patient believes they are already on the register” was introduced in February 2018 when on consultation with staff and research team it was highlighted a method of recording this response to the question needs to be included. If a patient does believe they are already on the register, they will have the option to re-register choosing to donate all their organs or selected organs will also be recorded.

4.3 The Control Arm
Practices randomised to the control arm will not receive any part of the intervention (training, prompted choice and leaflets and posters) and will be instructed to continue registering new patients as normal on the GMS1 form (usual care). The number of NHS ODR registrations via these forms in the 3 months prior to intervention period and 3 months during the intervention period will be collected and recorded by the CI.

4.4 Stratification & Randomisation
A list of practices based within the county of Bedfordshire and specifically in the Luton and Central Bedfordshire Districts has been obtained and includes 27 practices from each district excluding the practice that previously participated (NHS England, 2017). Practices will be stratified by two variables, practice size and district. List size into two blocks ‘small’ and ‘large’. To determine small and large practices the list of practices per district will be divided into thirds, the bottom third will be defined as small and the top third defined as large.

4.5 Recruitment
Practices within Luton and Central Bedfordshire will be recruited according to the following inclusion and exclusion criteria:

Inclusion criteria
The practice uses SystmONE computer software
An organ donation intervention has not taken place within the practice in the previous year
Located in the districts of either Luton or Central Bedfordshire

Exclusion criteria
The practice does not use SystmONE computer software
An organ donation intervention has taken place within the practice in the previous year
Not located in the districts of either Luton or Central Bedfordshire

Following this eligible practices will be sorted based on their list size and district to finalise stratification blocks. After which two practices from each block, eight in total, aim to be randomised according to Table 1.
Table 1: Stratification and Randomisation of Practices

<table>
<thead>
<tr>
<th>District</th>
<th>Practice Size</th>
<th>Arm</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Bedroom</td>
<td>Small</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Large</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Luton</td>
<td>Small</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Large</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

4.6 Randomisation procedure
Stratified practices will be randomised into either the intervention or control arm using Microsoft excel. Practices will be numbered either 1 or 2 and the RANDBETWEEN function used to randomly select either number 1 or 2. The selected number will correspond to the practice in the intervention arm, the other practice will be randomised into the control arm. Randomisation will occur once both practices in one stratification block have been recruited e.g. 2 small practices in Luton.

4.7 Data Collection & Analysis
4.7.1. Registration Data (Intervention practices only)
Table 1 shows the data which will collected through SystmONE in the intervention arm practices only.

Table 1: Data to be collected in intervention arm only

<table>
<thead>
<tr>
<th>Variable</th>
<th>Response Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Type</td>
<td>SystmONE</td>
</tr>
<tr>
<td>Date of Consultation</td>
<td>Dd/mm/yy</td>
</tr>
<tr>
<td>Patient Age</td>
<td>Years</td>
</tr>
<tr>
<td>Patient Ethnicity</td>
<td>ONS Categories</td>
</tr>
<tr>
<td>Patient Gender</td>
<td>Male or Female</td>
</tr>
<tr>
<td>Patient asked</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Reason Patient Not Asked</td>
<td>Not Appropriate/Time/Clinician Personal Beliefs/Other (Free text)</td>
</tr>
<tr>
<td>Patient joined NHS ODR</td>
<td>Yes/No/Patient believes already on register</td>
</tr>
<tr>
<td>Organs selected</td>
<td>All/Kidneys/Heart/Liver/Corneas/Lungs/Pancreas</td>
</tr>
<tr>
<td>If no, which response</td>
<td>Think about it/Do not ask again</td>
</tr>
<tr>
<td>Patient believes already on register. Re-register</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Organs selected</td>
<td>All/Kidneys/Heart/Liver/Corneas/Lungs/Pancreas</td>
</tr>
<tr>
<td>Staff Group</td>
<td>Clinical–GP/Clinical-Other/Administrative-Clinically trained/Other</td>
</tr>
</tbody>
</table>

Quantitative analyses will be conducted using SPSS version 23 to explore the influence of the variables listed in table 1. The aim of this is to compare who the intervention successfully targets, whether this translates to actual registration, compare recruitment methods and if these differences are related to staff group.
Assessment of baseline recruitment rates to the ODR by intervention practices (for 3 months prior to the intervention through new patient registration) will be compared to the total registration rates in the intervention period (both paper and SystmONE). To conduct this analysis, access to data concerning 3-months new patient registration for those patients who decided to join the organ donor register is required. This will be collected through SystmONE and through paper forms not yet inputted by the CI.

4.7.3 Registration Data (Intervention & Control practices)
In both control and intervention arm practices, registration data will be collected from the GMS1 forms completed by new patients registering at the practice. Data will be recorded manually into an excel spreadsheet by the CI from both paper forms and SystmONE and will span the three months prior to intervention commencement and the during the three month intervention period. Table X displays the data that will be collected in control practices.

Table X: Registration data to be collected from GMS1 Forms

<table>
<thead>
<tr>
<th>Variable</th>
<th>Response Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Registration</td>
<td>Dd/mm/yy</td>
</tr>
<tr>
<td>Patient Age</td>
<td>Years</td>
</tr>
<tr>
<td>Patient Ethnicity</td>
<td>ONS Categories</td>
</tr>
<tr>
<td>Patient Gender</td>
<td>Male or Female</td>
</tr>
<tr>
<td>Patient joined NHS ODR</td>
<td>Yes/No</td>
</tr>
<tr>
<td>If only selected organs - Organs selected</td>
<td>All/Kidneys/Heart/Liver/Corneas/Lungs/Pancreas/Any part of my body</td>
</tr>
<tr>
<td>Time point</td>
<td>Pre-intervention/Post-intervention</td>
</tr>
</tbody>
</table>

4.7.2 Staff Consultation Numbers (Intervention practices only)
It is also important to examine the fidelity of the prompted choice element of the intervention. To do this, the number of face to face consultations had by the practice staff undertaking the prompted choice element during the intervention period will be collected. These will be manually counted for each participating staff member by the CI on SystmONE, using the appointments overview screen. This screen allows for appointments to be counted without the CI viewing any identifiable patient data. The aim of this will be to examine how often staff were able to a. ask patients to join the ODR. This data will also be analysed quantitatively on SPSS version 23.

4.7.3 Patient Online Survey
A qualitative & quantitative online survey to access acceptability will be distributed to patients who are over 18 years of age and who attended intervention arm practices for consultation within the 3-month period. Practices will be asked to send a recruitment text message to all those registered to receive text messages from the practice who attended in the 3-month intervention arm period and for whom a SystmONE questionnaire was completed (Appendix 4). This will contain a link to the questionnaire hosted on Qualtrics which consists of the participant information sheet and consent form (Appendix 5) followed by three quantitative demographic and screening questionnaire. Following this questions about the intervention will be presented; 10 quantitative questions on 5 point Likert scales
and 6 qualitative questions with a free text box. Finally, a debrief will be presented which displays again the contact details for the study CI and supervisors, along with telephone numbers for bereavement support services. A link to the questionnaire will also be displayed on the website of intervention arm practices for patients to complete.

4.7.7 Qualitative Data Analysis
All qualitative data captured will be analysed via framework analysis using Nvivo 11. Framework analysis allows for themes to be compared across the medium they were captured and by their participants. In this instance, by method focus group, online survey or training evaluation, and by participants (patients or staff). Themes will be categorised based on the underpinning theoretical framework for this study, Lau et al’s (2016) conceptual framework for implementation of primary care interventions and the IFF Model of Organ Donation Registration (Siegel, Alvaro and Hohman, 2010; Lau et al., 2016).

4.7.8 Quantitative Data Analysis
All quantitative data analysis will be conducted on SPSS version 23 and Microsoft Excel version 15. The registration data will be analysed quantitatively to inform a sample size calculation for a future trial. Analyses will be conducted at the practice-level and require a measure of effect size and the standard deviation of each group. Both within-group and between-group sample size calculations will be conducted. Cohen’s d will be used to calculate the effect size between the intervention and control arms. Cohen’s d will also be used to calculate the effect size of 3-months pre intervention NHS ODR registration rates with 3-month during intervention period registration rates (in both intervention arm and control arm practices). Cohen’s d will also indicate if the intervention works in the way in which it is intended, namely that more patients register on the NHS ODR in the intervention arm than control arm. Significance testing will not be conducted as the aim of this study is to assess feasibility not intervention effectiveness.

5.0 Research outcome
The aim of this research is to evaluate whether primary care is an appropriate setting for the organ donation intervention described above. If the intervention is deemed feasible for this setting, future research can endeavour to evaluate the efficacy of the intervention through pilot randomised controlled trial. Additionally, barriers and facilitators to implementing interventions in this setting could help inform future interventions, in organ donation or other health behaviour change areas. Additionally calculating values which can inform a future sample size calculation is a key objective of feasibility studies as stated by the MRC Guidelines to inform the development of complex interventions(Craig et al., 2013).

6.0 Ethical considerations
The intervention has been developed in partnership with and is endorsed by the practice who previously participated and NHS Blood and Transplant who are part funding it (letter of support can be viewed in appendix 1). Support from the Patient Participation Group at the practice who previously participated was also gained. These stakeholders were involved at all stages of the research protocol development to address the following ethical considerations.
6.1. Distress
A key ethical concern when developing this research is the issue of distress to patients and staff during organ donation conversations. Predicting whom will become distressed by these conversations or questions is challenging. To help ensure as minimal distress to patients occurs as possible, staff will be trained in how to best have these conversations by the experienced specialist organ donation nurse training division, a part of NHS Blood and Transplant. These staff have these conversations daily with grieving families and will help guide staff in this. The training sessions will consist of example conversations in the form of role plays and staff will be able to practice these conversations. Staff who have not had this training, will not be allowed to have this conversation with patients through question displayed on their computer screen prior to being prompted to discuss the NHS ODR with patients.

Additionally, staff will be informed that they must use their professional judgement as to whether a conversation is appropriate for the patient they are about to see. For example, if the patient is experiencing mental health problems which could be exacerbated by conversations concerning organ donation or is receiving test results which could cause distress themselves. If staff are unsure, they will be instructed to refrain from having the conversation with patients.

For staff and patient wellbeing, the contact details for bereavement support services will be displayed throughout the practice. Staff will be advised to direct patients to these contact details and staff will be informed that they can refrain from having conversations if it will cause them distress. If staff do not have the conversation for these reasons, this will be recorded to ensure accurate assessment of feasibility can be conducted and take into account the element of distress.

6.2. Coercion
A second issue is coercion. In the context of joining the organ donation register, it is vital that these decisions made by are elective. Therefore, staff will be trained that, as opposed to normal clinical practice, they are not advising or recommending a patient join the register, merely offering them the opportunity if they wish too. This will be a significant part of staff training and staff will be scripted examples to help guide them in the appropriate language to use to avoid coercion. Additionally, if they believe the patient may feel under pressure to join, they will be advised to stop the conversation and ask the patient to think about it. As above, if this occurs it will be recorded on to SystmONE by the GP.

6.3. Locum GPs
Do not attend the same training sessions that other staff do and may not have discussions with patients appropriately. Therefore, as discussed above, a prompt will be included in the data collection system which asks the staff if they have had the training to conduct an organ donation conversation, prior to them being able to complete other information on the form. If they have not had training, they will be instructed not to have the conversation. Additionally, weekly monitoring visits will be conducted and the raw data accessed. The CI will be able to view who has received the prompt. If any untrained staff member has discussed this with patients, a meeting will be conducted with them to ensure they do not do so in future.
6.4. Impact on normal running of practices
The intervention will be mindful of the normal running of practices. Ensuring the impact on the working practice is minimal has been achieved by collaborating with the practice and patient group throughout the design. Staff will be informed that the priority is patient care, the intervention should always come second.

6.5. Consent
Formal informed consent will be sought from the practice, and additionally from patients prior to their involvement in the online survey, once the intervention has ceased. The Information Sheet and consent form addresses the key consent principles highlighted by the HRA: will ensure participants understand the purpose and nature of the research, what the research involves, its benefits (or lack of benefits), risks and burdens, the alternatives to taking part, how long data will be stored for, that participation is voluntary and that they are able to make a decision on consent at the time of the focus group.

After discussion with the stakeholders, in particular the PPG of the previously participating practice, overt informed consent will not be sought for each patient with whom an organ donation question occurs. This is due to the practical difficulties of obtaining formal consent in each consultation, in a working primary care practice, over a 3-month period. The data to be collected without overt patient consent will be that which is already collected by NHS Blood and Transplant, namely gender, age, ethnicity, registration status and organs chosen for donation. Additional data collected concerning the consultation will not be related to the patient.

6.6. Data Protection and Sensitive Data
The data will be accessed through SystmONE and paper form at the practices by the CI. Through this access the CI will be able to access patient records. The CI however, will only access data relevant to the present study, including the data specified above concerning registration status. When data is removed from SystmONE and extracted from paper forms for analysis it will be anonymised and only the sensitive variables of age, gender, ethnicity included. It will be password protected on a memory stick. Also included will be staff group of the member who took the consent (intervention arm), and if the patient was not asked the reason for this. This process has been approved by stakeholders. The CI has extensive experience in data management and privacy procedures, during employment with the Medical Research Council Clinical Trials Unit. They also have experience and training on SystmONE.

Online survey data will be securely hosted on Qualtrics, who adhere to the data protection act and online data protection procedures. At no point will participants be asked their name, the only identifiable data for the participants collected on Qualtrics will be their IP address. This will be deleted in all data sets extracted for analysis.

6.7. Anonymity and Confidentiality
Participants will be informed that all responses will be confidential and anonymous, but also that responses may be traceable back to practices in publication. Any quotes published will
not be referred to participants by name. The principles of anonymity and confidentiality will be adhered to throughout the project and participants will be made aware of these.

7.0 Publication and dissemination
Research findings will be presented in various publications throughout this study. Namely, conference presentations, academic journals and media releases. The intention being to inform future researchers of the success of implementing an organ donation intervention in a primary care setting.
Appendix 4: Patient Recruitment text message.

Organ donation research has been conducted in your practice. As a patient who visited the practice during this time we would like to invite you to complete an anonymous online survey about your views on this. To do this, please click on the following link. Thank you.

[INSERT LINK]

Appendix 5: Patient Online Survey - Information Sheet, Consent Form and Survey Content

ONLINE SURVEY – Patients

Title of Project: **Organ donation intervention in primary care: A feasibility study.**

Name of Researcher: Catrin Pedder Jones

IRAS ID: 230702

I am Catrin Pedder Jones, a PhD Student working with the University of Bedfordshire and NHS Blood and Transplant. I am conducting research on the feasibility of organ donation interventions in a U.K. primary care setting.

**Summary**

The NHS Organ Donor Register is a database which keeps a record of everyone who wants to donate their organs after death. However, only 35% of the U.K. population are on the NHS Organ Donor Register. To help increase this, we have developed an intervention in partnership with a GP practice. The intervention has been conducted in your GP surgery for the past three months and is over. We now wish to see what patients thought of our intervention.

This research will involve your participation in a short online survey that will take approximately **15 minutes.**

You have been invited to take part because we feel you could give us valuable information about our intervention, are a patient and have visited your practice within the 3-month intervention period.

**Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at your GP Practice will continue and nothing will change.

**Procedures**

We are asking you to help us learn about how you, the patients, found the intervention. You will be presented with 3 questions about you (your age, gender and ethnicity) followed by 16 questions about the intervention. These questions are open and you can write as little or as much as you like in response.

The questions will be about the organ donation intervention. For example, if you liked it, disliked it, noticed it and what impact it had on you. We will not ask you to share personal
beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.

**Risks**
There are few risks to taking part in the research. However, questions involve the topic of organ donation and death, which some people might find difficult. Telephone numbers of support services can be found at the end of this form and again at the end of the survey. You do not have to answer any question if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question.

**Benefits**
There will be no direct benefit to you, but your participation is likely to help us adapt our intervention and help us increase membership of the NHS Organ Donor Register in other GP Practices.

**Reimbursements**
You will not be provided any incentive to take part in the research.

**Confidentiality**
We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private.

**Sharing the Results**
Nothing that you tell us today will be attributed to you by name and at no point will we ask your name. It may however be attributed to your practice. The knowledge that we get from this research may be published in academic journals or distributed by the media. This is so that others may benefit from our findings in this research project.

Additionally, we may quote parts of what you say in these publications and responses may be traceable back to your practice in publication. However, these will be anonymous and not include your name.

**Right to Refuse or Withdraw**
You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your treatment at your practice in any way. You may stop participating in the discussion at any time that you wish.

**Ethical Approval**
This proposal has all been reviewed and approved by the Heath Research Authority and London Brent Research Ethics Committee which is a committee whose task it is to make sure that research participants are protected from harm.
This proposal has also been reviewed and approved by the University of Bedfordshire Research Ethics Committee who are part-funding the study.

**GDPR Statement**
The University of Bedfordshire is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the
data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bedfordshire will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Catrin Jones, catrinpedder.jones@beds.ac.uk.

**Who to Contact**
If you wish to ask questions about this research, you may contact any of the following:

Catrin Pedder Jones, PhD Student.
Telephone: 
Email: catrin.jones1@study.beds.ac.uk

Dr. Chris Papadopoulos, Supervisor
Email: chris.papadopoulos@beds.ac.uk

Prof. Gurch Randhawa, Supervisor
Email: gurch.randhawa@beds.ac.uk

If you feel affected in any way by these discussions, please see below for some local support services who may be able to help.

Samaritans: 116 123
Cruse Bedfordshire, Bereavement Counselling: 01582 595300
Keech Hospice Care Bereavement Service: 01582 492339

IF YOU WISH TO TAKE PART IN THE STUDY, PLEASE CLICK NEXT.

**CONSENT FORM**

Title of Project:  **Organ donation intervention in primary care: A feasibility study.**
Name of Researcher: Catrin Pedder Jones
Study Element: Online Survey - Patient

- I confirm that I have read the information for the above study. I have had the opportunity to consider the information.
• I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

• I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

• I agree to take part in the above study.

DEMOGRAPHIC AND SCREENING QUESTIONS
Thank you for agreeing to participate in this research, first we will ask you 3 demographic questions.

16. How old are you in years? ......

17. What is your gender?
   a. Male
   b. Female
   c. Other
   d. Prefer not to say

18. What is your ethnicity?
   a. White – English/Welsh/Scottish/Northern Irish/British
   b. White – Irish
   c. White – Gypsy or Irish Traveller
   d. White – Other
   e. Mixed – White & Black Caribbean
   f. Mixed – White & Black African
   g. Mixed – Other
   h. Asian/Asian British – Indian
   i. Asian/Asian British – Pakistani
   j. Asian/Asian British – Bangladeshi
   k. Asian/Asian British – Chinese
   l. Asian/Asian British – Other
   m. Black – African
   n. Black – Caribbean
   o. Black – Other
   p. Other – Arab
   q. Other – Any other ethnic group

INTERVENTION QUESTIONS.
Thank you, we will now ask you a maximum of 11 questions about your experience of the intervention.

19. Were you asked during a consultation at your practice if you would like to join the NHS Organ Donor Register?
   a. Yes (questions 5,6 & 7 will open)
   b. No (question 8 will open)
20. If yes, do you remember which type of staff member asked you this question?
   a. Doctor/GP
   b. Nurse/Healthcare Assistant
   c. Other

21. (If yes) Overall please rate your experience of being asked to join the NHS Organ Donor Register.
   a. Mostly Negative
   b. Somewhat Negative
   c. Neither positive nor negative
   d. Somewhat Positive
   e. Mostly Positive

22. (If yes) can you write about your experience of being asked if you would like to join the organ donor register?
   o For example:
     § Was it an easy conversation?
     § Were you comfortable?
     § Did you understand what you were being asked?

23. (If yes) To what extent do you agree with the following statement ‘being asked to join the organ donation register helped me make a decision on whether to register’
   a. Disagree
   b. Somewhat disagree
   c. Neither agree nor disagree
   d. Somewhat agree
   e. Agree

24. (If yes) Please explain your answer

25. (If no) Overall please rate your agreement with being asked to join the NHS Organ Donor Register by staff in your GP practice.
   a. Disagree
   b. Somewhat disagree
   c. Neither agree nor disagree
   d. Somewhat agree
   e. Agree

26. (If no) Please explain your answer

27. Did you notice the leaflets and posters in the waiting room?
   a. Yes (questions 10&11 open)
   b. No (goes straight to question 12)

28. To what extent do you agree with the following statement ‘the leaflets and posters in the waiting room of my GP practice were helpful for me’?
29. To what extent do you agree with the following statement ‘the leaflets and posters helped me make a decision on whether to register as an organ donor or not’?
   a. Disagree
   b. Somewhat disagree
   c. Neither agree nor disagree
   d. Somewhat agree
   e. Agree

30. Please explain your answer

31. To what extent do you agree with the following statement ‘I believe the intervention (being asked to join the organ donor register & organ donation leaflets and posters) is appropriate’?
   a. Disagree
   b. Somewhat disagree
   c. Neither agree nor disagree
   d. Somewhat agree
   e. Agree

32. To what extent do you agree with the following statement ‘I believe my GP practice is an acceptable place to have an organ donation intervention’?
   a. Disagree
   b. Somewhat disagree
   c. Neither agree nor disagree
   d. Somewhat agree
   e. Agree

33. Do you have any recommendations for us on how we can improve the intervention?

34. Is there anything else that you would like to tell us about our intervention?

END PAGE

Thank you. You have now completed the online survey element. We appreciate the time you have taken to do this.

Who to Contact
If you wish to ask questions about this research, you may contact any of the following:
Catrin Pedder Jones, PhD Student.
Telephone:
Email: catrin.jones1@study.beds.ac.uk

Dr. Chris Papadopoulos, Supervisor
Email: chris.papadopoulos@beds.ac.uk

Prof. Gurch Randhawa, Supervisor
Email: gurch.randhawa@beds.ac.uk

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Cruse Bedfordshire, Bereavement Counselling: 01582 595300
Keech Hospice Care Bereavement Service: 01582 492339
Appendix 43: Multi-Practice RCT Recruitment Data Collection Protocol

1. Introduction

This protocol outlines the recruitment phase of a multi-practice feasibility randomised controlled trial (RCT). A single practice study was conducted between March – September 2018 with the intervention found to be feasible to test further (IHREC800). The intervention to be tested aims to provide an opportunity for patients visiting their GP to join the NHS Organ Donor Register (ODR). This is facilitated by clinicians asking during consultations if they would like to join the NHS ODR (prompted choice). Two additional elements are included to support the intervention, leaflets and posters for information and awareness and training of staff prior to prompted choice.

1.1 Background and rationale

The rationale for the present study is based on the discrepancy between the number of people awaiting transplant in the U.K. and the current number of organ donors (1). In an attempt to combat this discrepancy, intervention is required to increase the number of people donating their organs after death (2). The Taking Transplant to 2020 strategy was created to increase donation rates and propose increasing membership to the NHS Organ Donor Register. Primary care interventions have previously proved to be successful in recruitment to the organ donor registry in the U.S.A (3–5) and U.K. (6, 7) however, more research is required to form clear conclusions. Further, barriers to implementation and acceptability of these were expressed by General Practitioners and primary care staff in the U.K. (6, 7). Prior to the development and evaluation of intervention efficacy in this setting, the feasibility of primary care needs to be established based on the barriers expressed. Feasibility studies investigate if the setting for the intervention is appropriate, through assessment of patient views, staff views and resources required to implement it. A key objective of feasibility to studies is to inform researchers whether a full RCT testing efficacy and or effectiveness can be conducted. Recruiting to these RCTs is key in their ability to run effectively. As previously discussed unique barriers are present in U.K. primary care which require a comprehensive assessment of recruitment at the practice level.

1.2 Overall Trial Design & Summary

A stratified randomised controlled trial using a mixed experimental design (both between-groups and within-groups) will be used to test the intervention. Eight practices from Luton and Central Bedfordshire districts aim to be recruited, 4 practices randomised to the intervention arm and 4 practices randomised to the control arm. Practices will be stratified based on district and practice list size and the intervention will commence for a 3-month period. Following this evaluation of the intervention will occur. This evaluation will use mixed methods design, combining both quantitative and qualitative data collection techniques. Quantitative data includes evaluation of training, registration information and acceptability investigation using online surveys for staff and patients. Qualitative data will also be captured using these online surveys. By combining these, both breadth and depth of intervention feasibility and acceptability can be examined. Those practices randomised to the control arm will not receive training or conduct the prompted choice intervention, only
data on the number of registrations to the NHS ODR collected via new patient registration form will be collected in the control arm.

2. **Objectives**

The overall feasibility cluster randomised controlled trial objective is as follows:

1. To assess the feasibility and acceptability of an organ donation intervention implemented in U.K. primary care.

The objectives of the present recruitment protocol are as follows:

To examine:
1. How many practices are eligible in the recruitment target area?
2. How many practices were approached for participation?
3. How many practices declined to take part in the study?
4. How many practices did not respond to recruitment invitations?
5. How many practices expressed an interest in participating in the study?
6. How many practices formally enrolled in the study?
7. How many practices were randomised?

3. **Design and Methodology**

3.1 **Stratification & Randomisation**

A list of practices based within the county of Bedfordshire and specifically in the Luton and Central Bedfordshire Districts has been obtained and includes 27 practices from each district excluding the practice that previously participated (8). Practices will be stratified by two variables, practice size and district. List size into two blocks ‘small’ and ‘large’. To determine small and large practices the list of practices per district will be divided into thirds, the bottom third will be defined as small and the top third defined as large.

3.2 **Recruitment**

Practices within Luton and Central Bedfordshire districts will be contacted via telephone to confirm their eligibility for the study according to the following practice inclusion and exclusion criteria:

**Inclusion criteria**
- The practice uses SystmONE computer software
- An organ donation intervention has not taken place within the practice in the previous year
- Located in either Luton or Central Bedfordshire district.

**Exclusion criteria**
- The practice does not use SystmONE computer software
• An organ donation intervention has taken place within the practice in the previous year
• Not located in either Luton or Central Bedfordshire district

Following this eligible practices will be sorted based on their list size and district to finalise stratification blocks. After which two practices from each block, eight in total, will be approached to be a part of the study (Table 1). An email will be sent to the practice containing a letter of invitation to participate, advertisement sheet and study information (appendix a-c). The practice will also be contacted via telephone to discuss interest in participation. One week following this initial contact practices will be contacted again to confirm interest or decline to participate. If a practice is undecided this will be recorded and the practice will be contacted one-week intervals until a decision has been made. Following this, if required, more practices will be approached in the same way. Additionally, if recruitment through initial email approach is poor, the practice who previously participated will be contacted to aid recruitment via snowballing. Recruitment will cease on 30th June 2019 with all undecided practices contacted to confirm or decline participation. The intervention will then be run from July – December 2019 with all practices who confirmed participation.

Table 1: Stratification and Randomisation of Practices

<table>
<thead>
<tr>
<th>District</th>
<th>Practice Size</th>
<th>Arm</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Intervention</td>
</tr>
<tr>
<td>Central Bedfordshire</td>
<td>Small</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Large</td>
<td>1</td>
</tr>
<tr>
<td>Luton</td>
<td>Small</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Large</td>
<td>1</td>
</tr>
</tbody>
</table>

3.3 Randomisation procedure

Stratified practices will be randomised into either the intervention or control arm using Microsoft excel. Practices will be numbered either 1 or 2 and the RANDBETWEEN function used to randomly select either number 1 or 2. The selected number will correspond to the practice in the intervention arm, the other practice will be randomised into the control arm. Randomisation will occur once both practices in one stratification block have been recruited e.g. 2 small practices in Luton.

3.4 Data Collection & Analysis

As key part of feasibility studies is collecting data on study recruitment. A ‘recruitment’ diary consisting of ‘recruitment forms’ will be used to collect this data (appendices d-f). The first recruitment form collects data on which practices are eligible to participate (appendix d). Form two lists the eligible practices sorted by stratification blocks (appendix e). Form 3 (appendix f) is the approach and expression of interest form, which collects information on how and how many times practices were contacted, whether they expressed an interest in participating and if this led to randomisation. All forms will be completed digitally in one Microsoft excel password protected spreadsheet.
4. References

6. Pradeep A. Increasing organ donation from the North West South Asian community through targeted education. University of Salford, United Kingdom; 2014.
Appendix 44: Practice Recruitment Participation Email, Advertisement Sheet and Study Information Sheet

Subject: Ground breaking organ donation research – call for practices

Dear [insert name of practice manager & lead GP Partners]

My name is Catrin Pedder Jones and I am a researcher working in partnership with NHS Blood and Transplant. We are looking for practices willing to take part in our new ground breaking research in organ donation. Our simple intervention was co-created with a Luton based GP practice and their PPG. This practice conducted the intervention over a 3 month period in 2018 with positive feedback from staff and patients.

Our intervention aims to work with GPs to offer patients the opportunity to sign-up to the NHS Organ Donor Register in their consultations. Currently approximately 3 people die every day waiting for a transplant and our simple intervention has the potential to significantly improve and save lives.

I have attached details of the study to this email for your consideration. Thank you very much for taking the time to read this email and information as we are very aware how busy you are.

We would appreciate it if you could get back to me via email catrin.jones1@study.beds.ac.uk if you are interested in participating or for more information. Looking forward to hearing from you.

Kind Regards,

Catrin P Jones
On behalf of the GPOD study team
Dr. Chris Papadopoulos, Prof. Gurch Randhawa & Mr. Zeeshan Asghar
GPOD – General Practice Organ Donation Study – Call for Practices

The GPOD Study team are looking for GP Practices to take part in revolutionary organ donation research. We would like {Insert practice name} to join our study and believe you could be a perfect fit.

What is the GPOD study?
The GPOD organ donation study aims to test whether a new intervention to offer all patients the opportunity to join the NHS Organ Donor Register (NHS ODR) is feasible to conduct in GP practices. The study is funded and supported by NHS Blood and Transplant in conjunction with the University of Bedfordshire.

What is the new organ donation intervention?
The intervention is very simple. It involves all clinical staff asking their patients, where feasible and appropriate, during consultations if they wish to join the NHS ODR. New patients already have the opportunity to register on the NHS ODR via the GMS1 form, we wish to expand this opportunity to all patients.

Why do we need this intervention?
We do not have enough organs available for transplantation in the U.K. (NHS Blood and Transplant, 2018a). Interventions are key in helping to reduce the gap between the number of people waiting for an organ and the number of people donating them. An important part of the organ donation pathway is that families must give final consent for organ donation, in both the opt-in and opt-out systems we have in the U.K. (Hulme et al., 2016). The research literature shows it is very important for people to express their wishes to their family before their loved ones have to make a decision at a time of great grief and trauma (Ralph et al., 2014; de Groot et al., 2015). Also clear is that the public expect to be exposed to organ donation in their GP practice (Rea and Meakin, no date). By bringing up the topic of organ donation and offering patients in GP practices the opportunity to sign-up to the ODR, this intervention has the potential to make these family decisions easier and subsequently increase the number of people donating their organs.

Has the intervention been run before?
Yes, the intervention successfully ran for 3 months (April-July 2018) in a practice in Luton (Jones et al., 2018). We worked closely with the practice during the design of the intervention and their views were instrumental in shaping how it is run. Results showed that staff were able to ask patients to join the NHS ODR in many of their consultations. However, we now need to run the intervention in more practices as part of a randomised controlled trial. Here are some quotes from practice staff about taking part in the intervention:
“I still think general practice would probably be the best place for these things to happen and it’s a real shame if we cannot do this” (GP)

“I found when I had the conversation it was actually fun, because it was something we don’t do every day and people sort of tend to have these really frank discussions about their belief” (GP)

“Many of the consultations did lead to a conversation, and so if I could impart information to clarify for a person to make their own mind up, that was where it was quite satisfying for me” (Nurse)

“I would be happy to continue asking my patients if the intervention was reintroduced as I feel it is a tremendously worthwhile/beneficial process to contribute towards. I’m grateful I was given the opportunity to possibly contribute to such a fantastic service” (Nurse)

What are the benefits to my practice through taking part?
If your practice is randomised into the intervention arm, you will receive a one-hour training session on organ donation and the intervention. Training is conducted by a Specialist Nurse in Organ Donation and was very well received when conducted previously:

“as far as the training goes I thought it was quite good and it gave us quite a bit of ideas about how to do this” (GP)

“I found the training session very very useful, bit of an eye opener in terms of what ages and who they can and can’t use, so that was really good.” (Healthcare Assistant)

“the initial training session was very informative, it was good to have someone there from the actual organ donation service, to give extra information and give hints and tips as to how to discuss, this with our patients” (Nurse)

“It is done in a tone that "normalises" for us a difficult conversation. I feel as if I have been given "permission"!” (GP)

This is your opportunity to have a say on the future of our intervention. Feasibility studies do not examine whether an intervention works, but if an intervention can be conducted in the setting of choice.

What are the wider benefits to society of taking part?
Between April 2017 – March 2018, 168 people did not donate their organs due to their family not knowing what their wishes were (NHS Blood and Transplant, 2018a). In the same time period 411 people died whilst awaiting a transplant (NHS Blood and Transplant, 2018a). Our intervention primarily will bring up the topic of organ donation with many more people who come from many different walks of life. If our intervention can encourage discussion and registration on the NHS ODR, we can help guide families to make the right decision for their loved one. Therefore, the potential for positive social impact is substantial.
What will {insert practice name} need to do?
As this study is a feasibility randomised controlled trial your practice will be randomly allocated to be in the intervention arm or control arm. Below outlines what we would need you to do in each arm:

**Intervention arm**
- We would need you to allow our lead researcher to access the practice computer system to set up the study. This involves adding a simple prompt and questionnaire into the system.
- As many staff as possible should attend a 1-hour training session on organ donation and the intervention. This can be conducted at a time appropriate for your practice.
- For a three-month period staff should try and ask their patients in consultations if they wish to join the NHS ODR. To help with this a prompt will pop up on SystmONE at the start of consultations for all staff who attend training session. This prompt then opens into a questionnaire to complete to record patient responses or reasons why the patient was not asked.
- For the same 3-month period the lead researcher will display posters and leaflets in the practice. These will be provided by NHS Blood and Transplant and aim to provide information on organ donation.
- During the 3-month period the lead researcher will require fortnightly access to a computer with SystmONE on which the intervention can be monitored and extract questionnaire responses extracted.
- After the intervention period has ended, we would need you to allow our lead researcher to come into your practice and view the new patient registration forms for a specified 6-month period.
- The lead researcher will collect anonymised data from these forms into their own password protected spreadsheet.
- The lead researcher will download responses to the questionnaire and manually count the number of consultations the staff who received the prompt had in the 3-month period.
- We would also need you to advertise an online survey for patients to complete about the intervention on your website and if applicable via a text message to patients.
- Finally after the intervention we would need you to email an online survey out to participating staff to capture their experiences and thoughts on the intervention.

**Control arm**
- Very little would change, we would like you to continue registering new patients as normal and have them complete the GMS1 form.
- We would need you to allow our lead researcher to come into your practice and view the new patient registration forms for a specified 6-month period.
- The lead researcher will collect anonymised data from these forms into their own password protected spreadsheet.
Frequently asked questions.

**We are very busy, what if we struggle to run the intervention after agreeing to participate?**

Your participation is still welcome, this is absolutely fine and would actually be important finding for us. The main aim of this study is to understand whether staff are able to ask patients, and understand the reasons why they can or cannot do this. All we ask is that you’re honest with us when we ask for feedback.

**It may not be appropriate to ask all our patients to join the NHS ODR, what do we do then?**

This will be discussed during the training session but ultimately the decision will be down to your staff about whether it is appropriate or not to ask a patient. Asking the question is not compulsory for every patient, instead staff should try to ask as many patients as ethically possible.

If you have any other questions or concerns please feel free to contact the study Lead Researcher - Catrin P Jones at catrin.jones1@study.beds.ac.uk

Thank you for taking the time to read about the GPOD GP Organ Donation Study.

*Our study is funded by The University of Bedfordshire and NHS Blood and Transplant and is being conducted as a PhD by Ms Catrin Pedder Jones.*

## GPOD Research Information Sheet for Practices

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Investigating an organ donation intervention in primary care: A multi-practice feasibility study (GPOD).</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRAS ID</td>
<td>230702</td>
</tr>
<tr>
<td>Sponsor</td>
<td>University of Bedfordshire</td>
</tr>
<tr>
<td>Funders</td>
<td>NHS Blood and Transplant</td>
</tr>
<tr>
<td></td>
<td>University of Bedfordshire</td>
</tr>
<tr>
<td>Chief Investigator(s)</td>
<td>Catrin Pedder Jones</td>
</tr>
<tr>
<td>Intervention</td>
<td>The GPOD Intervention aims to encourage GP Practice staff to ask their patients during consultations if they would like to join the NHS Organ Donor Register (prompted choice). Specialist training and leaflets and posters will be provided to support staff with this.</td>
</tr>
<tr>
<td>Study Design</td>
<td>A stratified feasibility randomised controlled trial using a mixed experimental design (both between-groups and within-groups) will be used to test the intervention. Eight practices from Luton and Central Bedfordshire districts aim to be recruited, 4 practices randomised to the intervention arm and 4 practices randomised to the control arm.</td>
</tr>
<tr>
<td>Primary Study Aim &amp; Objectives</td>
<td>To assess the feasibility and acceptability of an organ donation intervention implemented in U.K. primary care.</td>
</tr>
<tr>
<td>Study Duration</td>
<td>5 Months</td>
</tr>
<tr>
<td>Intervention Period</td>
<td>3 Months</td>
</tr>
</tbody>
</table>
| Summary of Practice Eligibility Criteria | Inclusion criteria  
- The practice uses SystmONE computer software  
- An organ donation intervention has not taken place within the practice in the previous year  
- Located in either Luton or Central Bedfordshire district. |
| Exclusion criteria |  
- The practice does not use SystmONE computer software  
- An organ donation intervention has taken place within the practice in the previous year  
- Not located in either Luton or Central Bedfordshire district |
| Core Practice Activities | Intervention & Control Arms  
New Patient Organ Donation Registrations  
- The practice will give access to the lead researcher to view new patient forms specifically for the recording of responses to the question to join the NHS ODR. The lead researcher will record anonymised responses onto a spreadsheet complete with |
gender, age and ethnicity of registrants. New patient registration forms should span 3 months prior to intervention start and the 3 months during which the intervention is taking place.

### Intervention Arm Only

#### Training
- To liaise with lead researcher to organise training session 1 month prior to intervention start
- Staff attend specialist organ donation training session (duration 1 hour)

#### Prompted Choice
- All staff who attended training attempt to ask their patients if they would like to join the NHD ODR as part of their consultations for a 3-month period
- A SystmONE prompt will appear at the start of consultations and staff will be instructed to record responses on SystmONE via questionnaire

#### Leaflets & Posters
- The practice will allow lead researcher to display leaflets and posters in patient waiting areas

#### Monitoring & Data Collection
- The practice will provide access to the practice and computer access for the monitor to conduct monitoring activities on SystmONE (fortnightly approximately 2 hours)
- The practice will provide access to the practice to conduct study set-up and close activities including computer access (pre-intervention & post-intervention 2 hours)

#### Feasibility Assessments
- The practice will send a text message to all patients for whom a questionnaire has been completed to advertise the online patient survey, complete with link to survey (post intervention).
- The practice will display a link to the online patient survey on their website during the intervention and for 2 weeks post-intervention.
- The practice will email a link to the online staff survey to all staff who took part in the intervention.

### Patient Involvement

In intervention practices patients will be exposed to the leaflets and posters in the waiting area. Then patients will potentially be asked if they would like to join the NHS ODR in their consultation. Patients may also receive a text message advertising an online survey to give their view on the intervention.

### Resources provided by study team

The study team will provide a one-hour training session in organ donation and study procedures. This session is run by NHS Blood and
Transplant and includes an in-depth session by a Specialist Nurse in Organ Donation. An opportunity for Q&A with the specialist nurse is also included alongside a theatre forum session and practical demonstration.

**Preliminary work**

This intervention was co-designed by the research team, NHS Blood and Transplant, a large Luton based GP practice and their PPG. It was successfully run for 3 months in 2018 in this participating GP practice. Results from this preliminary work suggest the intervention is feasible to run by staff and acceptable to both staff and patients.

<table>
<thead>
<tr>
<th>What are the likely benefits to the practice/patients?</th>
<th>Practice Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>To help encourage discussion of organ donation amongst their staff, patients and local community.</td>
</tr>
<tr>
<td></td>
<td>A training session in organ donation.</td>
</tr>
<tr>
<td></td>
<td>Practice staff are given an opportunity via the survey to express any challenges they experience with the intervention. These could be applicable to other interventions and practices within primary care and could be published to aid future developers.</td>
</tr>
</tbody>
</table>

**Patient Benefits**

- To be provided with an opportunity to sign-up as an organ donor verbally, which is currently unavailable anywhere else in the UK.

<table>
<thead>
<tr>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catrin Pedder Jones</td>
</tr>
<tr>
<td>Institute for Health Research</td>
</tr>
<tr>
<td>University of Bedfordshire</td>
</tr>
<tr>
<td>Putteridge Bury</td>
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<tr>
<td>Luton</td>
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<tr>
<td>LU2 8LE</td>
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### Appendix 45: Recruitment Diary Data Collection Forms

**Recruitment Diary Form 1 – Practice Eligibility V1 Feb 19**

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### Appendix 46 Completed Multi-practice RCT Recruitment Forms

Recruitment Diary Form 2 – Stratification V1 Feb 19 Completed

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*Practice names removed to maintain anonymity*
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<th>Date First Email Sent</th>
<th>Name, Role &amp; Email address of person email sent to</th>
<th>Email response notes</th>
<th>Date &amp; details of follow up email sent</th>
<th>Date Follow up call conducted</th>
<th>Name, Role &amp; telephone number of person spoken to</th>
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<td>No Response by 28th March 2019</td>
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<td>Re sent 19th March cc'd in supervisors</td>
<td>14th March 2019</td>
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<td>Reception</td>
<td>Put through to practice manager and no response, told to call again.</td>
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<td>14th March 2019</td>
<td>Reception</td>
<td>Waiting 20 mins - practice manager unavailable</td>
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*Practice names removed to maintain anonymity*