


Organs for Transplants

THE SUPPLEMENT REPORT

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The Objective of This Paper

This paper should be read in conjunction with the Organ Donation Taskforce's Report - *Organs for Transplants - A Report from the Organ Donation Taskforce.*

This paper seeks to:

- Provide the wider evidence behind the work of the Taskforce. Examples includes a detailed economic analysis of the contribution that transplantation makes to the wider healthcare economy and an impact of increased organ donation has on net costs. Other examples included health inequalities, ethics of donation and the challenges along the donation pathway.
- Explain the benefits, both qualitative and quantitative, behind each of the recommendations and to explore some of the wider implications.

Structure of Paper

This paper has five main headings, followed by several appendices from 1 to 12. The five main headings are:

- Executive Summary,
- Benefits,
- Recommendations,
- Why Change is Important,
- The Basis for Change,

The objective is to present the wide range of evidence to support:

- *The reasons why current arrangements are not adequate*,
- *The rationale for each of the recommendations*,

The detailed evidence is presented in appendices 4 to 12.

Appendices 10, 11 and 12 provide a glossary of terms used throughout this report, Taskforce membership and the Terms of Reference.

Executive Summary

The sustained increase in organs for transplantation will bring substantial benefits to patients and the NHS. Rarely in health is there such a direct and rapid link between the action to address a problem and its resolution to save lives. Experiences from leading countries such as Spain, the US and North Italy have demonstrated that developing robust arrangements for organ donation with strong leadership delivers a sustained increase in organs.

Organ donation is unlike many other services in healthcare. Given the need to ensure the right organ is matched to the right patient, organ donation is a national enabling function aimed at supporting local transplantation delivery. Organ donation is both medically challenging and logistically difficult. For bereaved families and healthcare professionals it is emotionally demanding and occurs in an environment where timescales are tight.

Currently, organ donation is not adequately performance managed or funded. Key elements, such as organ retrieval and donor transplant co-ordination, are heavily reliant on a variety of ad hoc arrangements. Despite the hard work of organisations, such as UK Transplant (UKT) and hospital Trusts/Divisions, it is neither stable nor fit for the future. Despite this, we know that organ donation and transplantation is widely supported amongst members of the public and those in healthcare.

This paper summarises a series of recommendations that centre on building a robust structure for the future, removing obstacles to donation and making clear what people are responsible for. The Taskforce is confident that the cumulative effect of these recommendations will increase the number of organ donors by approximately 50%.

Benefits

This section aims to show the broad benefits of implementing the Taskforce's recommendation.

Quantified Benefits. Conservatively, it is known that if all hospitals were undertaking organ donation at a rate of the top 20% performing hospitals for identification of organ donors, carrying out brain stem death testing and obtaining consent, this will lead to an extra 40% of organs. However, the Taskforce believes the rate is more likely to be in the region of 50%. This is based upon experience in other countries such as Spain and the US. This will potentially realise at least an extra:

- 720 kidney transplants
- 300 liver transplants
- 70 heart transplants
- 55 lung transplants

Organ transplantation offers substantial and rapid benefits for patients where the alternative treatment is medical management with the likelihood of death in the case of those with liver, heart or lung failure transplant or dialysis for those with End Stage Renal Failure (ESRF).

From a health economic perspective organ transplantation, in almost all cases, is shown to be a cost effective use of resources. This is particularly the case for ESRF. In 2005-06 England alone spent £932m on renal services, of which 46% was on dialysis.

With respect to net costs (as opposed to wider healthcare benefits) the picture is positive. For each annual cohort of renal patients that have received a transplant the cost savings over a 30 year period are likely to amount to at least £100m (discounted to £70m using HM Discount Rate of 3.5%). When all organs are taken into account there is a saving of over £60m for the same period (discounted to £33m using HM Discount Rate of 3.5%).

Qualitative Benefits. There are significant qualitative benefits in adopting the Taskforce's recommendations. Most of these are included in the column to the right of the detailed recommendations below. In summary the main qualitative recommendations include:

- Improved organ retrieval services is likely to lead to better quality organs, which in turn will impact on improved patient outcomes. There will also be benefits in terms of compliance with working time regulations, clinical governance and capacity to deal with additional donors.
- Improved donor transplant co-ordinator (DTC) services will be more robust in dealing with future demands, both in terms of increased numbers of organs that are planned but also new ways of working (e.g. changes in "good practice", legislation, technology). By meeting the potential donor's family at an earlier stage the rate of consent, and therefore organs, is likely to increase.
- A single organisation responsible for managing the entire donation pathway offers benefits in terms of driving greater efficiencies and better use of resources.
- An increase in the number of Black, Minority and Ethnic (BME) families giving their consent for donation will decrease health inequalities and raise the "legitimacy?" of transplantation amongst the BME communities.

Disbnefits. There are likely to be several disbenefits to an increase in the number of organs. These include the shift in capacity constraint further down the transplantation pathway to the transplant units (this piece of work was outside the remit of the Taskforce) and cost of implementing the recommendations, see "Indicative costs of Recommendations" section.

The benefits of individual recommendations are discussed in the next section.

Recommendations

It is accepted that these recommendations will be challenging. However, the Taskforce is of the opinion that the longer term risk of not implementing these recommendations is far greater, particularly for the thousands of people each year that depend upon organ transplantation.

This section takes each Taskforce recommendation and identifies:

- The problem or issue it addresses,
- The rationale for the approach,
- What the benefits will be,
- Additional detail of how it may be implemented.

Objective: A UK Wide Service - Developing Clarity on Accountability, Responsibility and Relationships		
Issue that Recommendation Addresses	*Outline Recommendations*	*Benefits will include:*
Nationally organ donation is fragmented with a substantial degree of variability in performance and quality.	*Recommendation 1*: A UK-wide Organ Donation Organisation should be established. *<u>Rationale for the recommendation:</u>* This recommendation is aimed at developing a national focus for organ donation that will develop and drive improved national standards. *<u>Detail of the Recommendation:</u>* It is likely that the Organ Donation Organisation will form two substantial elements: a commissioning element e.g. organ retrieval; and, a provider function e.g. DTC services (See Appendix 7) *Commissioning Functions* The development of an intelligent commissioner, over time, will contribute to increased focus on efficiency, clinical outcome and the number of organs available for donation. Rarely, in commissioning, is there the wealth of information available on clinical outcome that is already present within UKT. This needs to be built upon. Commissioning functions could include: • Statistics and audit that could focus on: • Improving clinical outcome.	• Greater focus on cost, quality and efficiency along the whole donation pathway leading to • Improved clinical outcome. • Better use of resources

	• Identifying future needs and modelling capacity requirements to more closely match that need. • Developing professional networks, via advisory group structures for example. These networks will build on statistics and audit to inform and influence good transplantation practice. • Finance, planning and performance management. • Clinical governance and assurance. • Commissioning specific services as described in *Recommendation 8.* *Provider Function* This would include the organisational home of the DTCs whose functions would include: • Developing relationships with intensive care units (ICUs). • Seeking consent from families. • Assisting in operating theatres in organ retrieval and the offering of organs to transplant units. Further details see *Recommendation 9 (part 1).*	

There is no single organisation with responsibility for oversight of the entire donation pathway. Experience has shown that meticulous attention to each area is critical if the cumulative effect of recommendations is to be realised.	*Recommendation 2*: The establishment of the Organ Donation Organisation should be the responsibility of NHSBT.
	<u>Rationale for the recommendation:</u>
	The Taskforce recommends that NHSBT has the remit for the Organ Donor Organisation, see *Recommendation 1*. The reasons are listed in the benefits Appendix, but include the organisation's existing national remit and infrastructure.
	<u>Detail of the Recommendation:</u>
	• Recommendation 9 discusses the direct employment of the DTCs. This will have a number of implications for NHSBT, these include:
	• *Transitional*
		• NHSBT already has a national remit.
		• There are opportunities for synergies that could deliver cost efficiencies and improved service. These could include:
		  • Laboratory support.
		  • Merging with Tissue Services.
		  • Transport infrastructure.
		  • Accommodation.

	• Transfer of existing DTCs under TUPE regulations to NHSBT.
	    • Redesign of job functions and locations.
	• *Ongoing*
	    • Provision of management and supervisory arrangements.
	    • Provision office accommodation.
	    • Provision of equipment (e.g. phones, computers, cars etc).
	    • Additional support services such as IT and human resources.
	• Recommendation 10 discusses the commissioning of Organ Retrieval.
		• NHSBT already has a substantial infra-structure that could support in-house provision of services (e.g. DTCs). Infra structure includes:
		    • Support services e.g. IT and HR.
		    • An estate that covers England.

<table>
<tr><th colspan="3"><i>Objective: Ethical Issues</i> - Resolving legal, ethical and professional issues</th></tr>
<tr><td><i>Issue that Recommendation Addresses</i></td><td><i>Outline Recommendations</i></td><td><i>Benefits will include:</i></td></tr>
<tr><td>There are several ethical issues that are affecting healthcare professional’s willingness to actively participate in organ donation.</td><td><i>Recommendation 3</i>: Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice. Additionally, an independent UK-wide Donation Ethics Group should be established.
<u><i>Rationale for the recommendation:</i></u>
There are two parts to this recommendation. The first seeks to reduce ethical issues that are affecting day-to-day organ donation in hospitals, and secondly to anticipate and develop appropriate responses to new and emergent ethical issues.
<u><i>Detail of the Recommendation:</i></u>
• Working with the Department of Health (DH) and relevant stakeholders to resolve ethical and legal concerns over futility of care and other end of life issues.
• Under the sponsorship of NHSBT a Donation Ethics Group will be established. It would co-ordinate the deliberations into new and emerging ethical issues and</td><td>• Improved ability to deal with new and emergent ethical issues in order to maintain or improve the availability of organs.
• Over time the removal of obstacles to donation, particularly in non heartbeating donation (NHBD), that will result in increased organs for transplantation.</td></tr>
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	consider the practical implications on organ donation in general and NHSBT specifically.	

Objective: Making Donation Usual, Not Unusual - Making organ donation routine work in the NHS, including making it a standard part by which the success of hospitals are measured		
Issue that Recommendation Addresses	*Outline Recommendations*	*Benefits will include:*

Currently organ donation does not feature highly amongst many health care professionals.	*Recommendation 4:* All parts of the NHS must embrace organ donation as a usual, not an unusual event. Local policies, constructed around national guidelines, should be put in place. Discussions about donation should be part of all end-of-life care, when appropriate. Each Trust should have an identified Clinical Donation Champion and a Donation Committee to help achieve this.
	Rationale for the recommendation:
	This recommendation aims to increase the visibility of organ donation by providing clear expectations from UK healthcare leadership along with appropriate action at each hospital to make donation a reality.
	Detail of the Recommendation:
	• A clear statement from UK's healthcare leadership that organ donation forms a standard part of end of life care. With this, the following frameworks could be developed to support hospitals to achieve this:
	  • Clear expectations of roles and responsibilities within each hospital.
	  • Clear and simple information available to each hospital as to its performance and areas for improvement or recognition.
	  • Training and support provided by NHSBT to enable the work of the Donation Champion.
	  • Guidance to support trusts to carry out their responsibilities including in establishing Trust/Divisional Donation Committees,
	  • Nationally available information on the performance of each hospital.
		• Increase the consistency of individual hospital performance. This will contribute to an increase in organs.

Objective: Notification and Monitoring – Assessing organ donation amongst hospitals		
Issue that Recommendation Addresses	*Outline Recommendations*	*Benefits will include:*
Lack of knowledge, on a hospital by hospital basis, of key steps along the donation pathway that have a substantial affect on increasing organ donation.	*Recommendation 5:* Minimum notification criteria for potential organ donors should be introduced on a UK-wide basis. These criteria should be reviewed after 12 months in the light of evidence of their effect, and the comparative impact of more detailed criteria should also be assessed. *Rationale for the recommendation:* This recommendation is aimed at monitoring key steps along the donation pathway. By only focusing on the potential for organ donation the areas for improvement and support, on a hospital by hospital, can be identified. *Detail of the Recommendation:* The detail of the recommendation is likely to be developed with the Donation Advisory Group of UKT and stakeholders such as the Intensive Care Society and the Royal College of Anaesthetists.	• The identification of all potential donors which will, with other recommendations, lead to increased organ donation. • Identification of areas in donation where there are problems so that appropriate action can be taken to increase organ donation.
One reason why donation does not feature highly amongst many Chief Executives (CEOs) is that performance is not measured and shared in an open or accessible way. Also, information is not used by healthcare regulators to encourage donation.	*Recommendation 6*: Donation activity in all Trusts should be monitored. Rates of potential donor identification, referral, approach to the family and consent to donation should be reported. The Trust Donation Committee should report to the Trust Board through the Clinical Governance process and the Medical Director, and the reports should be part of the assessment of Trusts through the relevant healthcare regulator. Benchmark data from other Trusts should be made available for comparison. *Rationale for the recommendation:* This recommendation is aimed at acute hospital CEOs to encourage them to take a more active role in organ donation. Although it is recognised that the NHS is changing, with increased local accountability and more autonomy with Foundation NHS Trusts, it is clear that Trust CEOs/Chief Operating Officers should be accountable for their hospitals contribution to organ donation. *Detail of the Recommendation:*	• An increase in the visibility of organ donation amongst senior management, and its reflection in national standards, will contribute to increased organs.

	• This should be straight-forward to measure and be achievable. It is therefore recommended that accountability be restricted to the identification and referral of potential donors who are suitable for donation. • The role of the regulators should be explored with the aim of integrating organ donation within performance standards.	
	Recommendation 7: Brain stem death testing should be carried out in all patients where brain stem death is a likely diagnosis even if organ donation is an unlikely outcome.	• This would ensure consistency with national Guidance. • This would increase the number of potential heartbeating donors.

Objective: Costs of Donor Management - Removing the Obstacles to Donation, including financial disincentives		
Issue that Recommendation Addresses	*Outline Recommendations*	*Benefits will include:*
In England ICUs are not recognised for their essential contribution they make to organ donation.	*Recommendation 8*: Financial disincentives to Trusts facilitating donation should be removed through the development and introduction of appropriate reimbursement. *<u>Rationale for the recommendation:</u>* This recommendation seeks to remove financial disincentives for hospitals involved in organ donation. *<u>Detail of the Recommendation:</u>* • It is recommended that tariff is developed, using methodology consistent with Payment by Results in England, to reimburse hospital ICUs and Emergency Medicine Departments for each donor made available for organ retrieval. This is in recognition of the costs in keeping the donor stable in ICU/EM Department from the diagnosis of death to organ retrieval.	• Hospitals are supported and encouraged to actively participate in organ donation.

Objective: Donor Transplant Co-ordinators & Organ Retrieval Teams- Building a Robust Structure for the Future		
Issue that Recommendation Addresses	*Outline Recommendations*	*Benefits will include:*
Fragmented DTC arrangements.	*Recommendation 9 (part 1)*: The current network of donor transplant co-ordinators should be expanded and strengthened through central employment by a UK-wide Organ Donation Organisation. Additional co-ordinators, embedded within critical care areas, should be employed to ensure a comprehensive highly skilled, specialised and robust service. There should be a close and defined collaboration between donor co-ordinators, clinical staff and Trust Donation Champions. *<u>Rationale for the recommendation:</u>* This recommendation is focused on developing a DTC service that is robust for the needs of today and the challenges ahead. *<u>Detail of the Recommendation:</u>* The employer, under recommendation 2 this will be NHSBT, will: • Develop national job descriptions and grades. • Consider how best to ensure that people and resources are directed to areas of greatest donation opportunity. • Develop national standards with key stakeholders. • Develop Service Level Agreements (SLAs) with hospitals and other stakeholders along the donation pathway. • Establish a robust clinical governance framework. In order to make the role of the DTC more resilient and capable of dealing with future developments it is likely that the role of the DTC will be split into functions that will include: • Obtaining consent/authorisation from the family. • Supporting organ donation and retrieval in the ICU, EM department and the operating theatre, including arranging laboratory tests.	• Increased capacity and resilience to deal with increased demand which will lead to more donors. • A more resilient DTC network will be able to respond to local and national pressures. • Improved clinical governance and risk management. • Remove the potential for conflict of interest with local hospital requirements. • Able to respond quicker to variability in demand.

	• Allocating organs to transplant centres. • Supporting the family after organ retrieval. The current arrangement, whereby the above is carried out by one person, is to be replaced by more than one individual carrying out different tasks. The total headcount is likely to rise from 100 to in the region of 250 DTCs.	
Currently the offering of organs is carried out by phone. This can take considerable time that can delay the organ arriving at the transplant centre and divert the DTC's attention from dealing with the needs of the family and hospital.	*Recommendation 9 (part 2)*: Electronic on-line donor registration and organ offering systems should be developed. *Rationale for the recommendation:* This recommendation aims to increase the efficiency of organ allocation. The details below centre on an initial area of work to develop the scope for a future implementation phase. *Detail of the Recommendation:* • Investigating similar approaches to organ allocation internationally, for example the US. • Undertaking a feasibility study, with stakeholders, to scope out functionality, development timescales and cost. • Presenting a detailed proposal for implementation, including development programme, costing and project resources required.	• More effective allocation of organs leading to better clinical outcome and reduced time between the donor and recipient.

The retrieval of organs is not effectively managed nationally and there is a lack of capacity to deal with future increase in demand.	*Recommendation 10*: A UK-wide network of dedicated Organ Retrieval Teams should be established to ensure timely, high quality organ removal from all heartbeating and non-heartbeating donors. The Organ Donation Organisation should be responsible for commissioning the retrieval teams and for audit and performance management.
	Rationale of the Recommendation
	This recommendation is focused on developing an Organ Retrieval service that is robust for the needs of today and the challenges ahead.
	Detail of the Recommendation:
		• A more resilient organ retrieval service that is able to respond to the increase in organ donation.
		• Improved quantity of organs available for transplantation with the potential for:
		  • More organs per donor.
		  • Ability to cope with more

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[1] The analysis of the structure and number of Organ Retrieval Teams has been undertaken by a working group of the British Transplantation Society

	From an analysis of the distribution of potential donors there is a need for 9 teams, co-located with the existing liver units with additional teams to support the South West and North West of England[1].	donors. • Improved quality of organs available for transplantation with reduced travelling times and specialist organ retrieval teams. • Improved ability, consistency and capacity to implement new techniques e.g. retrieval techniques, new technologies, different organs etc • Compliance with EU working time regulations • Freeing up medical and surgical capacity in hospitals to deal with elective and emergency lists. • Reduced health inequalities with increased equality of access to organ retrieval.

Objective: Training, Education and Continuing Educational Support - Improving the understanding of organ donation amongst healthcare professionals		
Issue that Recommendation Addresses	*Outline Recommendations*	*Benefits will include:*
There is a general lack of awareness amongst clinical staff of the contribution of organ transplantation makes and the role of their role	*Recommendation 11*: All clinical and nursing staff likely to be involved in the treatment of potential organ donors should receive mandatory training in the principles of donation. There should also be regular update training. *<u>Rationale for the recommendation:</u>* This recommendation is aimed at increasing the level or awareness and competency	• Over time the support for organ donation amongst healthcare professionals in hospitals will increase. There is evidence to show that improved training leads to

in supporting organ donation	amongst healthcare professionals. The details below centre on an initial area of work to develop the scope for a future implementation phase. *Detail of the Recommendation:* • Undertaking a comprehensive training needs analysis that would focus on the following questions: • Who are the most appropriate people to receive training? • At what stages in their careers is it appropriate to receive training? • How best is training to be delivered? • Who are the best people to deliver training? • How is the effectiveness of the training being evaluated? • Who will be responsible for ensuring that the training is carried out and recorded? • How best to prioritise resources to deliver maximum effect at the earliest opportunity.	increased organ donors. • Improved training will support and develop a culture that organ donation forms a natural part of end-of- life care.

Objective: Honouring the Gift of Donation - Recognising and thanking the public for their commitment and support		
Issue that Recommendation Addresses	*Outline Recommendations*	*Benefits will include:*
Currently there are no formal means to recognise and thank the families who have supported their loved ones in becoming organ donors	*Recommendation 12*: Appropriate ways should be identified of personally and publicly recognising individual organ donors, where desired. These may include national memorials, local initiatives and personal follow-up to donor families. *Rationale for the recommendation:* This recommendation is focused on promoting organ donation and thanking those families and individuals affected by organ donation. *Detail of the Recommendation:*	• The families of organ donors feel appreciated and thanked. • Increased awareness of organ donation amongst the public reflected in increased numbers on the Organ Donor Register (ODR) which will lead to more organs for donation.

	• Developing a comprehensive approach to recognising the contribution that organ donors and their families make, this could include the following:
	• *Individual basis*
	  ◦ “Thank you” from prominent individuals within healthcare.
	  ◦ Appropriate means to follow up and remember the gift.
	• *Community basis*
	  ◦ National memorial days.
	  ◦ Local memorial events.	

Objective: Promoting Donation - Tackling Health Inequalities & Guidance for Coroners		
Issue that Recommendation Addresses	*Outline Recommendations*	*Benefits will include:*
Increasing the supply of organs available for BME groups is vital if health inequalities are to be reduced.	*Recommendation 13*: There is an urgent requirement to identify and implement the most effective methods through which organ donation and the “gift of life” can be promoted to the general public, and specifically to the BME population. Research should be commissioned through Department of Health Research and Development funding to enable donation–related research. *<u>Rationale for the recommendation:</u>* This recommendation is primarily aimed at reducing the health inequalities of organ donation. *<u>Detail of the Recommendation:</u>* Actions are likely to include: • To build upon the notion of gift that is culturally appropriate amongst BME groups in UK society. • To work with religious stakeholders to develop practical solutions at the local level	• To improve organ donation for BME groups is the essential. Morally it is right and it is central to many political and health initiatives. • If the gap between the supply and demand for organs for BME groups is not reduced, it will undermine the legitimacy and possible political and societal support for organ donation.

	to remove cultural and religious barriers to donation. • To consider barriers to living donation amongst BME groups, including cultural and financial barriers. This recommendation recognises that even with a steep increase in donation amongst BME groups, demand will still, in comparison with the white population, outstrip supply. • To review the outcomes of previous campaigns aimed at BME groups. • To develop a better understanding as to why the consent rates amongst BME groups is so low. • To increase the data we collect on health inequalities. • To work with others to increase our wider understanding of health inequalities. And sharing the transplant community's unique understanding amongst others in the health profession.	
Where a post mortem is required the Coroner (or Procurator Fiscal in Scotland) may refuse permission for organ retrieval. Coroners can vary widely in their interpretation of this requirement, with some willing to agree to donation in all but the most extreme circumstances, others refusing donation more frequently.	*Recommendation 14*: The Department of Health and the Ministry of Justice should develop formal guidelines for Coroners concerning organ donation. *Rationale for the recommendation:* This recommendation is aimed at Coroners (or the Procurator Fiscal in Scotland) to apply a more consistent interpretation as to when organ donation can occur after death. *Detail of the Recommendation:* To work with the DH, the Ministry of Justice and representatives from devolved Health Administrations to provide suitable guidance for Coroners (or the Procurator Fiscal)	• Increased number of donors due to a more consistent approach amongst coroners • Less stress for families who have given consent, but donation is delayed or can not take place.

Why Change is Important

This section considers why change is important. Building on the Taskforce Report, this section provides the detailed evidence relating to: Economics of organ transplantation

- Demographics
- Health inequalities
- Projected supply and demand
- Variably of performance within the NHS
- Donation pathway

As an introduction to this section it is worth considering that 3,086 people [2]in the UK had an organ transplant in 2006/07. This is a 10% increase on the previous year. Over the last four years initiatives and legislation have included:

- *Saving Lives, Valuing Donors – A Transplant Framework for England*[3]. This provided a clear framework and objectives for the NHS, the Government and other stakeholders.
- *The National Service Framework (NSF) for Renal Services, Pt One, Dialysis and Transplantation*[4]. It recognised that kidney transplantation is the most clinically and cost effective treatments for those with ESRF. As a result kidney transplantation features strongly in the pathway of care.
- *Human Tissue Acts*. These legislative changes made it clear that a person's wish in life, as expressed on the ODR, would over ride the families wish in death.

However, these improvements need to be seen in context of an 8% increase in demand for organs with over 7,000 people on the waiting list in the year to 31st March 2007. However, in the UK, approximately 1000 people die each year because they can't get the transplant they need. The main reason for this is the lack of organs. To put this into context, this is a similar number of women who die each year from cervical cancer

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[2] UKT Statistics: http://www.uktransplant.org.uk/ukt/statistics/statistics.jsp

[3] Department of Health (2003), Saving Lives, Valuing Donors A Transplant Framework for England, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006700

[4] Department of Health (2004), *The National Service Framework for Renal Services; Part One: Dialysis and Transplantation*, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4070359

i.e. 1093 women died in 2004 (http://info.cancerresearchuk.org/cancerstats/types/cervix/mortality/), an issue that has rightly attracted substantial resource and public attention.

Economics of organ transplantation

Section 1 describes the economic analysis that has been undertaken as part of the Taskforce's work.

Health Economics

The health economics of transplantation are important. We know that organ transplantation has saved and improved the lives of thousands of people in the UK, but the Taskforce also appreciates that, in a resource limited healthcare system, money must be spent in a way that achieves the greatest amount of benefit and good. It was for this reason that a literature review was commissioned from the Economic, Statistics and Operational Research (ESOR) section of the DH. This report is included in Appendix 1 and is titled "Review of the Economic Literature surrounding Solid Organ Transplantation".

Before discussing how individual organ types affect the health economy it is worth drawing several key themes together. Firstly, from a health economic perspective, organ transplantation makes sense. For all organs, particularly the kidney, transplantation is cost effective. Only in lung transplantation is there some ambiguity.

The report draws on national and international literature using common economic tools. It is worthwhile pointing out that these tools, in general, tend to understate societal benefit of organ transplantation. This includes the effect on the wider family and the impact of more economically active people after transplantation.

The report discusses the lack of meaningful information on the impact of organ transplantation within the UK health economy. Although the report is confident about the positive impact transplantation makes, it does stress that more research would be beneficial in the following areas: greater clarity of the impact transplantation makes in a UK context; changes and improvements in immuno-suppressive drug therapies; and, the impact that a greater supply of organs will have.

The Taskforce agrees with the report commissioned from the DH that organ transplantation makes economic sense and makes a positive contribution to the UK health economy.

The Taskforce also recognises the lack of UK specific research on the benefits of organ transplantation to the UK health economy. Although this did not detract from the strong economic argument for today, it was felt that there should be greater effort to understand the contribution organ transplantation makes to the UK health economy for tomorrow. This is both in terms of the overall economy and specific net costs.

With respect to individual groups of organs the following summaries are taken from the full report which can be found in Appendix 1.

Cost-effectiveness of Renal and Pancreatic Transplants

Renal transplants currently make up the minority of treatments encompassed in Renal Replacement Therapy (RRT) in the NHS. International evidence has consistently shown renal transplantation to be a cost-effective treatment and whilst the evidence from the UK is limited, the result is unlikely to change. Benefits will be similar across countries and costs vary between the international studies without the overall conclusion changing in anyway.

The studies that demonstrate the treatment's cost-effectiveness in various different patient groups, allay fears that the expansion of transplantation to patients with less to gain, will result in transplantation becoming a non-cost-effective treatment at the margin.

Renal, and by association, pancreatic transplants, are cost-effective treatments compared with the alternative and should continue to be so under a proposed increase in the transplant rate.

Cost-effectiveness of Liver Transplants

The studies on liver transplantation to date focus on the cost and benefits accrued in the first few years of a transplant. Whilst this is a limitation of the studies, it is unlikely to significantly affect the Incremental Cost-Effectiveness Ratios (ICERs). It is clear that different disease groups will have a bearing on the costs and benefits of transplantation. So far this has only been examined for a few groups of diseases which by no means reflects the rich case mix in the NHS.

Liver transplantation in general has been shown to be cost-effective in the UK and in other developed healthcare systems. Although the management of the programmes expansion must be carefully managed to ensure that it continues to be cost-effective.

Cost-effectiveness of Heart Transplants

There is very little economic literature on heart transplants and much of it focuses solely on trying to quantify the associated costs. There are undoubted benefits to it, however, these are typically not estimated to be as large as the benefits from liver or kidney transplants.

The estimates that do exist, show heart transplantation to be a cost-effective treatment. However, the small amount of evidence that has been gathered to date and the improvement in drugs to medically manage heart failure, both serve as notes of caution over the cost-effectiveness of heart transplantation in the future.

Cost-effectiveness of Lung Transplants

The published evidence from the UK shows lung transplantation to be on the edge of cost-effectiveness. Double lung and combined heart and lung transplants are more cost-effective owing to a greater Quality Adjusted Life Years (QALY) gain (3, 4.6 and 5.2 respectively).

There are significant threats to the cost-effective status of lung transplant including the cost of immunosuppressive drugs and the benefits that are accrued from the medical management of organ failure. Both of these factors are likely to vary in the future and therefore it will be necessary to monitor the effects on the incremental costs and benefits.

Net Costs of Transplantation

There can be few instances where healthcare initiatives are discussed in terms of saving money in addition to providing an overall health economic benefit. Because of the substantial reduction in patients requiring dialysis, which is expensive, an increase in organ donation can be discussed in this context.

The Taskforce has worked on the assumption that there will be a 50% increase in renal transplants a year.

The Taskforce commissioned ESOR to carry out a review of the net cost of transplantation.

This review included:

- The impact of additional kidney transplantation on renal dialysis costs.
- The overall impact of additional organs such as liver, heart and lung.
- HM Treasury's Discount Rate of 3.5%.

The review considered a one year cohort over a period of 30 years. However, given time, it was not possible to look at specific patient groups to include primary disease, co-morbidity, age etc. It is accepted that this should form part of a longer term study. However, it is not thought that this will substantially detract form the broad conclusions presented here.

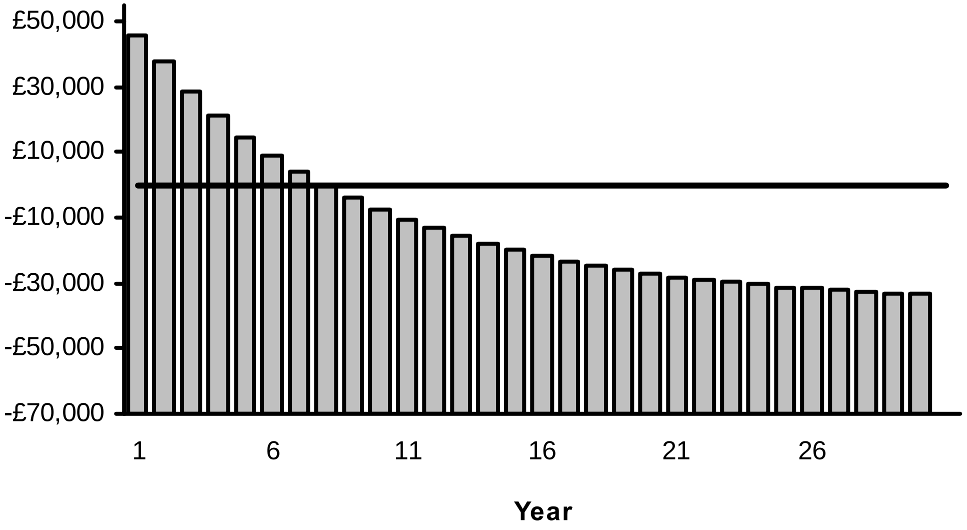
For the projected net cost position refer to Table 1.

Table 1: Net Cost Savings From a 50% Increase in Organ Donation in a One Year Cohort of Patients Assessed Over 30 Years

Cost component	**Net cost, £000s**	
	Undiscounted	**Discounted**
Kidney transplants	-£109,754	-£73,952
Liver transplants	£29,740	£23,816
Heart transplants	£8,909	£7,694
Lung transplants	£8,293	£8,044
Donation	£993	£993
All	-£61,819	**-£33,405**

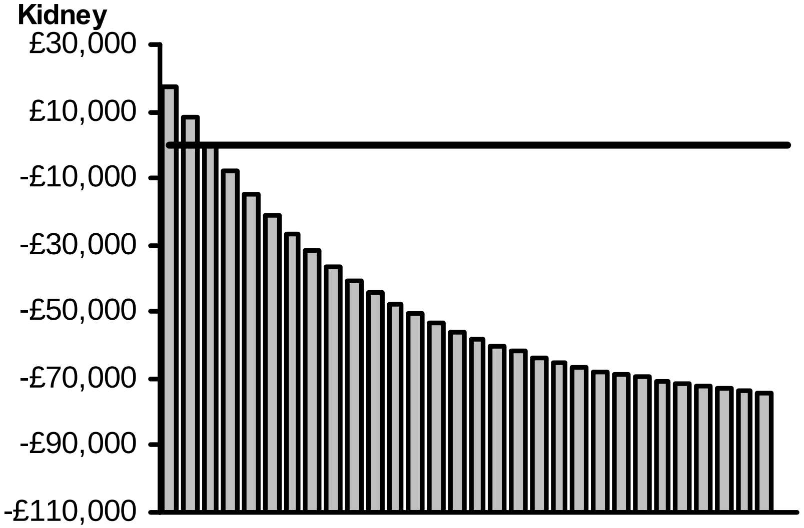
Over the 30 year period the cumulative cost effect for all organs, including the Discount Rate, is represented in figure 1.

Figure 1 Cumulative Cost Effect of for All Organs, Including the Discount Rate



Over the 30 year period the cumulative cost effect for kidney, including the Discount Rate, is represented in figure 2

Figure 2 Cumulative Cost Effect for Kidney, Including the Discount Rate



This is based upon the following assumptions:

- A 50% increase in both heartbeating and non heartbeating donors resulting in:
  - Deceased heartbeating donors rising from 639 to 959
  - Deceased non-heartbeating donors rising from 125 to 188
  - Living donors staying static at 599
  - Kidney transplants increasing from 1914 to 2576
  - Liver transplants increasing from 610 to 911

- Heart transplants increasing from 141 to 212
- Lung transplants increasing from 116 to 174
- All other assumptions Refer to Section 1.

Demographics

The changing picture of UK demographics will have important implications for transplantation. It was for this reason that the Taskforce commissioned the ESOR to undertake a review of UK demographics and how this could affect the demand for transplantation. As part of this work age, ethnic profile and the health profile were considered.

The objective was to build an understanding of the demographic impact on the demand for organs so as to ensure there is fair and equitable allocation, particularly amongst ethic groups.

The paper on demographics, included in Section 2, makes clear that the effect of changes in clinical practice and advancements in science pose challenges when it comes to predicting demand. Also, given that there is ‘over-demand’ for organs compared to supply, historical data to predict future demand is not robust. However, the paper has used information from the Office of National Statistics, information on transplantation from UKT and proxy data (e.g. mortality figures, hospitals episodes etc) to give a rounded perspective of the challenges ahead.

By far the greatest number of organ transplantations that occur each year are kidney. The paper makes clear that there is a robust link between those on the kidney transplant waiting list and those receiving RRT. 85% of those on the waiting list are receiving RRT. This is a reliable measure that can be used to give an indication of future demand. Studies that have included age, ethnicity and diabetes have indicated that there will be a substantial increase in those requiring a transplant over the next few years. The paper makes the point that the UK faces a 2% annual increase in the demand for renal transplantation. This figure has been supported by an analysis of the historical data from the Renal Registry which has provided evidence an actual increase of 8% from 2000 to 2004, or an average annual increase of about 2%. With this in mind there is a relevant point to raise when it comes to health economics, discussed in more detail in Appendix 1. This makes it clear that there are substantial economic benefits to renal transplantation when compared to the alternative, RRT. With growing demand for RRT the economic case for organ transplantation grows, this relates to both the wider health economics case and with respect to the net costs.

One of the particularly important demographic pressures is that of the change in ethnicity. The paper makes clear that the number of Asian people will increase and within that group, there is a greater demand for organ transplantation. Also, there is a less propensity to donate organs. This will pose particular challenges and will be explored in the health inequalities Appendix of this report, see Appendix 4.

Health Inequalities

As we have already seen from discussions on demographics, the most significant changes to the UK population will be in ethnicity, particularly with respect to BME groups. The Taskforce is aware that it needs to be conscious of, and make recommendations that are consistent with, the needs of different groups in UK society.

The first question is: what is the size and nature of the challenges ahead? Although evidence on ethnicity from UKT is sketchy (they have only been collecting data since 2000) there are a number of trends that are starting to emerge. These are demonstrated by the following graphs that expresses the demand for organs, with supply and transplantation. It needs to be stressed that the demand for organs is substantially under represented.

Figure 3: Kidney; Demand, Supply and Transplantation in the White Population

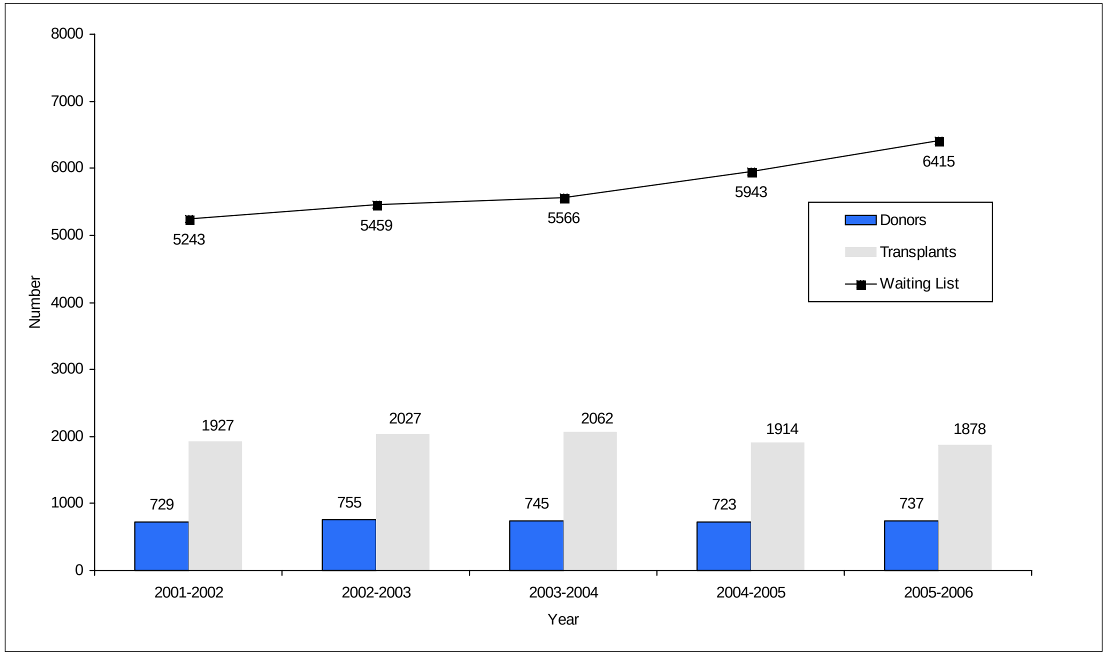
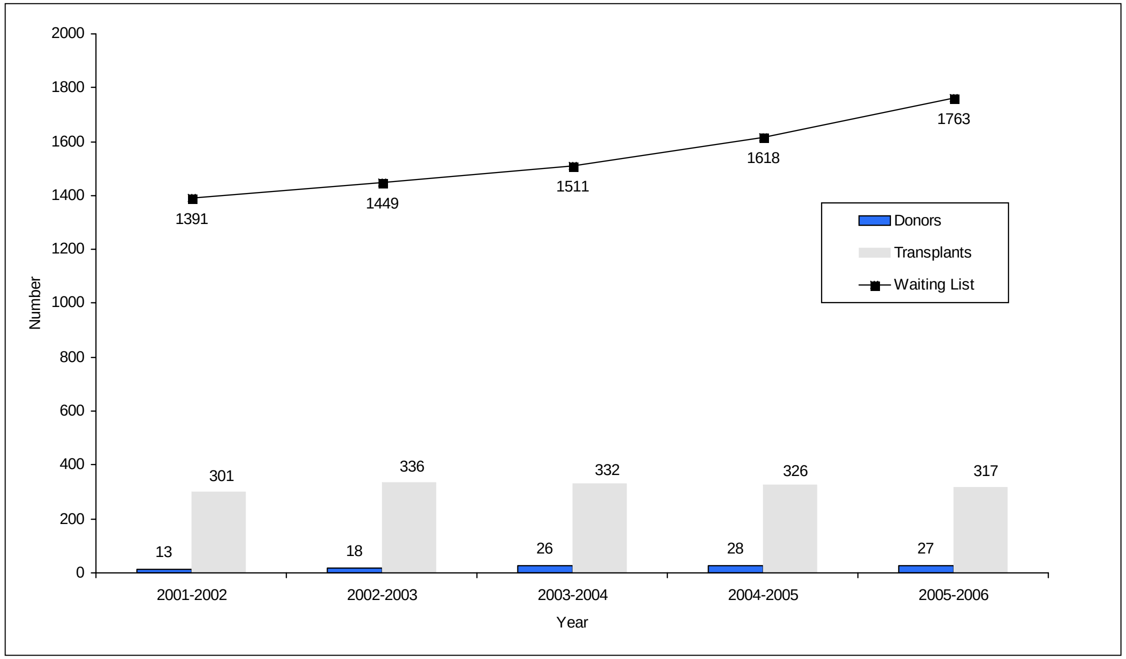


Figure 4: Kidney; Demand, Supply and Transplantation in the BME Population



Figures 3 and 4 and other data indicates that:

- The demand for organ transplantation is increasing for all groups, but particularly amongst BME groups
- The number of donors and transplantations have largely remained static
- There are very few donors amongst BME groups

Before discussing in more detail what can be done, it is worth considering the implications if health inequalities are not successfully addressed. If there is a substantial and sustained increase in the number of organs transplanted there is a risk of a widening gap between the white population and BME groups if health inequalities are not a central to the Taskforce's recommendations. As a consequence, this could erode the political and societal support for organ donation as well as being morally indefensible.

The paper on health inequalities, see Appendix 4, makes it clear that this is a complex area and that a holistic approach is required. This approach will result in both short and long term actions. Building on the discussion on demographics, Appendix 4 makes the point clearly that the incidence of Type 2 diabetes is higher in Asian populations (up to 13 times higher in one study) and this has a strong tendency to contribute to ESRF for which, often, kidney transplantation is the optimum solution. Combined with the fact that the Asian population tends to be younger, the problem will get worse in the future

When it comes to actions and recommendations, those centring on health inequalities will differ. It is unlikely that, compared with other recommendations, the majority of actions will see an immediate and corresponding increase in organ donation. Tackling health inequalities will take a long time and will need to address deep seated cultural and religious beliefs. Actions will also need to overcome the issue of trust between BME groups and a healthcare system that can often not reflect their needs. It is for these reasons that some of the recommendations in Appendix 4 have stepped outside the strict remit of the Taskforce and have sought to address, in a more holistic way, the increasing gap between the supply and demand for organs amongst BME groups.

Although the UK has done more work on health inequalities than most of its other European neighbours, additional work is needed. The recommendations will focus on the following areas:

- To build upon the notion of gift that is culturally appropriate amongst BME groups in UK society.
- To work with others, for example the NSF tsars, to increase our wider understanding of health inequalities, and sharing the transplant community's unique understanding amongst others in the health professionals.
- To work with religious stakeholders to develop practical solutions at the local level to remove cultural and religious barriers to donation.
- To develop a better understanding as to why the consent rates amongst BME groups is so low.
- To consider barriers to living donation amongst BME groups, including cultural and financial barriers. This recommendation recognises that even with a steep increase in donation amongst BME groups, demand will still, in comparison with the white population, outstrip supply.
- To review the outcomes of pervious campaigns aimed at BME groups.
- To increase the data we collect on health inequalities.

There are other possible areas of health inequality too. In a study of access to renal replacement waiting lists and transplantation in Scotland[5] there is evidence of inequality in access to renal transplant waiting lists with respect to age, social deprivation and gender.

Projected Supply and Demand

The number of deceased donors, transplant activity and those registered for a transplant is shown below, figure 5[6].

The message is clear; the number of organs available for transplantation has remained largely static in the face of increasing demand. In Scotland the number of identified cases of ESRF is increasing from 60 per million population (pmp) in 1989 to 108 pmp in 1999[7].

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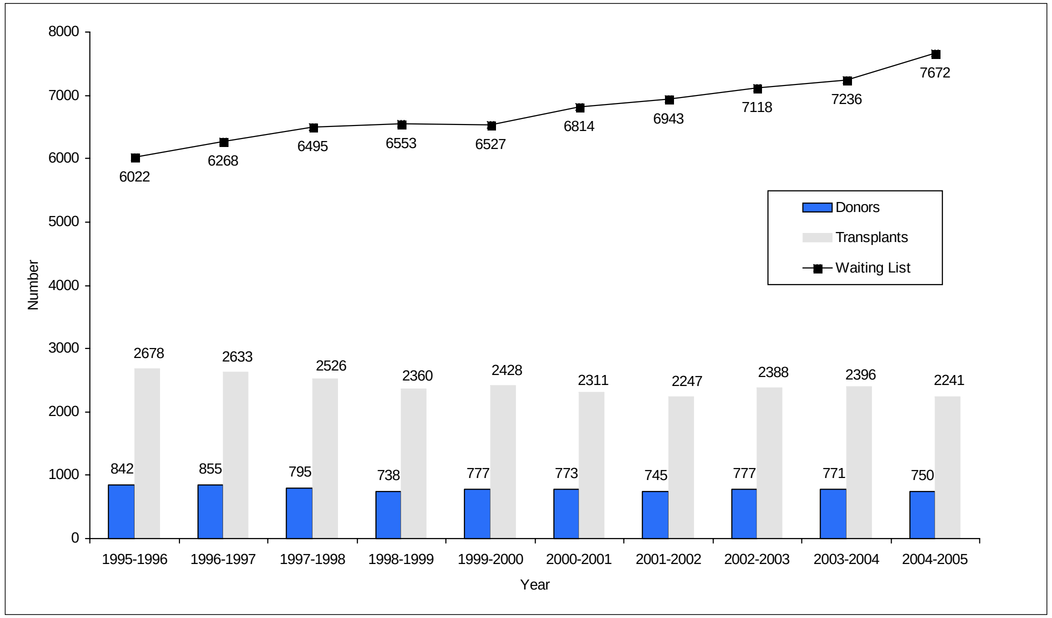
[5] Oniscu, G,C; Schalkwijk, A,H; Johnson, J; Forsythe, J, L, R (2003), *Equity of Access to Renal Transplant Waiting List and Renal Transplantation in Scotland: Cohort Study*, British Medical Journal, 327: 1261

[6] UKT (2006), *Transplant Activity in the UK 2005 – 2005*, http://www.uktransplant.org.uk/ukt/statistics/transplant_activity_report/current_activity_reports.jsp/ukt/transplant_activity_uk_2005-2006_v2.pdf

[7] Oniscu, G,C; Schalkwijk, A,H; Johnson, J; Forsythe, J, L, R (2003), *Equity of Access to Renal Transplant Waiting List and Renal Transplantation in Scotland: Cohort Study*, British Medical Journal, 327: 1261

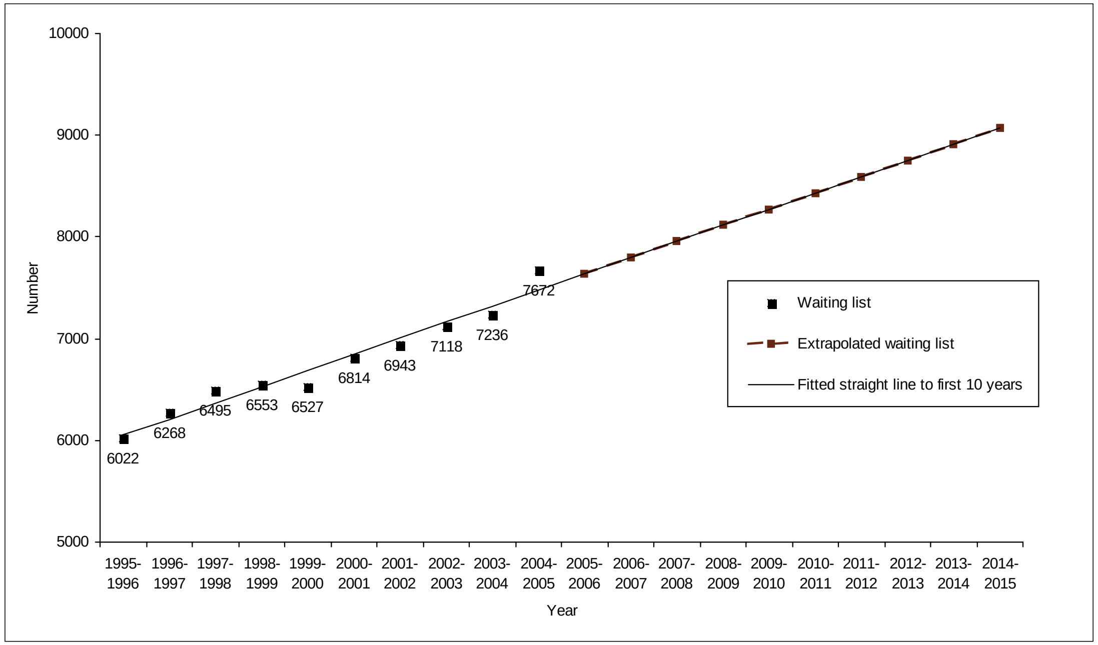
Figure 5: The Difference Between the Supply & Demands for Organs



The above graph, figure 5, implies that the demand for organs is robust, by which we mean that everyone who needs an organ is on the transplant list. This is not the case. Of the 1000 or so people who die each year who need an organ transplant only about 500 are on the waiting list. The reasons for this vary; on the one hand clinicians are cautious about raising the expectations of patients that have little chance of being met. On the other, there are indications that there are some health inequality issues discussed in the previous section.

Figure 6 shows the projected demand for the next ten years. Based upon experience of the last few years there is nothing to suggest that demand will do anything but increase at a linear rate. Unless there is a step change in organs available for donation, societal and political opinion is likely to become increasingly critical.

Figure 6: Projected Demand Over the Next Ten Years



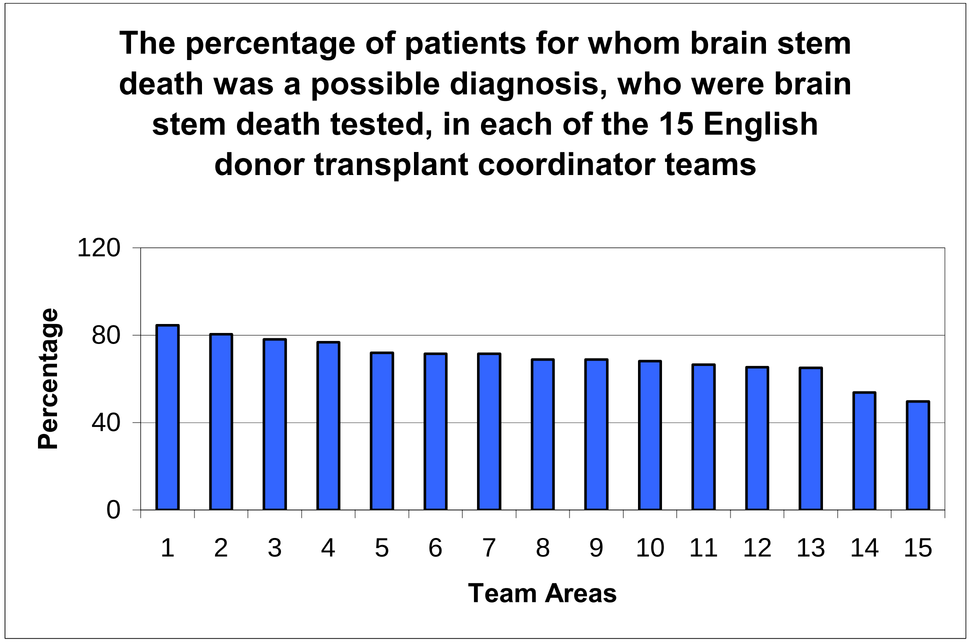
Variability in Performance

This section describes the results of the three year study up to 31st March, 2006, from the Potential Donor Audit (PDA) administered by UKT, see Appendix 5.

The objective of this section is to highlight the current variance in performance and the opportunity that exists with improved and more consistent performance.

Figures 7 and 8 explore the variability in performance from one team area[8] to another. It is also worth considering that within each region there is also variability so the differential between the best and worst performing hospitals is even greater.

Fig 7: The percentage of patients for whom Brain Stem Death was a possible diagnosis, who were BSD tested.



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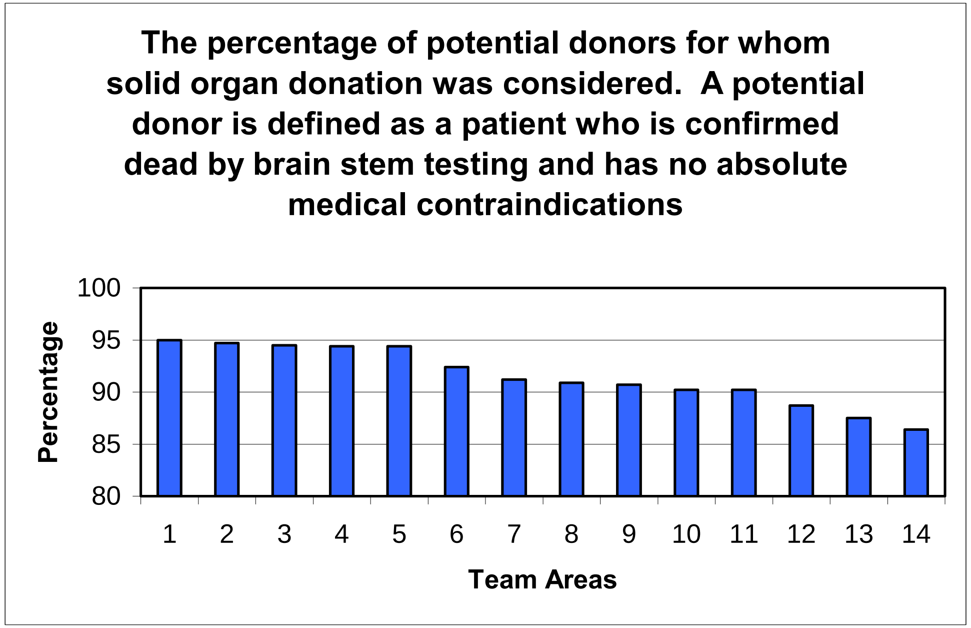
[8] For the sake of this study, a Team Area is the geographical region where a donor transplant co-ordinator may work. The information is drawn form the PDA.

Fig 8: The percentage of patients for whom solid organ donation was considered`



The key message is the significant variability in the system. It is this variability that provides the greatest opportunity for increasing the numbers of organs for transplantation.

The table below shows the *actual donation rates* for 2006 and the *predicted number of heart beating donors* if all hospitals were performing at or above the top 20% of hospitals in the UK for the three critical steps along the donation pathway.

For example, if the brain stem death test rate for 2006 data was increased from the actual rate of 78.6% to 86.5%, and all other rates remained the same, the effect would be to increase the number of donors by 55. If both the BSD test rate and approach rates were increased to that achieved by the top 20% of hospitals, the effect would be to increase the number of HB donors by 91, see Table 2.

Table 2: Cumulative Effects of Brain Stem Death Testing, Approach and Consent Will Have on Overall Organ Donation Rates

	BSD test rate (%)	Approach rate (%)	Consent rate (%)	No. of HB donors	Change in no. of donors (%)	
PDA 2006 actual data[1]	78.6	94.2	59.1	542		
Increase BSD test rate	**86.5**	94.2	59.1	597	55	(10.1)
Increase approach rate	78.6	**100.0**	59.1	576	34	(6.2)
Increase consent rate	78.6	94.2	**71.1**	652	110	(20.4)
Increase BSD test and approach rates	**86.5**	**100.0**	59.1	633	91	(16.9)
Increase BSD test and consent rates	**86.5**	94.2	**71.1**	718	176	(32.5)
Increase approach and consent rates	78.6	**100.0**	**71.1**	693	151	(27.8)
Increase BSD test, approach and consent rates	**86.5**	**100.0**	**71.1**	762	220	***(40.6)***
[1] Patients aged over 75 and cardiothoracic ICUs are excluded, as they have not been audited since 1 April 2006						

As expected the largest improvement in the number of donors occurs when the cumulative effect is taken into account.

The accumulated increase in donor for hospitals working at, or above, the top 20% for the 3three (out of 9nine) key areas on the PDA is 40%. It is for this reason that the Taskforce believes that an increase of 50% is entirely achievable.

Donation Pathway

This section discusses the challenges that we face today and the impact this will have for tomorrow if recommendations in the Taskforce Report are not implemented. When reading this, it is important to be aware of the cumulative affects of these issues – how they build up in the donation pathway leading to a lack of organs for donation and the impact this has for patients.

There are several important factors to bear in mind when considering the donation pathway. These have a direct effect on how organ donation can be increased. These include:

- The donation pathway is long and complex. It can involve many different hospitals. It also involves many disciplines, for example anaesthetists, transplant surgeons, laboratory and nursing staff, transport, donor and recipient co-ordinators who work with donor families and patients.
- A successful transplant from a deceased donor begins with a tragic event. The impact of this is felt by the families of the donor, and health care professionals involved in their care. This can affect the culture of an ICU or emergency medicine department and their willingness to actively engage with organ donation. This also includes theatres and theatre staff.
- Compared with other activities in a hospital, organ donation doesn't occur very often and doesn't form part of mainstream activities. Organ donation isn't included in many of the measures by which the hospital and senior management team are judged to have succeeded or failed.
- Although organ donation occurs at a local level it supports a national allocation framework. Therefore the patients of hospitals involved in organ donation are not likely to directly benefit.
- Organ donation can't be planned and often occurs at night and must be carried out swiftly. Currently the teams involved in organ retrieval (anaesthetists, transplant surgeons, nurses etc) have to balance their emergency and elective surgical lists to support organ retrieval. This can have an impact on the general running of the hospital.
- For many reasons along the donation pathway donation may not be successful, for example the organ(s) may not be suitable, laboratory tests may indicate a contraindication to donation and so on. However, despite this the hospital where the donation occurred will still have to pay the costs.
- Although funding is provided by various means for organ transplantation, there is no funding for hospitals in England and Wales involved in organ donation. This means that the highest performing hospitals, providing more organs for transplantation, are incurring a greater proportion of cost compared with hospitals with less commitment.

The following two diagrams give an overview of the donation pathway. It is important to stress that this is a simplified view and that many of the individual processes occur at hospitals, sometimes hundreds of miles apart, occurring within tight timescales and often at night. Figures 9 and 10 below highlight the key stems along the donation pathway.

Figure 9: Donation Pathway - Process Overview

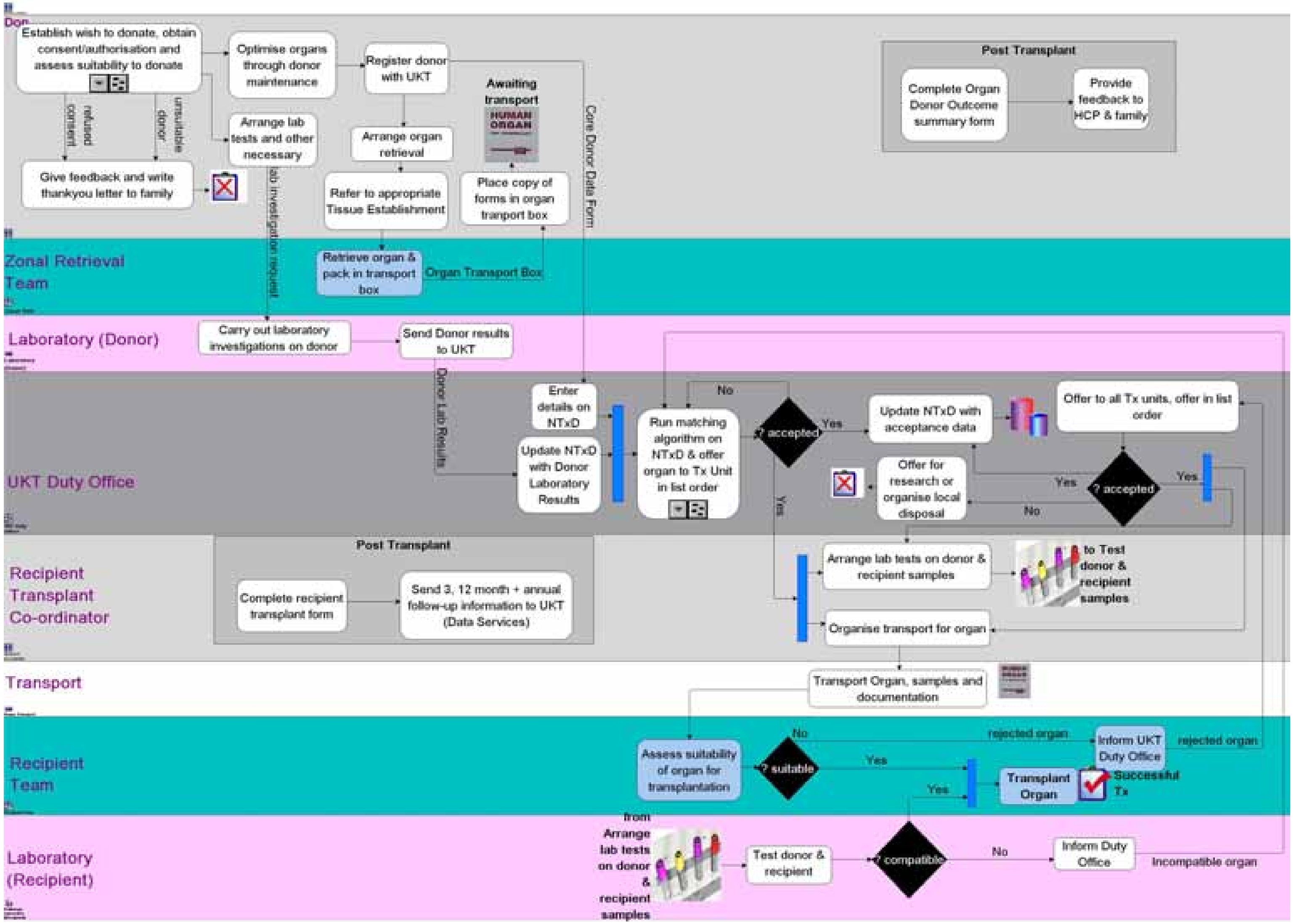
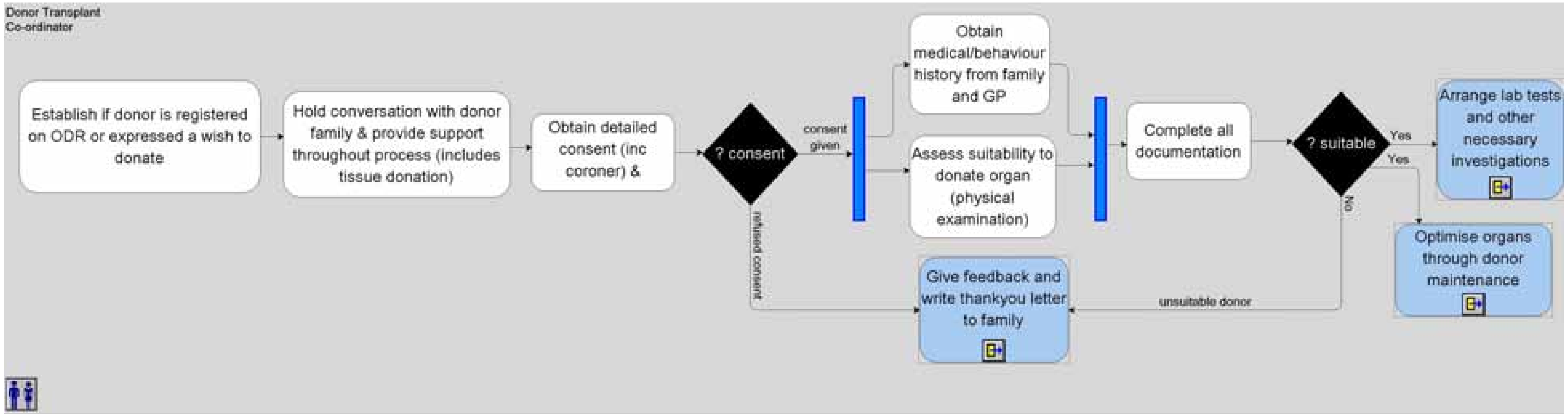

Don
Establish wish to donate, obtain consent/authorisation and assess suitability to donate
refused consent
unsuitable donor
Give feedback and write thankyou letter to family
Optimise organs through donor maintenance
Arrange lab tests and other necessary
lab investigation request
Register donor with UKT
Arrange organ retrieval
Refer to appropriate Tissue Establishment
Awaiting transport
HUMAN ORGAN
Place copy of forms in organ tranport box
Core Donor Data Form
Post Transplant
Complete Organ Donor Outcome summary form
Provide feedback to HCP & family
Zonal Retrieval Team
Retrieve organ & pack in transport box
Organ Transport Box
Laboratory (Donor)
Carry out laboratory investigations on donor
Send Donor results to UKT
Donor Lab Results
UKT Duty Office
Enter details on NTxD
Update NTxD with Donor Laboratory Results
Run matching algorithm on NTxD & offer organ to Tx Unit in list order
No
? accepted
Yes
Yes
Update NTxD with acceptance data
Offer to all Tx units, offer in list order
? accepted
Yes
Yes
No
Offer for research or organise local disposal
Recipient Transplant Co-ordinator
Post Transplant
Complete recipient transplant form
Send 3, 12 month + annual follow-up information to UKT (Data Services)
Arrange lab tests on donor & recipient samples
to Test donor & recipient samples
Organise transport for organ
Transport
Transport Organ, samples and documentation
Recipient Team
Assess suitability of organ for transplantation
? suitable
No
Yes
rejected organ
Inform UKT Duty Office
rejected organ
Yes
Transplant Organ
Successful Tx
Laboratory (Recipient)
from Arrange lab tests on donor & recipient samples
Test donor & recipient
? compatible
No
Inform Duty Office
Incompatible organ

Figure 10: Establish wish to donate, obtain consent /authorisationand assess suitability to donate



The process is similar for NHBD with the following exceptions or points of clarity:

- Agreement that the continuation of treatment is no longer in the patient's best interest is decided by multidisciplinary ICU team, and withdrawal of treatment discussed with the family.
- DTC should be available to ensure that a collaborative/planned approach can be made to the relatives for consent/authorisation for donation.
- Treatment including respiratory support would be withdrawn after consent/authorisation and after the retrieval team were on site to remove organs for transplantation.
- Following cessation of heart beat a period of 5 minutes is observed before death is confirmed.
- In terms of uncontrolled NHBD the patients may come to the A/E Department unaccompanied and so consent/authorisation may not be ascertained until relatives are traced.

- Minimal steps, such as the cannulation of blood vessels to perfuse the organs, may be taken prior to consent but after certification of death in order to preserve the option for donation
- Blood samples may also be obtained but not tested until consent obtained.

The following sections explore the features of key elements along the pathway.

Donor Transplantation Co-ordinator Network

Currently there are about 100 DTCs in the UK. They are the vital link between the family of the deceased, the hospital where the donor died and the arrival of the organ at the transplant centre.

Each DTC undertakes a variety of complex tasks. These include:

- Obtaining consent/authorisation for organ donation from the family. In England, Wales and NI this must comply with strict requirements on informed consent as required by human tissue legislation
- Developing a culture of organ donation within ICUs. This includes identifying areas of concern, provision and supporting training, building and developing relationships and so on.
- After consent has been obtained managing the entire procedure. This includes:
  - Arranging laboratory tests,
  - Co-ordinating the organ retrieval teams,
  - Allocating organs according to strict allocation methodology. This can involve many phone calls to different transplant centres,
  - Arranging the transport of the organs,
  - Undertaking last offices, and, when required, arranging for the family to view the body,
  - Supporting the family through the whole process.

This requires quite an exceptional person, typically a person who:

- Has excellent communication skills to deal with acutely bereaved families and diplomatic skills to encourage the active engagement of staff in the donor hospital.

- When they are on call they have to be immediately available and often have to focus for up to 20 hours on highly complex tasks in a very emotional atmosphere.
- Has the clinical and technological experience to work in ICU and operating theatres to undertake a variety of support roles.
- Is exceptionally well organised, being able to remember and co-ordinate a number of very different and complex tasks.
- Has the knowledge and ability to apply the requirements of human tissue legislation.

Currently the DTCs are employed by a number of NHS organisations throughout the UK. Although they are professionally led by the standards and support provided by UKT, they are directly accountable to their NHS employing organisation. Reporting lines differ, as do Agenda for Change bandings for the same role.

Increasingly, employing NHS trusts/divisions are becoming more unwilling to accept the clinical risks of the DTC service. This is on the basis that the clinical activity of the DTCs doesn’t contribute to the Trust’s Local Delivery Plans, the activity purchased by their commissioners and National Service Frameworks etc. Given the highly specialised nature of DTC work many hospital directors feel unequipped to deal with detailed professional issues, relying on UKT for advice and support. With increased emphasis on good clinical governance in the NHS, this pressure will only increase.

There is increasing conflict between the national (UK Wide) responsibility of the DTC role and that of their employing NHS authority as some Trusts don’t see the DTCs contributing to the targets by which they are measured and, on occasions, have sought to re-assign DTCs with other roles.

Additional requirements on the DTC, with respect to being with the family at an earlier stage and undertaking more tasks make the role responsibilities increasingly complex and longer. Over time this will affect recruitment of new staff and the retention of existing DTCs.

Current arrangements are unstable and are prone to collapse.

The Retrieval of Organs

Most organ retrieval in England occurs from one of the 7 Liver Transplant Centres that are funded by National Commissioning Group (NCG) in England. Retrieval, although critical to the success of transplantation, it is neither explicitly funded or performance managed. Surgeons have to juggle their elective and emergency surgical lists to attend retrievals. There can often be back-to-back sessions which can not only compromise the quality of care to their patients and organ retrieval, but will become increasingly at odds with the Working Time Regulations.

A functioning integrated organ retrieval team consists of a variety of highly trained individuals[9]. Members of the team include:

- Anaesthetist and/or support from a donor care physiologist,
- Cardiothoracic surgeon,
- Intra-abdominal surgeon,
- Surgical assistant,
- Multi-skilled theatre team (scrub, floor, perfusion etc).

Organ retrieval often takes place at night in a theatre that the surgical team is unfamiliar with. The team could also have taken several hours travelling to the hospital. The point is also made that, as currently organised, organ retrieval suffers from[10].

- The inability to draw together a retrieval team during the day (0900 – 1700).
- The inability to deal with donors that require retrieval at the same time.
- Other delays that arise from the cumulative effects of a poorly managed and highly complex pathway.

Currently, the capacity of the organ retrieval teams can hardly cope with the existing donors. Given the planned increase in donors and other pressures, such as Working Time Regulations, there won't be the staff to retrieve the organs.

The Taskforce was fortunate to draw on recent evidence from Scotland[11]. These reports explain in far more detail the logistical, complexity and technical difficulties of organ retrieval and the affect that an unstructured and uncoordinated service has on those involved.

The Task Force also benefited from the outputs of:

- A year's pilot study of dedicated organ retrieval service in Scotland.
- A four-year study by the British Transplant Society that expired the optimum configuration and operation of organ retrieval covering England, Wales and Northern Ireland.

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[9] UKT (2004), *Organ Retrieval Working Group, Options for Further Provision of Organ Retrieval*, Unpublished

[10] UKT (2004), *Organ Retrieval Working Group, Options for Further Provision of organ Retrieval*, Unpublished

[11] NHS Lothian (2006), *Review of Scottish Organ Retrieval Team SORT Final Evaluation*, Unpublished

NHS Lothian (2006), *Scottish Organ Retrieval Team – A proposal for a Scottish Organ Retrieval Team 2007 and beyond (September 2006),* Unpublished

The experience in Scotland combined with the four-year study by the British Transplantation Society offers practical and tested ideas for organ retrieval.

Funding & Performance Management Along the Donation Pathway

The following bullet points highlight general drivers within the NHS Operating Framework[12]. Although several areas are of little direct applicability for organ donation the general direction of travel is clear. Areas include:

- National standards to ensure quality, safety and equity.
- Drive to build a commissioning framework to increase quality of outcome, cost and plurality of supply.
- Sound financial management and improved financial incentives.
- Greater and more effective stakeholder engagement.
- A drive to increase transparency and consistency of service.
- Driving quality and productivity improvements through a more systematic use of information and analysis to benchmark performance.
- Sound information management to support improvements

The existing arrangements for organ donation do not sit comfortably with the direction of travel. The recommendations of the Taskforce are an opportunity to re-align organ donation in light of new and emergent demands. Current issues of particular concern include:

- The lack of transparency of funding. There is uncertainty as to how much organ retrieval costs. In England, NCG funds the activity of a transplant centre. A proportion of which will go on organ retrieval. How this is spent in each centre is not clear. There tends to be different arrangements for kidney only retrieval and those operating in devolved health assemblies.
- The performance of organ retrieval is not regularly reviewed in a cogent and structured manor that reconciles value for money and clinical outcome, both in terms of sufficiency of organs and their quality. On a positive note, this information is collected and is available from UKT.
- DTCs are funded in a variety of ways which include direct funding from UKT and NHS Trusts/Divisions with corresponding variety of reporting and performance management arrangements.

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[12] Department of Health (2006a), *The NHS in England: Operating framework for 2007-08,* http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063267

- There is a lack of clarity over the whole donation pathway between those who carry out a commissioner and performance management role and those who undertake to provide services.
- The donation pathway involves many different people, working in different disciplines in many different locations. There is a lack of clear co-ordination that brings this all together.
- There is a lack of structured understanding of key stakeholders and how those stakeholders can contribute to organ donation. With respect to performance, these stakeholders include Trust CEOs and the medical community. With respect to wider implication, stakeholders include patients and donor families.

International Lessons

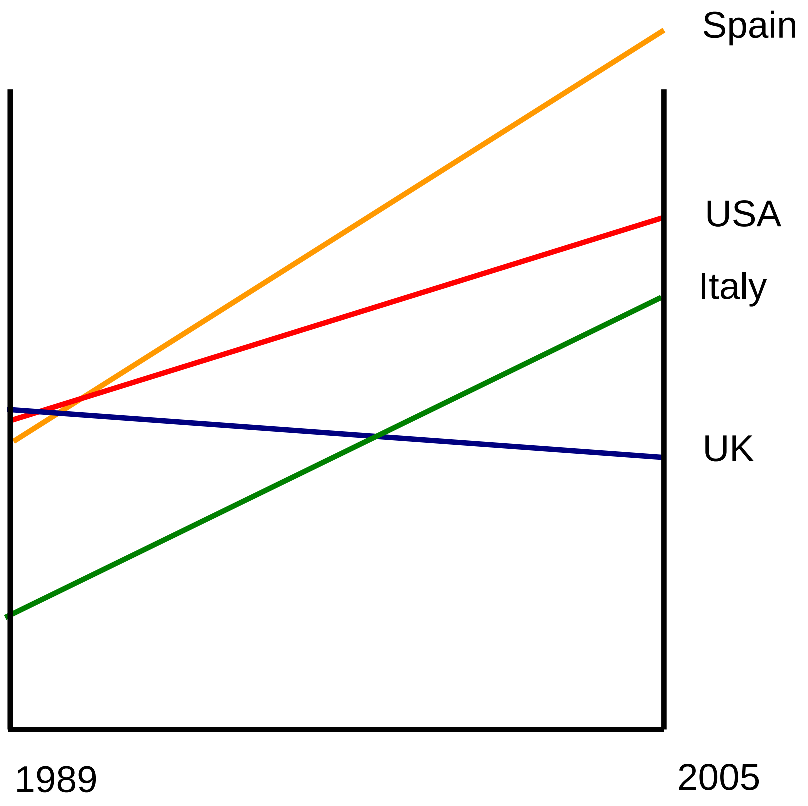
At the January 2007 Taskforce meeting there were presentations from Rafael Matesanz and Francis Delmonico from Spain and the US respectively. Both countries have had major success in delivering increased organs for transplantation. These increases have been achieved relatively quickly and are being sustained over the longer term.

Before discussing how they increased donation there is one key point to consider: both approaches are different. The legal environment is different as are their cultural and societal influences. However, the similarities are important too. Similarities include:

- Clear and visible leadership,
- Identification of clear roles and responsibilities throughout out the donation pathway,
- A holistic view of the donation pathway, ensuring that each step is properly managed and measured,
- Recognition of the important contribution all those on the donation pathway make,
- Established culture whereby organ donation is the routine, rather than the exception.

Figure 11 is a slide taken from Rafael’s presentation. It clearly shows the improvements that have been made in Spain, the US and Italy, seen in context with the decrease in donation elsewhere (the figures are expressed in PMP).

Figure 11: Improving Organ Donation Rates in Spain, Italy and US



Approaches that the Spanish have taken to increase organ donation:

- The importance of a central co-ordinating organisation
- Structured DTC network that focuses on performance, but recognises:

  - The contribution that doctors make in increasing organ donation,
  - That organ donation can be stressful and that DTCs can be subject to “burn-out”,
  - That DTCs within hospitals can have a bigger impact than those coming in from outside,
- The impact that the mass media has on organ donation,
- They haven’t relied upon changes to the legislation and donor registries to increase donation,
- Hospitals are compensated for the effort and resources they put in to organ donation,
- Organ donation features as a main part of doctors’ training,
- Each step on the donation pathway is audited and measured, for example the declaration of brainstem death,
- The appropriate use of organs from more elderly donors.

It is interesting to note that, according to Rafael Matesanz, of the British who died in Spain in 2005 all, who were eligible for donation (41 in total), went on to become organ donors. This 100% consent rate compares to 40% in the UK.

Approaches that the US have taken to increase organ donation:

- To take a very direct approach as to what is expected from hospitals, this is included in agreements with hospitals. Failure to meet expectations can have severe consequences on a hospital,
- There are very “aggressive” goals along the wider transplantation pathway, including the number of donors and transplants, increased quality and quantity of life after transplant and cost efficiency,
- Clear guidance on death and when donation is appropriate,
- Robust infra-structure from donation to transplantation.

Consent – Opting In or Opting Out

The remit of the Taskforce was to consider actions to increase organ donation within the existing legislative framework. This excluded the questions as to whether there should be a change in the law to move towards presumed consent (ie opt-out).

It has been noted previously [13]that in Spain, a country that has had an opt-out system since 1979, it took the creation of the Spanish National Transplant Organisation in 1989 to increase the rate of organ donation from 14.0 to 32.5 pmp.

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[13] National Services Division, NHS Scotland, *Review of Scottish Organ Retrieval Team in Scotland*, February 2007

The Basis for Change

The last major heading was titled “Why Change is Important” and focused on the evidence as to why current arrangements in the UK are not adequate to deal with the challenges of today or tomorrow.

The following sections look at the individual recommendations made by the Taskforce and consider the evidence to support the recommendations and, for those that require significant investment, the various options and costings.

A UK Wide Service - Developing Clarity on Accountability, Responsibility and Relationships

Taskforce Recommendation 1: A UK-wide Organ Donation Organisation should be established.

Taskforce Recommendation 2: The establishment of the Organ Donation Organisation should be the responsibility of NHSBT.

International experience from Spain and the US has shown that increasing organ donation involves all parts of the donation pathway. Any weakness in one area has a knock-on effect elsewhere. As already indicated in the section “Why Change is Important – Donation Pathway” the pathway is complex, it occurs over several hospitals often hundreds of miles apart, it is stressful and speed is of the essence. The above section also indicates that there are currently substantial weaknesses in the majority of areas. The meticulous attention to detail, seen in organ donation organisations in Spain and the US, is not dis-similar to those required in managing a successful supply chain organisation in the commercial sector.

In January 2007 two managers from NHSBT visited IKEA in Holland. IKEA have a world class supply chain operation with over 12,000 suppliers. It is by their effective management of the supply chain, over many years, that IKEA have been able build a highly successful worldwide organisation.

Organ donation in the UK and selling furniture are, of course, completely different. However, there are several areas where lessons can be learnt. This is particularly the case with respect to the culture of the organisation and behaviours.

From the visit to IKEA the following messages were clear: the difficulty of managing the supply chain cannot be underestimated nor can the benefits of getting it right. There was meticulous attention and control on every part of the supply chain. This included the companies that supply the suppliers, working in long term partnership with suppliers (including providing investment capitol and support), design, logistics, marketing and the store. There was clear understanding that a weakness in one part would have a “ripple effect” in other parts of the organisation. The way people were paid and rewarded related directly to their contribution to the supply chain and the wider performance of the organisation.

Lessons in terms of organ donation include:

- Everybody in the ‘supply chain’ sharing a common goal and owning the problem to overcome obstacles to improving donation rates,
- Establishing good working relationships between (DTCs, retrieval teams and hospital staff with each understanding their role and accountabilities,
- Providing training and education to hospital staff in organ donation and transplantation so that they understand and appreciate its importance and are committed to identifying and referring potential donors,
- Investment in donor hospitals to support them in developing procedures to improve donation rates e.g. live donor schemes, NHBD schemes and In House Co-ordinators (IHCs),
- Performance management of funded schemes, working with hospitals to understand issues affecting the delivery of agreed targets,
- Joined up marketing and promotional activities so that a consistent message is given about the benefits of organ donation and transplantation,
- Recognising and reimbursing donor hospitals for the cost of providing donor organs.

Some of the areas of good practice identified within the IKEA supply chain already exist in relation to organ donation others need to be developed or improved upon.

The Taskforce had presentations from Spain and the US, both countries that have significantly improved organ donation. It is interesting to note that many of the features above were either explicitly stated or implied in their presentations.

In developing a new approach to organ donation in the UK we have an opportunity to build in many of these values to develop a culture that appreciates the complexity of donation and for everyone to be enthusiastic to identify and deal with the obstacles to donation.

Recommendation 1

Robust organisational structures will be vital if the UK is to deliver substantial and long term improvement in organ donation. It will also be key in dealing with new and emergent issues that could affect the transplantation “environment” and to identify and make the most of opportunities for innovation in the future. Structures also need to create the climate where efficiency and optimal clinical outcome is rewarded. Within both the public and private sectors these objectives are often best characterised by clarity between the commissioner and provider functions. Features of the relationship will include all parties working together collaboratively and constructively to advance clinical quality, efficiency and quantity to improve the outcome for the patient.

Recommendation 2

With respect to commissioning functions, UKT within NHSBT already undertakes several of these activities. The statistics and audit function provides data on many aspects of organ donation and transplantation. Along with the clinically focused advisory groups there is the strength to build upon and interpret this data. This, along with focus on practice and performance measures, could form the core of an "intelligent" commissioner. There can be few other cases in healthcare where there is such strength of data that is directly applicable to clinical outcome. Areas that the commissioner could be responsible for could include:

- Analysis of demographic and economic data to appreciate future demand,
- Commissioning vital services, including organ retrieval, based upon clinical quality, cost and responsiveness,
- Building appropriate capacity to meet the demands placed upon it,
- Where necessary to decommission and reallocate services.

Ethical Issues - Resolving legal, ethical and professional issues

Taskforce Recommendation 3: Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice. Additionally, an independent UK-wide Donation Ethics Group should be established.

Ethics have an increasingly important role to play. In its most practical and positive sense it helps to remove barriers and increases society's view of the legitimacy of organ donation. By having a forward thinking approach to the ethical issues of organ donation, many of the future problems can be anticipated.

The Taskforce held a workshop to consider the ethical issues of organ donation in the UK, the issues raised can be found in Appendix 3.

Unresolved Issues

The most significant issue to come through was the importance of the few unresolved areas. These include the decision to withdraw inappropriate treatment, best interest and ethical/legal standing of NHBD. It was felt that recent legislative changes had done little to resolve these issues. And without a test case or other legislation it would be difficult to achieve an optimal degree of certainty. Given the potential of NHBD, these ethical and legal ambiguities will become more challenging. However, as the human tissue legislation has only recently been introduced it was felt that, in the short term at least, changes in the law would be unlikely. That said, the longer ethical and legal ambiguity remains the greater impact it is likely to have on organ donation and clinicians willingness to engage with it.

Pathway Vs Context

Members of the workshop considered ethical issues from two perspectives:

- along the donation pathway
- within the general context of donation and transplantation, for example health inequalities, demographics, economics

It is recognised that the separation between the two was a little artificial with several issues appearing in both areas.

The "Home" of Ethical Issues

Having identified a large number of broad ethical issues, time was then spent to look for a natural home for their "resolution". It soon became apparent that there were few, if any, natural locations where issues could be resolved. This would have implications those involved in organ donation and contributed to the view that there was a need for an organ donation ethics group.

Focus of Attention

As already mentioned, those areas that attracted most debate and attention were the unresolved issues. Longer term issues such as new technology, directed donation, globalisation in organs, new tests etc featured lower on the group's priority. The focus on shorter term important topics, at the expense of longer term considerations, could pose challenges as to how NHSBT and UKT manages with new and emerging ethical challenges.

Implications for the Organisation Charged with Managing Organ Donation

From the points above there are a number of issues that NHSBT and UKT should consider, these include:

- How best to engage with stakeholders to develop a proportionate and proactive approach to ethics,
- Given the number of issues identified, the development of a reasonable "test" to help prioritise resources, (What do you mean by test?)
- The role of the organisation in sponsoring and co-ordinating ethical considerations outside the organisation,
- Accountability and responsibility,
- In the absence of greater legal clarity on best interest, withdrawal of treatment and NHBD, action that can reasonably be done to provide those with appropriate assurances.

Making Donation Usual, Not Unusual - Making organ donation routine work in the NHS, including making it a standard part by which the success of hospitals are measured

Taskforce Recommendation 4: All parts of the NHS must embrace organ donation as a usual, not an unusual event. Local policies, constructed around national guidelines, should be put in place. Discussions about donation should be part of all end-of-life care, when appropriate. Each Trust should have an identified Clinical Donation Champion and a Trust Donation Committee to help achieve this.

In a previous section, titled “Variability in Performance”, the donation figures for hospitals were discussed. Two key areas were considered: carrying out brainstem death testing and referral of potential donors to the DTC. The variance was presented as a proportion of the potential, not just absolute numbers. The variance was substantial. However, this was not surprising as organ donation hardly featured on the radar of most hospital CEOs/COOs (see Appendix 6).

To increase the number of organs available for transplantation there needs to be a move away from the current voluntary approach, where clinicians have the option to support organ donation, to one where organ donation is performance managed – in essence, for it to be mandatory.

Within the recommendations the expectations of hospitals are limited and achievable. They will be expected to undertake brainstem death testing for all appropriate patients and to refer those patients to a DTC. Where consent has been obtained by the DTC the hospital will need to make theatres and other facilities available for organ retrieval, for which they will be financially compensated.

With respect to incentivising hospitals there are several important points to consider from the interviews with CEOs/COOs and senior mangers (see Appendix 6) these include:

- There was universal support for organ donation,
- A lack of understanding of who was responsible for driving organ donation,
- The reported absence of performance indicators and results.

The above recommendation builds on this feedback. Recommendations centre on supporting hospitals to develop a Trust /DivisionalDonation Committee. The aim will be to visibly enable the trust to meet its obligation on organ donation. The work of the Committee will be tailored to bridge the gap between current performance and its potential. The Committee’s work should be proportionate and tailored to the individual need of the hospital. The emphasis will focus on development that is achievable and visible through the hospital’s Medical Director and clinical governance arrangements.

In order to support Donation Committees the following is envisaged:

- Providing clear and concise information on hospital performance, preferably one page that highlights hospital performance compared to the national average with local competitors,
- Recognition of high performing hospitals,
- Supporting the appointment and funding of a local Donation Champion. This could include a person within the hospital, for example the director of ICU, or an external appointment of someone who has credibility and enthusiasm for organ donation,
- The provision of practical support to identify local obstacles to donation,
- Interventions with particular issues. This could include the funding of Intensivists to work with local doctors and nurses in ICUs who have concerns over organ donation,
- Local campaigns and promotions to communicate the value of organ donation.

Trust CEOs/COOs should be accountable for organ donation in their hospital. The role of the regulators, such as Monitor, the Healthcare Commission and similar structures in the Devolved Health Administrations, for example NHS Quality Improvement Scotland (NHS QiS), should be explored with the aim of integrating organ donation within performance standards.

However, the nature of such accountability should be easy to measure and be achievable. It is therefore recommended that accountability be restricted to the identification and referral of potential donors who are suitable for donation.

Notification and Monitoring – Assessing organ donation amongst hospitals

Taskforce Recommendation 5: Minimum notification criteria for potential organ donors should be introduced on a UK-wide basis. These criteria should be reviewed after 12 months in the light of evidence of their effect, and the comparative impact of more detailed criteria should also be assessed.

Taskforce Recommendation 6: Donation activity in all Trusts should be monitored. Rates of potential donor identification, referral, approach to the family and consent to donation should be reported. The Trust Donation Committee should report to the Trust Board through the Clinical Governance process and the Medical Director, and the reports should be part of the assessment of Trusts through the relevant healthcare regulator. Benchmark data from other Trusts should be made available for comparison.

Taskforce Recommendation 7: Brain stem death testing should be carried out in all patients where brain stem death is a likely diagnosis even if organ donation is an unlikely outcome.

In a previous section “Why Change is Important – Variability in Performance” evidence was presented to show the inconsistency of performance in key areas of the donation pathway which was evident from one part of the country to another. There was also evidence to show that if all hospitals were performing at or above the top 20% the number of organ donors would increase by 40%. A closer look at the PDA, see Appendix 5, highlights that there are nine critical decision points for HBD, where the opportunity for donation can be stopped. Of the nine there are at least three opportunities to substantially increase organ donation by focused attention on performance. It is worth pointing to the fact that despite the hard work of many involved in organ donation; performance has reminded static for the last three years with respect to ventilated Heart Beating patients, see below.

	Figures range from in 3 years
• No record of discussion/approach regarding HB solid organ donation (percentage of potential donor families)	*14 – 16%*
• Consent given for HB solid organ donation (percentage of families who were approached)	*58 – 61%*
• Actual HB solid organ donors, based on data provided through the PDA (percentage of patients with family consent)	*90 – 91 %*

The high level of variability needs to be seen in context with the views and attitudes of senior managers in the NHS, particularly CEOs/COOs of hospitals and those within Strategic Health Authorities. Whilst the majority of CEOs/COOs were very supportive of organ donation it was not a Trust activity of which they were very aware, in part, because it did not feature in how their performance was managed.

Recommendations 4 and 5 therefore seek to address the variability in performance by:
- Making referral mandatory.
- Keeping hospitals involvement clear and simple.
- Providing support to hospitals to address blockages that prevent donation.
- In association with Recommendations 7 and 9 to minimise the burden on hospitals.

Costs of Donor Management - Removing the Obstacles to Donation, including financial disincentives

Taskforce Recommendation 8: Financial disincentives to Trusts facilitating donation should be removed through the development and introduction of appropriate reimbursement.

Keeping a donor in ICU until the organ retrieval team arrives has the effect of tying up resources, both in terms of cost and availability of that bed for another patient. Whilst additional resource in organ retrieval (See Recommendation 9) will aim to shorten the time it takes to get the donor into the operating theatre the hospital will still have to incur costs. It is these costs that this Recommendation aims to support. This approach is consistent with high performing countries such as Spain as well as being well established in Scotland.

Donor Transplant Co-ordinators & Organ Retrieval Teams- Building a Robust Structure for the Future

Taskforce Recommendation 9 (Part 1): The current network of donor transplant co-ordinators should be expanded and strengthened through central employment by a UK-wide Organ Donation Organisation. Additional co-ordinators, embedded within critical care areas, should be employed to ensure a comprehensive highly skilled, specialised and robust service. There should be a close and defined collaboration between donor co-ordinators, clinical staff and Trust Donation Champions.

It is clear that the ad hoc employment arrangements, where local Trusts/Divisions employ DTCs under a professional leadership framework from UKT, is becoming increasingly unstable, both from a quality and clinical governance perspective. An options appraisal was undertaken to determine the most viable employment arrangements. The options considered were: carry on with existing arrangements, direct employment of DTCs and commissioning their services from hospitals. Appendix 7 explores a variety of options available in more detail. The option with most merit was direct employment by a central organisation.

Advantages here include:

- Improved flexibility with DTC workforce,
- Improved delivery of new DTC model,
- Improved synergy with new organ retrieval team model,
- Ability to standardise terms and conditions of employment through UK,
- Removes dichotomy between professional and managerial lines of support,
- Increased ability to develop, implement and enforce national standards and policies and procedures,
- Increased size of DTC services increases the ability to respond to recruitment problems,

- Location of local DTC services matched to where donor potential exists,
- Improved retention within DTC profession,
- Ability to develop, implement and enforce national standards and policies and procedures,
- Clearer clinical governance arrangements.

Additional work of the Taskforce has indicated how the separate functions of the DTC can be separated into two or three roles.

These roles will focus on:
- Working with bereaved families to obtain consent/authorisation,
- Developing relationships with ICUs to make donation a routine part of their work,
- Assisting in theatre and undertaking a role in the allocation of organs.

The role will therefore be more achievable, not requiring staff to work for continuous prolonged periods. It will also be capable and flexible to deal with new requirements (clinical, quality or technical).

ICUs will also be supported by the appointment and of IHCs. These IHCs, will be able to identify and refer donors within optimum timescales.

Currently there are approximately 100 DTCs along with 5 Regional Managers. With a new robust service the number of DTC is likely to increase to 250 – 275.

Taskforce Recommendation 9 (Part 2): Electronic on-line donor registration and organ offering systems should be developed.

Staff at UKT have visited Eurotransplant in Europe and the United Network for Organ Sharing in the US. Experience from these countries has shown that electronic offering of organs is fully achievable within the short to medium term and offers substantial benefits.

Taskforce Recommendation 10: A UK-wide network of dedicated Organ Retrieval Teams should be established to ensure timely, high quality organ removal from all heartbeating and non-heartbeating donors. The Organ Donation Organisation should be responsible for commissioning the retrieval teams and for audit and performance management.

Current organ retrieval arrangements are a substantial constraint on the ability to increase the number of organs for transplantation. As previously stated, organ retrieval is not explicitly funded or performance managed and it puts a substantial strain on the donor hospitals, particularly with respect to anaesthetic support.

The British Transplant Society (BTS) were asked to consider the number of teams across the UK and their composition in order to provide a sustainable multi-organ retrieval service to deal with the anticipated increase of 50% in organ donors. 9 multiorgan retrieval teams will be required. It is envisaged that these will be based at the 7 existing liver transplant units with additional teams to support the North West and South West of England. Although not included within current proposals, there will be the option of incorporating cardio-thoracic organ retrieval at a later date.

Training, Education and Continuing Educational Support - Improving the understanding of organ donation amongst healthcare professionals

Taskforce Recommendation 11: All clinical and nursing staff likely to be involved in the treatment of potential organ donors should receive mandatory training in the principles of donation. There should also be regular update training.

Training is important for all professions and medical, nursing and professions allied to medicine are certainly no exception. There is evidence to support investment in training for both donor transplant co-ordinators, who come from a predominantly nursing background, and those who work in ICU and A&E.

With respect to the DTCs it is relevant to point to a recent DH publication, *Towards Modern Nursing Careers – Priorities for Action* that was published last year[14]. The report identified several environmental factors that have direct relevance to the modernisation of DTC services. The report concluded that action was needed in the following areas:

- Develop a competent and flexible workforce,
- Update career pathways and career choices,
- Prepare nurses to lead in a changing healthcare system,
- Modernise the image of nursing and nursing careers.

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[14] Department of Health (2006), *Towards Modernising Nursing Careers*, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4138756

Recommendation 10 is consistent with the above, and other healthcare initiatives, to develop a competent workforce able to meet the challenges of tomorrow. Both Spain and the US have focused heavily on developing a competent workforce, with structured training and assessing effectiveness in practice.

With respect to the wider healthcare community, organ donation is often a rare event (other than in larger hospitals). Many ICU staff go through their training without being involved in organ donation. Organ donation occurs in an emotionally charged environment. There is evidence to indicate that adequate training to enable staff to feel confident and to be competent increases the rate of organ donation[15].

Honouring the Gift of Donation - Recognising and thanking the public for their commitment and support

Taskforce Recommendation 12: Appropriate ways should be identified of personally and publicly recognising individual organ donors, where desired. These may include national memorials, local initiatives and personal follow-up to donor families.

Two members of the Taskforce met with a donor family. The aim was to understand what was important to them. There were very positive comments on the professionalism of the DTC service and the support offered. Without this donation would not have occurred.

It was important to the family that the gift of organ donation should be recognised but this recognition should be appropriate to the wishes of the family and the donor. This is one family's view.

Throughout the country there are very well attended thanksgiving services for the families of donors and recipients and their families. Although the reason for attending these services may be different for each family it demonstrates the need for public recognition.

Promoting Donation - Tackling Health Inequalities & Guidance for Coroners

Taskforce Recommendation 13: There is an urgent requirement to identify and implement the most effective methods through which organ donation and the "gift of life" can be promoted to the general public, and specifically to the BME population. Research should be commissioned through Department of Health Research and Development funding to enable donation–related research.

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[15] Ehrle R, Shafer T, Nelson K (1999), *Referral, Request, and Consent for Organ Donation: Best Practice - A Blueprint for Success*. Critical Care Nurse, Vol 19, No 2,

Evidence for this recommendation focuses on the gap between the supply of organs and their demand amongst BME groups. Gurch Randhawa, a Taskforce member, along with members of the UKT Review Group[16], undertook a review of the main issues and work already underway to tackle the problem, please refer to Appendix 4. The paper makes the following points:

- Tackling health inequalities, particularly amongst BME groups, is major political objective.
- There is little understanding of the notion of “gift” amongst BME groups, namely what are the key factors that will make bereaved families from BME groups give consent for organs donation.
- Although a considerable amount of work has been done to engage BME groups this has had little effect on increasing the number of organs from BME groups.
- In order to get more meaningful information it is relevant to include more demographic information on the ODR.

Taskforce Recommendation 14: The Department of Health and the Ministry of Justice should develop formal guidelines for Coroners concerning organ donation.

An assessment of the PDA by Dr Paul Murphy (See Appendix 8) has indicated that although the biggest reason why brainstem dead patients did not go onto become organ donors was family refusal there were other circumstances where the opportunity for organ donation was lost, particularly with respect to legal issues with the coroner.

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[16] UKT Review Group was formed by NHSBT to support the Organ Donation Taskforce

The Donation Pathway: Network of Recommendations and Performance

It is relevant to ask the question: how will the recommendations come together and what effect this will have on performance. Figure 12 below gives a diagrammatic view the donation pathway, within a wider healthcare environment. The Recommendations have been added to the diagram along with the effect this will have on performance (based upon cumulative effects of brainstem death testing, approach and consent/authorisation, see table 2). The diagram illustrates:

- Improving organ donation is complex –improvements across the whole pathway are needed if the rate of organ donation is to increase.
- Recommendations have a cumulative effect, each contributing to the 50% increase in organ donation the Taskforce predicts.
- Organ donation sits within a wider healthcare context – here too, action is needed to improve donation.
- There are well tested metrics to measure the impact of each Recommendation.

Figure 12: Diagrammatic View of the Organ Donation Pathway

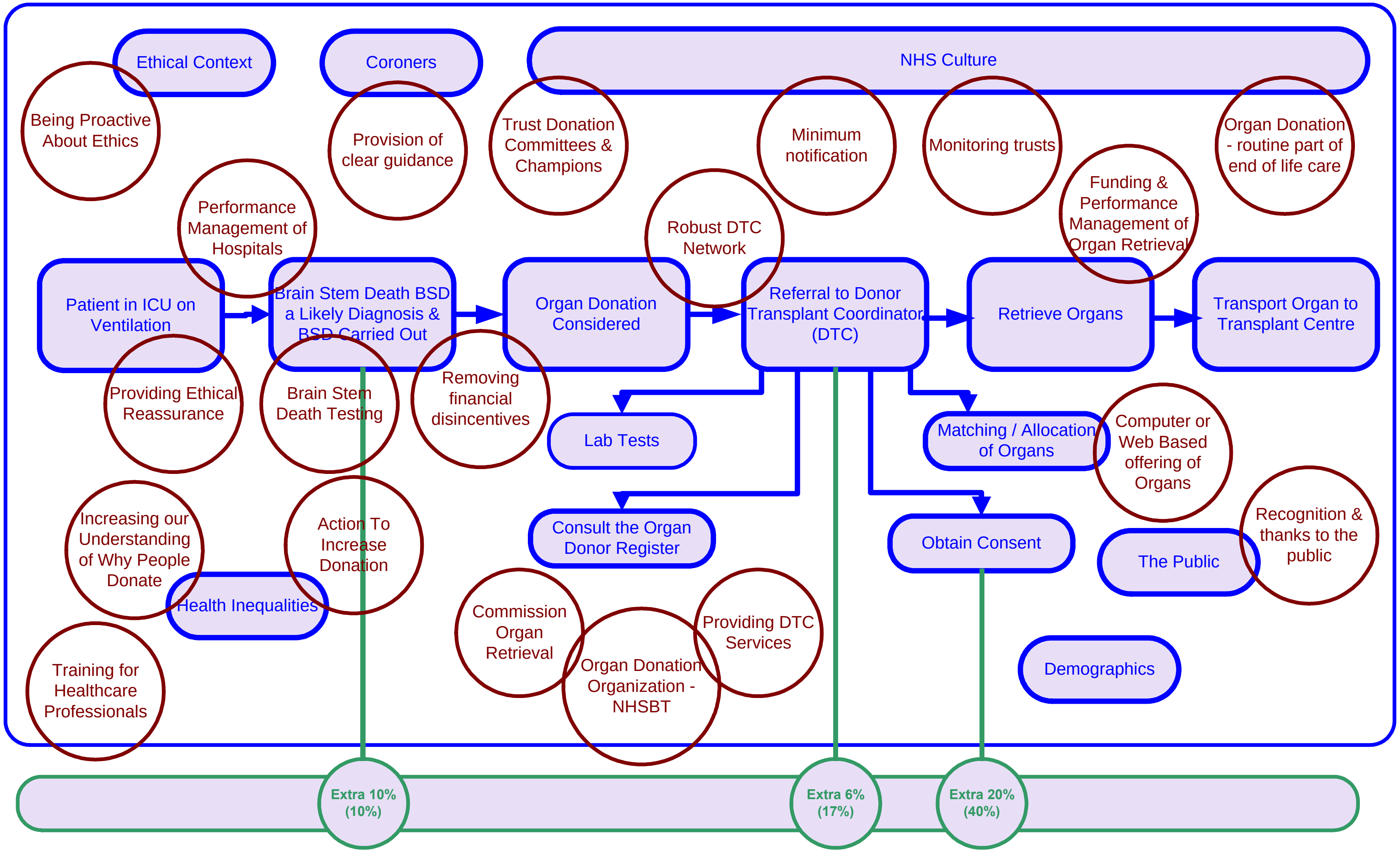


Figure 13 and 14 are two Process Maps that compare the how organ donation looks today and how it will change following the recommendations. Figure 14, which includes the recommendations, varies considerably from the process today. In addition to making existing structures more robust and fit for the future the following additional steps have been included to increase organ donation:

- Referral of the potential donor at an early stage following minimal referral criteria.
- Monitoring of hospital performance on key area
- Hospital reimbursement
- Electronic offering of organs to transplant centres

Figure 13: A summary of the Process of Organ Donation as it is Today

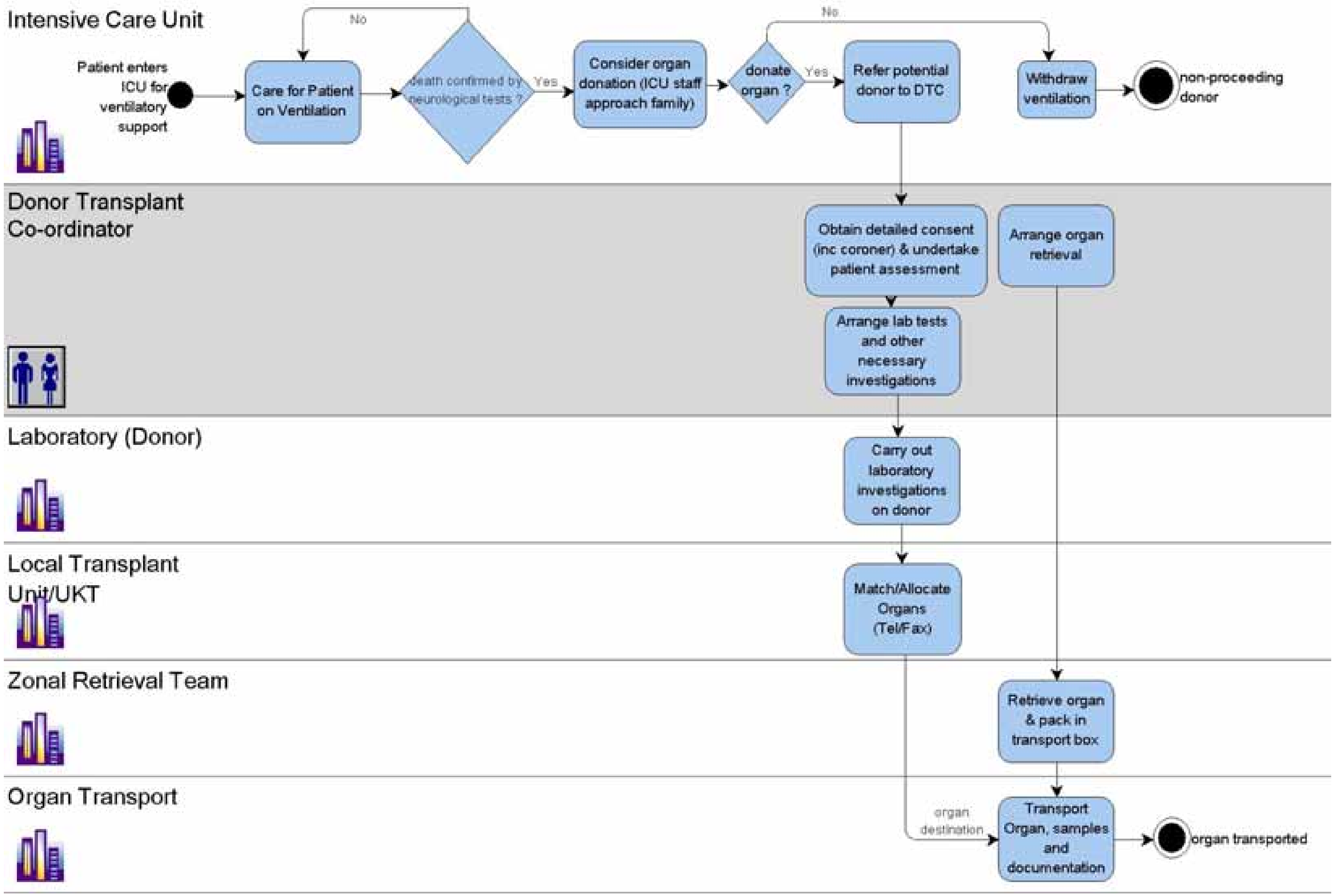
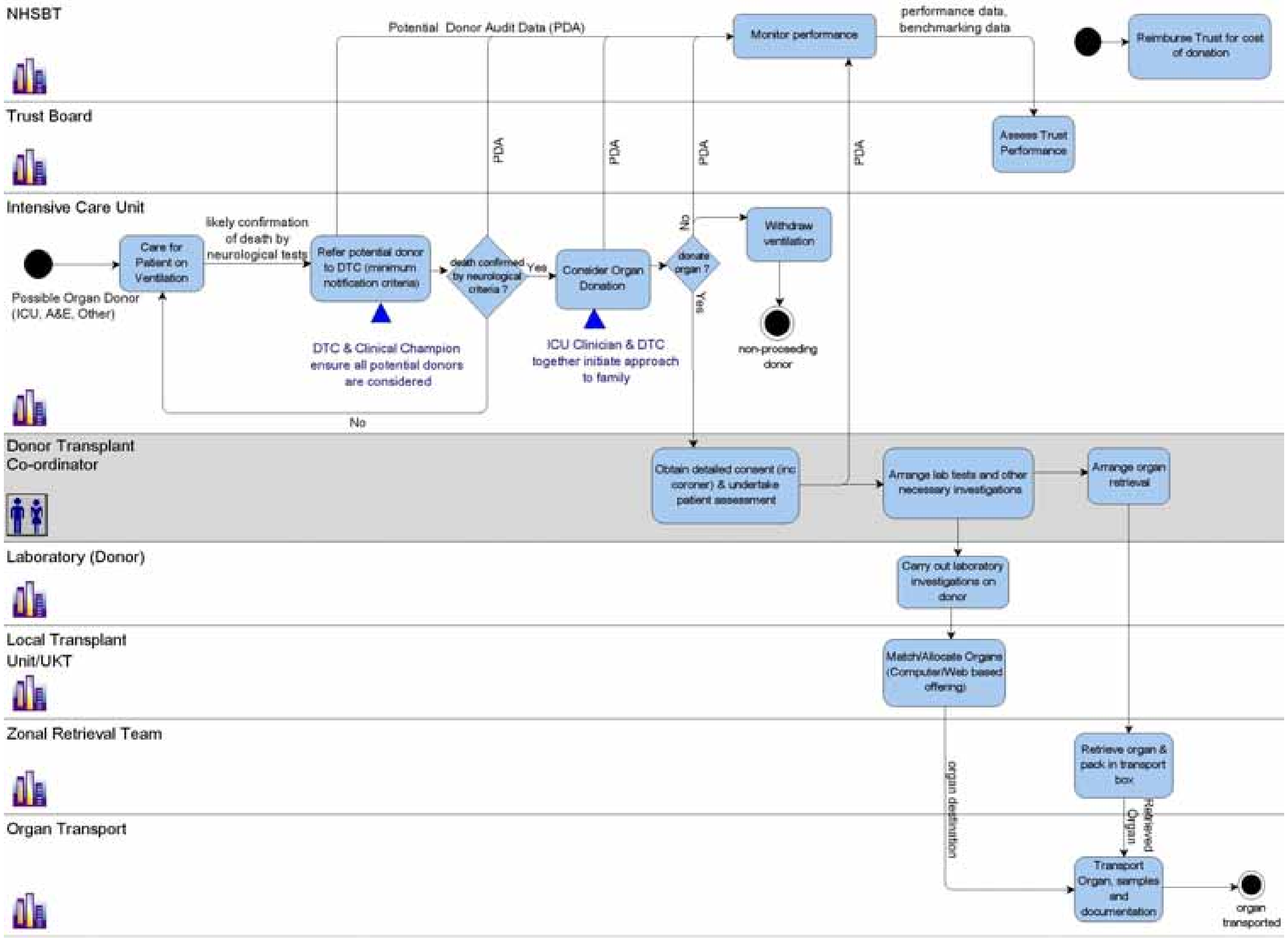


Figure 14: A summary of the Process of Organ Donation as it Will Look Following the Implementation of the Recommendations



Indicative Costs of Recommendations

Organ Donor Taskforce Indicative Financial Summary Report

Organ Donation Task Force Recommendation	A UK wide ODO should be established. NHSBT should have remit for this.		Organ Donation Champions & Committees.		Reimburse Hospitals for costs incurred during the donation process.		Strengthen UK Donor Transplant Co-ordinator network.		Create more robust Organ Retrieval Teams.		Total	
	£ 000's	WTE(C)	£ 000's	WTE(C)	£ 000's	WTE(C)	£ 000's	WTE(C)	£ 000's	WTE(C)	£ 000's	WTE(C)
Pay Costs												
Clinical Staff			4,015.5	0.00					10,851.0	163.00	14,866.5	163.00
Nursing Staff							9,619.3	196.00			9,619.3	196.00
Managerial and Administrative Support Staff					19.6	1.00	1,591.5	50.50	639.0	28.00	2,250.2	79.50
Sub Total Pay Costs	**0.0**	**0.00**	**4,015.5**	**0.00**	**19.6**	**1.00**	**11,210.8**	**246.50**	**11,490.0**	**191.00**	**26,735.9**	**438.50**
Non Pay Costs												
Activity Driven					2612.0				2,583.1		5,195.1	
Transport & Logistics									1,266.3		1,266.3	
Training							640.0				640.0	
Accommodation							541.4				541.4	
Other Support			1,325.0				523.0		171.0		2,019.0	
Other Professional Fees	500.0										500.0	
Sub Total Non Pay Costs	**500.0**	**0.00**	**1,325.0**	**0.00**	**2,612.0**	**0.00**	**1,704.4**	**0.00**	**4,020.4**	**0.00**	**10,161.7**	**0.00**
TOTAL COST	**500.0**	**0.00**	**5,340.5**	**0.00**	**2,631.6**	**1.00**	**12,915.1**	**246.50**	**15,510.4**	**191.00**	**36,897.7**	**438.50**

Outline Risk and Assurance

The following risk and assurance frameworks identifies key risks, how those risks will be controlled and what assurance can be given. However there is still a residual risk that there will be a drop in donor numbers during implementation due to possible anxiety and uncertainty on the part of existing DTCs during a period of change and a lack of focus on "day-to-day" issues.

This short term risk needs to be seen in the context of the medium to longer term risks of doing nothing. If nothing is done risks will increase to an unacceptable high level. This will undermine existing provision and future planned improvements. This risk will be long-lasting and will result in a deterioration of patient care.

The way that the recommendations have been structured means that the control of one risk can often be found in a recommendation elsewhere. It is for this reason that recommendations can't be pursued, or dropped, in isolation from each other – in short, the recommendations can't be only partially implemented.

Only higher level risks have been identified here. Risks associated with recommendations 11 -14 were not felt to be substantial. This assessment of risk was carried out as part of several workshops with members of the UKT Senior Management Team and the NHSBT Directorate of Strategy Management

Strategic Recommendation	Strategic Risks	Location of risk	Key Controls	Assurance on Control
What the objective aims to deliver	*What could prevent this objective being achieved*	*Which area within the donation pathway the risk primarily relates to*	*What controls/systems will there be in place to assist securing delivery of the objective.*	*Where we can gain evidence that controls/systems, on which we are placing reliance, are effective.*
A UK Wide Service - Developing Clarity on Accountability, Responsibility and Relationships *(Recommendations: 1 & 2)*	• The "national" structures being suggested run counter to the culture of UK healthcare with increasing emphasis on local delivery and service. • Lack of funding.	• Department of Health. • Devolved Health Administrations. • Organ Donation Organisation (ODO).	The production of realistic, clear and fully costed plans. This will include clear project plans with actions and timescales. Proactive client relationship between the ODO and stakeholders. Devolved Health Administration have been	Adherence to the project plans during implementation. This will include: • Clear accountabilities. • Regular reports to the Board and other committees. Positive feedback from

			part of the Taskforce in developing recommendations.	stakeholders.
Recommendation 1	Unmitigated Risk: LOW			
Recommendation 2	Unmitigated Risk: LOW			
Ethical Issues – Resolving legal, ethical and professional issues *(Recommendation: 3)*	• Not being able to find an authoritative forum (e.g. GMC or the DH) where the ethical issues could be resolved. • No resolution of the ethical or legal issues.	• Organ Donation Organisation.	In the short term to seek clarity on the existing ethical and legal situation. In the medium to longer term to lobby stakeholders (for example legislators and professional bodies) to move to a position that supports organ donation.	Given that the ODO does not have control over of the outcome assurance will be in the form of meetings, minutes and actions to support key controls.
Recommendation 3	Unmitigated Risk: HIGH			
Making Donation Usual, Not Unusual - Making organ donation routine work in the NHS, including making it a standard part by which the success of hospitals are measured. *(Recommendations: 4)*	• The message that organ donation should form a part of end of life care is not accepted by the wider healthcare community. • Organ donation competes with other hospital priorities for bed occupancy and operating theatres.	• Organ Donation Organisation.	Performance management of hospitals to monitor compliance. Donor reimbursement to support hospitals with additional cost. Minimising the impact of organ retrieval on hospitals by speedy arrival of fully staffed organ retrieval teams with anaesthetic support. Provision of support to the hospital from DTC.	Monitoring compliance by the Potential Donor Audit.
Recommendation 4	Unmitigated Risk: HIGH (LOW if part of performance management standards)			
Notification & Monitoring –	• Lack of compliance with	• Organ Donation	Staged implementation of	Monitoring compliance by

Minimum notification criteria for potential donors and monitoring donation activity in all trusts (Recommendation: 5,6 & 7)	the minimal testing and notification. • Hospitals may see the overhead of a Donation Committee and performance measures as an overhead for which they don't receive benefit. • Lack of clear and meaningful measures that have adequate buy-in. • Healthcare regulators are unwilling to engage in, or find it impractical, to include organ donation as part of their remit.	Organisation. • Department of Health. • Devolved Health Administrations.	recommendations. Straightforward means to identify and refer potential donors. Provision of support to the hospital from the DTC.	the PDA.
Recommendation 5	Unmitigated Risk: HIGH			
Recommendation 6	Unmitigated Risk: HIGH			
Recommendation 7	Unmitigated Risk: HIGH			
Costs of Donor Management - Removing the Obstacles to Donation, including financial disincentives *(Recommendation: 8)*	• Lack of funds.	• Organ Donation Organisation.	Appropriately costed reimbursement that reflects the costs incurred by trusts in maintaining a donor	None
Recommendation 8	Unmitigated Risk: LOW			
Donor Transplant Co-	• The existing DTC network becomes	• Organ Donation	Communication and dialogue with DTC, employers and	Documented and

ordinators - Building a Robust Structure for the Future *(Recommendations: 9)*	unstable before substantive arrangements are in place. • Difficulty in dis-associating donor and recipient co-ordinator activities. • Anxiety and lack of support towards the proposals from DTCs and/or the hospitals. • Poor retention of existing, and recruitment of new, DTCs.	Organisation.	other stakeholders. Consultation with Donor Transplant Co-ordinators and employers. Speedy implementation of recommendations. The development of clear Job Descriptions and roles that are achievable. This includes career pathways and sustainable work life balance. The establishment of robust management arrangements.	implemented plans that involve communication and consultation with Donor Transplant Co-ordinators and stakeholders. Progress with realistic, clear and fully costed plans. This will include a clear project plans with actions and timescales (see recommendations 1 & 2). This will include: • Clear accountabilities. • Regular reports to the Board and other committees. Turnover of existing DTCs at, or marginally above, existing rates. Positive feedback form staff attitude surveys.
Recommendation 9	Unmitigated Risk: LOW			
Organ Retrieval Teams- Building a Robust Structure for the Future *(Recommendations: 10)*	• Lack of adequate consensus for a national organ retrieval service.	• Organ Donation Organisation (ODO).	British Transplantation Society have been commissioned to develop recommendations for the optimum organ retrieval service to cater for 50% increase in organs.	Progress with realistic, clear and fully costed plans. This will include a clear project plans with actions and timescales (see

			Development of a clear commissioning framework between the ODO and providers.	recommendations 1 & 2). This will include: - Clear accountabilities. - Regular reports to the Board and other committees. Achievement of standards set by the commissioner for organ retrieval.
Recommendation 10	Unmitigated Risk: MEDIUM			
Training, Education and Continuing Educational Support - Improving the understanding of organ donation amongst healthcare professionals *(Recommendation:11)*	- No substantial risks identified.	- Organ Donation Organisation (ODO).		
Recommendation 11	Unmitigated Risk: LOW			
Honouring the Gift of Donation - Recognising and thanking the public for their commitment and support *(Recommendation: 12)*	- No substantial risks identified.	- Organ Donation Organisation (ODO).		
Recommendation 12	Unmitigated Risk: LOW			
Promoting Donation - Tackling Health Inequalities & Guidance for Coroners	- No substantial risks identified.	- Organ Donation Organisation (ODO).		

(Recommendation: 13 & 14)				
Recommendation 13	Unmitigated Risk: LOW			
Recommendation 14	Unmitigated Risk: LOW			

Appendix 1: Health Economics of Organ Transplantation

Objective: *In a resource limited healthcare system to understand the economic contribution that organ transplantation can make to improving health*

Key Messages:

- The review of literature on organ transplantation finds kidney, pancreas, liver, heart and lung transplantation to be a cost effective treatment for end-stage organ failure. The economic case for kidney transplantation is strong. This includes assurance that expansion of the donor programme will not erode cost effectiveness. The economic case for liver transplantation is again positive. However the economic case is, to a degree, dependant upon the cause of liver disease. The only organ where the economic case was marginal was lung.
- In general Quality Adjusted Life Years (QUALYs) were used as a means to determine to effectiveness, comparing figures to those generally used by the National Institute for Health and Clinical Excellence (NICE). QUALYs tend to underestimate the wider societal benefit of health initiatives, for example greater employment and economic contribution.
- The amount of economic evidence for organ transplantation was poor.
- When considering net costs these were dependant upon the cost of the alternative treatment.
    - For patients with ESRF, where the alternative is dialysis, kidney transplantation is very cost effective. Beyond the first year the costs of organ transplantation are much lower than dialysis.
    - For other organs, where the alternative is medical management, transplantation increases net costs.
    - In summary, the greater the number of kidneys transplanted will offset the costs of other organs for which there is only limited medical treatment.

Contents:

- Review of the Economic Literature surrounding Solid Organ Transplantation
- Net Costs of Transplantion - Assumptions

Appendix Prepared by: Department of Health, Economics, Statistical and Operational Research

Review of the Economic Literature surrounding Solid Organ Transplantation

Introduction

The transition of solid organ transplantation from an experimental procedure to an accepted mainstream treatment for end-stage organ failure has been a rapid one. As a treatment, transplantation is very costly but can also yield many benefits. In a healthcare system with finite resources, economics has an important roll to play in guiding the allocation of those resources to maximise benefits.

It is important to assess whether those benefits are realised at an acceptable cost or whether resources used on other treatments might yield similar benefits at a lower cost. This is the question to which cost-effectiveness ratios were designed to answer.

They relate the extra benefits and extra costs that a transplant yields over the default treatment option (which is usually medical management) on a per patient basis. Hence, they are often referred to as Incremental Cost-Effectiveness Ratios (ICERs). Measuring the extra benefits and costs associated with treatment would ideally involve examining the effects of the two treatments on two identical, representative people. In reality, this option is not available; most studies examine the cost and benefits of two groups of patients, one group that undergo transplantation and a second group who receive the default alternative. The average costs and benefits are then measured and the ICER is derived from this. This economic framework is utilised in the administration of the majority of developed healthcare systems for the appraisal of new technologies[17].

The National Institute for Health and Clinical Excellence (NICE) is an example of one such body. This role ensures that new technologies entering the system are not reducing efficiency the system by achieving benefits at too high a price.

The benefits of new technologies are measured either using the expected life years gained (ELG) or quality adjusted life years (QALYs) gained. These measures form the basis of the ICER – i.e. cost per QALY or cost per ELG. QALYs measure the quantity (mortality) and quality (morbidity) of life. Patients are asked to attach satisfaction to different health states and these preferences can be expressed on a scale of 0 (death) to 1 (full health). The questionnaire most often used is the European Quality of Life health profile instrument (EQ-5D) which was validated in the renal transplant population. The scores are used to weight the number of expected life years gained - 2 years at a health level rated at 0.5 amounts to one QALY.

Wider societal benefits are not entirely captured by this framework but would be captured by cost-benefit analysis. However assessing healthcare technologies based on cost-benefit analysis would not lead to a definite answer as the benefits of the intervention would have to be quantified in monetary terms. Employment benefits may well arise from transplantation compared with the alternative treatment, however quantifying these would be very difficult. Patients' wages prior to falling ill would be the obvious proxy for the benefits of employment however

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[17] The Pharmaceutical Benefit Advisory Committee (PBAC) in Australia, Canadian Coordinating Office for Health Technology Assessment (CCOHTA) and New Zealand's PHARMAC all use cost-effectiveness as a basis for evaluating new technologies.

the outcome of the analysis would be heavily biased according to the employment status of patients i.e. transplantation would yield large benefits if the sample group were all company directors but if they were unemployed the benefit would be very small.

Cost-effectiveness ratios on the other hand do not suffer from this lack of consistency. They lend themselves to the evaluation of one programme or treatment versus another and, due to the per patient units, are easy to compare very different treatments as Weinstein (2002) asserted: "Cost-effectiveness is intended to determine the most efficient or productive use of limited health resources, and it does not require that a monetary value of life and health be assessed".

Cost-effectiveness ratios, although more robust than cost-benefit analysis, is not an intrinsic characteristic of a technology. Different factors will affect the magnitude of the ratio. In transplantation, as well as the type of organ being transplanted, the patient profile, stage of organ failure and disease leading to transplant are also important. Therefore, cost-effectiveness studies can also throw up useful lessons for the allocation of resources.

This type of framework is unable to make predictions about overall resource use. Whilst cost-effectiveness ratios can inform decisions over whether or not the uptake of a technology is worthwhile on a per patient basis. The issue of the extra resources required to introduce or extend the use of that technology is a very different, but not unrelated analytical question. The latter requires some knowledge of the demand for treatments, the proportion of resource savings that can actually be realised and some idea of the transaction costs associated with service redesign.

For the reasons outlined above, the economic literature on transplantation focuses on the cost effectiveness of transplants for different organs, which factors can affect this ratio and by how much. This report is a review of that international literature, in the context of a proposed increase to the level of solid organ transplantation in the NHS. The report examines transplantation in the context of each organ and provides some discussion of the wider issues involved in transplantation.

Kidney

Total expenditure on renal services in England, as reported in the 2005/6 reference costs collection was £932 million. A significant proportion of this expenditure is on transplantation (almost 16%) although the alternative treatment, dialysis, accounts for 46% of expenditure (Table 1).

Table 1: Estimated Expenditure on Renal Services, 2005-06

Haemodialysis	£344 m.
Peritoneal dialysis	£86 m.
Transplant	£37 m.

Kidney donors	£2 m.
Post-transplant maintenance	£107 m.
Other renal inpatients	£118 m.
Nephrology outpatients	£71 m.
Non-Dialysis Drug Treatment	£167 m.
Total	**£932 m.**

Estimates of the relative cost-effectiveness of transplant compared with dialysis can help to assess whether this current distribution of funds is an efficient one. There are many international studies, which look into the cost-effectiveness of renal transplants, however the volume of UK based research is very limited.

Yen et al. (2004) is one of the most comprehensive studies into the cost-effectiveness of renal transplantation. The primary purpose of the study is actually to assess the cost-effectiveness of lifetime immunosuppressive coverage. They modelled expected costs and benefits for dialysed patients for 20 years after the point of transplantation. They collected costs taking the average Medicare payments (broadly analogous to the Payment by Results Tariff for the NHS) for a sample of patients receiving transplantation (26,880). The term ‘costs’ in this instance refers to costs to the healthcare system rather than to the provider, as what is being measured is the level of reimbursement for the provider per patient[18]. The study finds transplantation to be dominant over dialysis in cost-effectiveness terms – transplantation costs less than dialysis per patient and yields greater benefits. Table 2 shows the costs and benefits they associate with each course of action.

Table 2: Costs and benefits of kidney transplantation versus dialysis.

	Average Medicare Cost ($)	Benefit (QALY)	Net Cost ($)	Net Benefit (QALY)	ICER ($ per QALY)
Dialysis	530,746	5.4	530,746	5.4	98,286
No Treatment	0	0			

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[18] Evans and Kitzmann (1997) advocate this approach as it very difficult to directly measure costs of complex medical interventions. However, Medicare payments are known to be below cost and therefore may represent an underestimate of the cost to the provider.

Kidney Transplant	320,676	8.5	-210,070	3.1	-67,765
Dialysis	530,746	5.4			

Note: Costs are in 1995-9 prices.

Source: Machinicki et al (2006) pp. 64.

The study assumes that the cost of not providing treatment is zero as there would be no payment to the provider. Whilst this is consistent with the methodology adopted, the provider will incur the costs of death. However, this is only a minor flaw and quite separate from the result this paper is concerned with.

Given that transplantation compared with dialysis leads to a QALY gain, many studies only focus on the costs of transplantation compared with dialysis. The extent to which transplantation is less costly than dialysis differs between studies, but it is consistently estimated to save between 30 - 40% of the costs of dialysis. Table 3 shows the output of some of these studies. Lifetime costs for patients in the NHS are not readily identifiable.

Table 3: Lifetime costs of transplant versus dialysis.

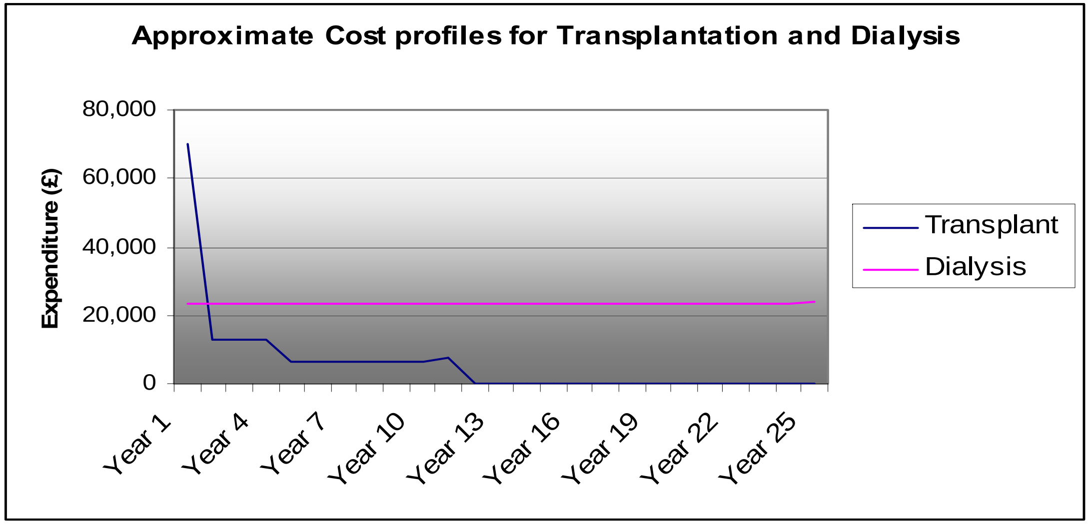
Country	Kidney Transplant Cost (£)	Dialysis Cost (£)	Difference (£)	Reference
US	260,106	430,498	170,391	Yen et al. (2004)
Canada	246,022	332,425	86,403	Whiting et al. (2004)
Germany	168,589	272,406	103,816	Roels et al. (2003)
Hungary*	86,036	133,646	47,609	Kalo et al. (2003)
Japan**	44,231	-	-	Nakajima et al. (2001)

Note: All costs are uplift and converted into 2005/6 prices in British Pounds.

* Denotes the first three years of transplant only. ** First two years post transplant.

As with many investment decisions in healthcare the cost is borne up front and the benefit is accrued at a later stage. Transplantation is no different. The costs of transplantation are very high in the first year of a patient's treatment but tail off dramatically thereafter, until a rise again for the costs of death. The costs of dialysis, on the other hand, do not vary so much between life years. A very approximate version of the cost profile for a dialysis and transplant patient is shown in Graph1.

Graph 1: Cost profile of Transplant versus Dialysis in 2006 prices.



Sources: 2005/6 Reference cost collection, Renal Registry 2005 and Yen et al. (2004). Kalo (2003) confirms that the cost of transplantation is lower then the cost of dialysis in 2 to 3 years.

The graph illustrates the net cost at the start of treatment (the triangle enclosed by the transplant and dialysis lines up to the intersection) and the net benefit (the area under the dialysis line minus the area under the transplant line after the intersection).

Jassal et al. (2003) study the cost-effectiveness of kidney transplantation in the elderly (over 65s) compared with continuing dialysis. A study, which given the current demographic background, has important implications. An implicit result of the study is that transplantation is no longer a dominant procedure. The life expectancy for an elderly patient receiving dialysis is around two years, which is similar to the life expectancy following transplant. The amount of QALYs gained is higher due to the increased quality of life. However, because the life expectancy has now been shortened the cost-saving stage has been eliminated (the cost profile has been reduced to 2 - 3 years). Conversely, their analysis highlights that the costs of transplantation are also reduced due to less active immune systems amongst the elderly and therefore a reduced need for expensive immunosuppression. The overall effect is that the lifetime costs of transplant over dialysis have gone from negative to around $60,000 per patient.

The results show that the cost-effectiveness of the intervention is very sensitive to the time the patient spends on the waiting list. Kidney transplants are cost-effective up to the age of 85 as long as there is no delay between the decision to treat and that they are treated through live donation. As the waiting time increases, the age at which transplantation is cost-effective, decreases. With a two year waiting list- 60 is the oldest at which a kidney transplant is still cost-effective. The authors admit that the study is likely to produce conservative estimates of the benefit of transplantation through the combination of the underestimation of the costs of dialysis, overestimation of the costs of transplantation and a pessimistic view of the complications likely to arise after transplantation.

Laupacis et al. (1996) studies the cost-effectiveness of transplant in ten different categories of patient in Canada including diabetics, over 60s, under 60s, cadaveric donors, functioning grafts and loss of grafts. They find that transplant is a cost-effective treatment in all types of patient. The most interesting result was that even failed grafts were deemed to be cost-effective due to the temporary increase in their state of health. This study emphasises the measurement of the benefits to the patient to the detriment of the measurement of the costs and therefore strict cost-effectiveness interpretations are not robust. However the statements it raises on benefits are valid.

Some studies include patient co-payments into their analysis in order to get a fuller appreciation of the costs involved. Co-payments are similar to a mandatory excess on a normal insurance policy in order to discourage over utilisation of services. Including these payments, Mutinga et al. (2005) and Hornberger et al. (1997) still find transplantation and retransplantation respectively cost-effective. Indeed Matas et al. (2004) include retransplantation as part of the assessment of the cost-effectiveness of kidney transplantation in general and find that it is still cost-effective.

Kidney Transplantation is found to be cost-effective compared with dialysis as a treatment for end-stage renal disease without exception in the established literature on the subject. However, studies based on data from the UK are notable by their absence. Whilst the amount of benefit derived from transplantation over dialysis is unlikely to be significantly different from those in the UK with the standardisation of clinical practise, the costs of treatment are likely to be a source of difference. Given the extent to which renal transplantation is a cost-effective treatment it is extremely unlikely that NHS specific factors would render it an inefficient alternative to dialysis.

Pancreas

Closely related to renal transplantation is the treatment of diabetes. Knoll and Nichol (2003) show that type 1 and 2 diabetes are the leading cause of end stage renal failure in the US. They model the decision options available to this group of patients that include dialysis, cadaveric or live kidney transplant, simultaneous kidney-pancreas transplant or pancreas transplant after a kidney transplant. They state that the essential trade-off between the types of pancreas transplant is one of resources. Separate transplants can be scheduled as elective operations and consequently some dialysis can be avoided. However there is a lower survival rate compared with simultaneous transplant. There is no firm consensus as to which treatment strategy is preferable over the other.

For these reasons, there are no explicit cost-effectiveness studies of pancreatic transplantation as the cost implications of the many permutations of treatment would render the conclusions very limited. Instead the literature, such as it is, focuses on the benefits derived from each strategy. Table 4 shows the results of Knoll and Nicholl's study in terms of the QALYs.

Table 4: Benefits derived from different treatment strategies for Type 1 diabetics with end stage renal failure.

	Life Expectancy (LY)	Δ LY	QALY	Δ QALY
Dialysis	7.82	-	4.52	-
Cadaveric Kidney Transplant	11.4	3.62	6.53	2.01
Simultaneous Pancreas-kidney Transplant	15.74	7.92	9.09	4.57
Pancreas after Kidney Transplant	17.21	9.39	10.00	5.48
Living Kidney Transplant	18.30	10.48	10.29	5.77

Source: Knoll and Nicholl (2003), pp.506, Table 3.

Setting aside cost considerations, living kidney transplant is the most preferable option although the results are not robust to a great degree. The authors conducted sensitivity analysis on the results and found that pancreas after kidney transplant would be the most favoured strategy amongst diabetic patients if the likelihood of severe metabolic complications was high[19].

No specific cost data on pancreatic transplants is collected by the NHS but given the high cost of dialysis and the fact that renal transplant is a dominant treatment it is unlikely to be non cost-effective.

Cost-effectiveness of Renal and Pancreatic Transplants

Renal transplants currently make up the minority of treatments encompassed in Renal Replacement Therapy (RRT) in the NHS. International evidence has consistently shown renal transplantation to be a cost-effective treatment and whilst the evidence from the UK is limited, the result is unlikely to change. Benefits will be similar across countries and costs vary between the international studies without the overall conclusion

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[19] The authors also assert that this is in agreement with the American Diabetes Association's stance on pancreas transplantation. In contrast, the NICE appraisal of Pancreatic Islet Cell Transplantation (2003) at the time regarded total Pancreas transplantation as an experimental procedure (http://guidance.nice.org.uk/IPG13).

changing anyway.

The studies that demonstrate the treatment’s cost-effectiveness in various different patient groups allay fears that with the expansion of transplantation to patients with less to gain from it will result in it becoming a non-cost-effective treatment at the margin.

Renal, and by association, pancreatic transplants are cost-effective treatments compared with the alternative and should continue to be so under a proposed increase the transplant rate.

Kidney and Pancreas transplantation treatments are different from the other solid organs that are considered in this report due to the nature of the alternative treatment. In the former the alternative treatment, dialysis, is very costly but for Liver, Heart and Lung the alternative treatment is medical management, which compared with transplant is low cost. Therefore, the cost considerations become much more important determinants of the cost-effectiveness ratio. For this reason a significant proportion of studies into these treatments focus solely on the costs and therefore are not full economic evaluations.

Liver

In contrast to the work done on renal there is a weight of evidence from the NHS concerned with liver transplants. There are two large studies that focus on the liver transplant programme in England and Wales (Longworth et al. (2003)). The first report focuses solely on the costs involved in the process of cadaveric liver transplantation and the results are utilised in the second, which examines the cost-effectiveness of liver transplant. The transplantation process was broken down into four phases; assessment (date of admission for assessment to date of listing), candidacy (date of listing to admission), transplant (admission to discharge) and post transplant (up to two years from discharge). The study found the transplant phase and in particular the inpatient stay to be the largest source of cost for the sample of 755 patients it included.

Table 5: Mean costs of liver transplantation in England and Wales in 2003 prices.

	Assessment	Candidacy	Transplant	Post-Transplant
Mean Total Cost (£)	6,148	4,770	30,635	17,797

They found that centre and indication leading to transplant were significant determinants of the variation in costs of the phases. As a result, the cost-effectiveness study looked at costs and benefits by disease group.

No randomised trials have been done in the UK with reference to liver transplantation and as a result, there is a lack of a control group in which the costs and benefits of medical management can be measured. To circumvent the problem only disease groups with published prognostic models were used, so that probable survival without transplant could be calculated using these models and the cost of patients on the waiting list was used to proxy for the costs of patients in the control group.

The disease groups used and the corresponding models were Primary Biliary Cirrhosis (PBC) - Hughes et al. (1992) and Christensen et al. (1985, 1993), Alcoholic Liver Disease (ALD) - Poynard et al. (1994, 1999) and Primary Sclerosing Cholangitis (PSC) - Dickson et al. (1992).

The study assesses both the cost-effectiveness of the intervention and of the wider programme in England and Wales. The difference being that in the first instance costs and benefits are measured from the point of transplantation and in the second they are measured from the point of listing.

Table 6: Cost-effectiveness ratios – cost per QALY in 2005/6 prices.

	PBC	**PSC**	**ALD**
24 months from transplant (£)	24,108	8,316	24,836
27 months from listing (£)	28,573	20,819	52,408

The results show that the liver transplant programme in general is cost-effective by NICE standards, although in the case of alcoholic liver disease the cost-effectiveness ratio is above the perceived threshold. Whilst the evidence may not be strong enough to exclude patients with alcoholic liver disease from receiving a liver transplant it should at least raise awareness of the efficiency implications that organ allocation policy may have in this area.

Agthoven et al. (2001) look into the costs and associated benefits derived from doing liver transplantation for acute and chronic liver failure in the Netherlands. They found that a liver transplant performed on a patient with acute liver failure was less expensive than transplantation performed on a patient with chronic liver failure. The difference, approximately €17,000, was due to higher hospitalisation rates, linked to higher survival, for chronic failure despite the higher immunosuppressant costs for acute liver failure. Through comparison of one year survival rates they find transplant of patient with chronic failure (which includes PSC and PBC) is more cost-effective than acute liver failure (in which they include ALD).

Virtually all of the studies around cost-effectiveness focus on the first few years of a transplant. The rationale for this is that it is a much more realistic timescale for a study and that data on survival after many years shows little change. In short, the accuracy gained by significantly increasing the observation period is outweighed by the extra time needed to complete the study. It is also assumed in many of the studies that a patient on the list incurs the same costs as a patient not on the list (a separate adjustment is made for death). There is a general consensus that the difference in costs is not significant enough to affect the outcome of a cost-effectiveness study.

As well as the differences between disease groups, some studies look at the cost-effectiveness of extending donation from cadaveric to live also. A recent NICE technology appraisal has approved the use of living donation for those adult patients whose condition is deteriorating significantly whilst waiting for a cadaveric donation.

Living donor transplantation has surfaced as a way to overcome the problem of limited supply of cadaveric livers and therefore the related problem of waiting times for organs. Studies in the US and Switzerland have looked at the cost-effectiveness of this treatment.

Sarasin et al. (2001) looks at the impact of introducing living donation into the transplant programme. They found that the costs of living donation were significantly higher than cadaveric transplantation due to the extra operation on a living patient. This gain could be outweighed by the reduction in waiting time. Living donation before 6 months was only cost-effective under the most favourable conditions, specifically a drop out rate of 4% or higher or a five year survival rate of 80% or higher. After 12 months, the gain ranged between zero and almost three life years.

Sarasin et al. (2001) produce three guidelines for the introduction of living donation in order to ensure that it represents a genuine productive gain. The waiting list should be sufficiently long in order to realise gains and the option of going to another centre with a shorter waiting time should be fully explored. The survival rate at 5 years should be sufficiently high in order to justify the extra cost compared with cadaveric transplant. Thirdly, the probability of developing contraindications should be sufficiently high, in their analysis if this probability is as low as 2% this has a dramatic affect on the benefits obtained by living donation.

Russo and Brown (2003) are similarly cautious about the additional cost and benefits of live donation as opposed to cadaveric and cite the need for greater accuracy and consideration of what should be included in costing the alternatives. This conclusion is supported by Trotter et al (2003) who find the costs of living donation 21% higher than cadaveric but are unable to prove this difference significant. The only European study, Sagmeister et al. (2002), finds both cadaveric and living donation to be cost-effective treatments although this study does not include the significant costs of living donor complications and the benefits attributed are higher than in other studies so the results are of limited value.

Cost-effectiveness of Liver Transplants

The studies on liver transplant to date focus on the cost and benefits accrued in the first few years of a transplant. Whilst this is a limitation of the studies it is unlikely to significantly affect the ICERs calculated. It is clear that different disease groups will have a bearing on the costs and benefits of transplantation. So far this has only been examined for a few groups of diseases which by no means reflects the rich case mix in the NHS.

The research to date has been cautious over the introduction of living donation and there may be a need here for a strategic approach to its introduction in order to ensure that it increases efficiency.

Liver transplantation in general has been shown to be cost-effective in the UK and in other developed healthcare systems. Although the management of the programme's expansion must be carefully managed to ensure that it continues to be cost-effective.

Heart

Even in the context of solid organ transplantation, the costs and benefits derived from heart transplantation are very high. However, there is comparatively little published work on the cost-effectiveness of heart transplant compared with the alternative, medical management. One reason for this may be that there are a plethora of drugs and treatments for heart failure involving different costs and therefore different benefits.

Ouwens et al. (2003) estimates the benefit of heart transplant to be 6.8 QALYs at a cost of around $529,000 more than medical management. The cost-effectiveness ratio was calculated to be $46,000 per QALY. Most studies are agreed that the costs are way above that of kidney transplant in both the inpatient phase and the maintenance phase. Table 7 shows a survey of these costs.

Table 7: The costs of Heart Transplantation.

Source	Cost	Unit	Country	Prices
Milliman Consultants[20]	$391,800	Procedure Costs	US	2002
Ouwens et al.	$73,100	First Year	Netherlands	1992
King et al.	$391,000	First Year Costs	US	2005
Ouwens et al.	$12,300	Inpatient Episode	Netherlands	1992
Reference Costs	£34,597	Inpatient Episode – E02	England	2005/6
Ouwens et al.	$24,200	Maintenance per annum	Netherlands	1992
Milliman Consultants[21]	$35,000	Maintenance per annum	US	2002
Weintraub	$21,000	Maintenance per annum	US	2002

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[20] http://www.milliman.com/pubs/Healthcare/content/research_reports/US-Organ-Tissue-Transplant-2002-RR.pdf

[21] Quoted in Machnicki et al. (2006).

King et al.	$21,200	Maintenance per annum	US	2005

The Dutch costs appear to be considerably lower than those in the US. The extra lifetime costs of heart transplantation compared with medical management implied by the work in the US is just over $570,000 whereas the extra lifetime costs of heart transplantation implied by the Ouwens study are $430,000 both in 2005 prices[22]. Taking the higher US costs and the gain of 6.8 QALYs from transplantation from Ouwens, the cost-effectiveness ratio is not favourable despite heart transplant being seen as a cost-effective treatment in the US. This could be explained through higher costs in the US being associated with better outcomes; this serves to highlight the country specific factors associated with medical practise and therefore the danger of drawing detailed inference based on international evidence.

Cost-effectiveness of Heart Transplants

There is very little economic literature on heart transplants and much of it focuses solely on trying to quantify the costs associated with it. There are undoubted benefits to it however these are typically not estimated to be as large as the benefits from liver or kidney transplants.

The estimates that do exist show heart transplantation to be a cost-effective treatment. However, the small amount of evidence that has been gathered to date and the improvement in drugs to medically manage heart failure both serve as notes of caution over the cost-effectiveness heart transplantation in the future.

Lung

Anyanwu et al. (2002) carried out a full economic evaluation on lung transplantation in the UK. They use four-year national survival data and extrapolate it to 15 years. Costs were assembled from a number of peer-reviewed sources both at the local and national level. Since the time of this study the introduction of Healthcare Resource Groups (including D01 – Lung Transplant and E01 – Heart and Lung Transplant) has meant that cost information on the inpatient stage of care has been nationalised and the quality has improved. Table 8 shows the costs used in the study compared with the latest reference cost collection.

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[22] This assumes an average inflation rate of 2.5% and that the annual costs of medical management are around $20k per annum. This is inline with data from Rich and Nease (1999).

Table 8: The costs of Lung transplantation in 2005/6 prices.

	Anyanwu		**Reference costs**	**Anyanwu**	**Reference costs**
	Single (£)	Double (£)	D01 – Lung (£)	Heart and Lung (£)	E01 - Heart and Lung (£)
Assessment	3,521	3,521		3,521	
Donor Acquisition	1,747	1,747		1,747	
Transplant costs	28,070	28,070		28,070	
Inpatient follow-up	5,620	5,377		6,322	
Lower Quartile			17,556		35,007
Upper Quartile			37,279		66,552
Total	**38,958**	**38,715**	**30,578**	**39,660**	**55,864**

Note: The reference cost figures are activity weighted averages of the elective and non-elective unit costs including excess bed days as this is likely to include a lot of the inpatient follow up.

The table shows that the costs used in the analysis are slightly higher than the range published in the 2005/6 reference costs in the case of lung transplant and lower than the mean in the case of heart and lung transplant. This is unsurprising given the small difference in costs that have been attributed to the different treatments despite the intuitive differences in resource use. This limitation will make single lung and double lung transplantation appear less cost-effective than they are and heart and lung appear more cost-effective than it is.

The study finds the cost per QALY for single lung, double lung and heart and lung transplantation as £29,415, £20,002 and £17,856. Single lung transplantation is therefore on the cusp of the cost-effectiveness threshold although as discussed, this is likely to be an overestimate and the other two treatments are found to be very cost-effective. They find that the results are very sensitive to the cost of follow up, for example transplant maintenance.

There is a large volume of work from the Netherlands on the question of the cost-effectiveness of Lung transplantation. This interest originated from the Dutch Health Care Insurance Board's decision to launch a comprehensive Medical Technology Assessment into the treatment in 1990.

A large element of this investigation was the cost-effectiveness aspect. They found the large benefits to be had but also the large cost implications particularly when compared with the technology assessments that have been done on liver and heart previously. Ouwens therefore replicates the assessment to further consider the relative cost-effectiveness of lung transplant. Table 9 shows the comparison of the original assessment and Ouwens' later study.

Table 9: Comparison of the cost-effectiveness of Liver, Heart and Lung transplant.

	DHCIB	Ouwens	
	ICER ($)	QALY gain	ICER ($)
Liver	25,600	11.5	31,000
Heart	36,900	6.8	46,000
Lung	61,000	5.2	61,000

The results are approximately comparable with that of Anyanwu et al. (2002). Maiwenn et al. (1998), also set in the Netherlands, also find a high ICER around £54,000 per QALY in 1992 prices.

There are a number of reasons for the less favourable ratio in the case of lung transplant, they fall into two categories low survival gain i.e. a low QALY gain and high follow-up costs.

The survival gain in lung transplant patients is partly explained by the high probability of developing complications. This was the focus of Sharples et al. (2000) study on clinical events after transplantation. The common occurrence of bronchiolitis obliterans syndrome was a major proportion of costs (57%). The cost pressure associated with new immunosuppressant drugs, a pressure which exists for all forms of transplant, was highlighted powerfully. They cite the example of replacing mycophenolate mofetil for azathioprine which would increase five year costs by 26%. The Anyanwu and Ouwens studies look at costs up to 15 years and the full lifetime respectively so they do include these factors. The poor comparative survival is influenced by the length survival of the control group - the average life expectancy of the control group in the Ouwens study is 3 years, far above the control groups of liver and heart (1.9 and 1.4 respectively). Indeed, the NICE guidance on living donor lung transplantation recommends the procedure be carried out on end-stage lung disease patients with a life expectancy of less than a year.

Cost-effectiveness of Lung Transplants

The published evidence from the UK shows lung transplantation to be on the edge of cost-effectiveness. Double lung and combined heart and lung transplants are more cost-effective owing to a greater QALY gain (3, 4.6 and 5.2 respectively).

There are significant threats to the cost-effective status of lung transplant including the cost of immunosuppressive drugs and the benefits that are accrued from the medical management of organ failure. Both of these factors are likely to vary in the future and therefore it will be necessary to monitor the effects on the incremental costs and benefits.

Other Economic Benefits of Transplantation

The cost-effectiveness framework utilised in the literature and reported here does not explicitly account for the effects on employment that result from transplantation. As Gold et al. (1996) asserted (and later echoed by Machinicki (2006)) QALYs do encompass some measure of productivity. A health state that allows the possibility to work will always be rated higher than a health state that does not. Therefore including some consideration of the cost reductions (from a societal perspective) and the productivity gains in a single ratio would lead to double counting.

There are undoubted employment gains, certainly in the case of renal, associated with transplantation. Quantifying the gain to society in monetary terms is riddled with difficulties and consequently there is very little in the published literature. Laupacis et al. (1996) attempt to measure the employment outcomes in Canada after renal transplant. They found that the employment rate (part and full time) amongst patients increased from 30% prior to transplant to 45% two years after. The employment rate was higher in patients with a functioning graft (51%) compared with failed grafts (21%).

Organ Supply

Organ supply is outstripped by demand in all the solid organ areas considered by this report, the manifestation of this are waiting lists. In this way, supply caps the resources that are devoted to transplantation.

There have been few economic evaluations looking at an increase in supply of organs but those that have been done focus on the supply of kidneys. Economic evaluations of the Donor action Foundation and expanded criteria donors have found them to be an economically sound activity. The approaches differ in methodology but essentially relate the benefit that can be accrued from an extra organ to the cost and activity required to get it. No such studies have been attempted in the UK so far.

Buxton (1997) provides a note of caution against large increases in the supply of organs. One characteristic of the current relation between supply and demand is that organs are able to be allocated to the best matches. If there is an exogenous increase in supply then the costs and benefits of transplantation will rely heavily on eligibility criteria. This is linked to the overall cost of transplantation being currently capped by supply. Therefore, there is a need for these criteria to be well defined before such an increase comes into effect.

Pharmacoeconomics

The effect of immunosuppressants on both the cost-effectiveness and overall cost of transplantation is very significant. As already discussed in the case of lung transplant the introduction of new immunosuppressive drugs can have a negative effect on the cost-effectiveness of a treatment. Machnicki et al (2006) reviews some of the economic evaluations of immunosuppressive drugs and finds that they vary widely in the quality and size of the studies. In a cash-limited system the influx of new, more expensive drugs, must be carefully monitored in order to ensure that older, more cost-effective treatments, are not abandoned. This is a point that has been recognised by the increase in bodies worldwide designed to carryout cost-effectiveness studies of new drugs but is worthy of particular attention in the case of transplantation where it is a very significant cost driver.

Organ Allocation

Equity of access is likely to be at the heart of the objectives of an organ allocation scheme. As with the allocation of all scarce resources there will be a trade-off between efficiency (i.e. the minimisation of cost-effectiveness ratios) and equity. A few studies have started to examine the equity implications of transplantation.

Mutinga et al. 2005 in particular looks at the implications of removing the HLA matching criteria in order to allocate kidneys more equally amongst ethnic minorities. They project a shift of 166 organs from Caucasians to minorities at a loss of 967 QALYs and a loss of $7.0 million. The benefits would be seen largely in the African American population with expected savings of $7.5 million and a gain of 243 QALYs. In total, they estimate that 649 QALYs would be lost at a saving rate of $5,400 per QALY lost. However, as the authors concede the most efficient way to improve equity would be to increase the donation rates amongst ethnic minorities.

Factors that affect ICERs

The literature reviewed in this report reflects the costs and benefits and therefore the cost-effectiveness of various types of solid organ transplantation at the time of the studies. Many refer to factors that may significantly affect the ratios that they have calculated; these can be split into generic factors associated with transplantation and organ specific ones. The organ specific ones are shown in table 10.

Table 10: Factors that affect ICERs of specific organ transplants.

Organ	Specific Factor	Study
Kidney and Pancreas	HLA – B antigen matching criteria. If this is not used in the allocation of organs then it raises the equity of the policy to the detriment of efficiency.	Mutinga (2005)
Liver	Disease group leading to transplantation. Significant differences have been found between acute and chronic liver disease and more specific disease groups.	Longworth (2003) and Agthoven (2001)

	Whether the donation is living or cadaveric. This is a factor in other organ types but is much more significant in liver as it has a large impact on both the costs and benefits.	Sarasin (2001), Sagmeister (2002), Russo & Brown (2003)
Heart	Country specific factors appear to have a bearing on costs and benefits. A more uniform picture may emerge from standardisation of practise.	Various.
Lung	Whether a single, double or heart and lung transplant is conducted.	Anyawu (2002)
	Survival under the alternative treatment regime. Medical management is comparatively more effective in lung transplant and so changes in the alternative are likely to significantly affect the cost-effectiveness of the treatment, more so than other organs.	Ouwens (2003)

The cost pressure associated with new immunosuppressants has already been discussed but there are other factors that will affect the ICERs. Many of the studies reviewed here are from countries with larger transplant programmes than the NHS currently runs. It is reasonable to assume that because the NHS is unable to exploit some of the economies of scale that larger programmes are able to and that there may be productive efficiency gains associated with a larger programmes that the ratios surveyed here may be aspirational with respect to the NHS. It may take a few years before the level of cost-effectiveness reported from other countries is obtained. Conversely because other countries transplant more people, at the margin there is less need and therefore less benefit to be gained from transplantation so the NHS could be more cost-effective than the studies from other countries.

The net impact of these two effects is unquantifiable in the general sense and so it remains to serve as a warning that the ratios contained in this report are a guide to the level of cost-effectiveness of these treatments.

Areas for further research

The volume of literature in the UK on the cost-effectiveness of transplantation is quite limited. The literature that does exist in the context of the NHS is concentrated on liver and lung transplantation. There is a need for ongoing work in certain areas.

A literature around the effects of an increase in supply and the various mechanisms that are available to do that and their impact, needs to be developed. It is a constant thread in the existing literature that policies to redistribute organs or increase the supply by relaxing matching criteria can have a very real effect on the benefits that the policy is designed to increase.

The production and availability of new drugs will have a significant and constant affect on the costs and benefits gained, now and in the future. Research that informs the introduction of these new drugs on a systematic basis will be key to ensuring that transplantation does not become a source of inefficiency for the NHS.

This report has been concerned with incremental costs and benefits at a ‘per patient’ level. There is need for a detailed and systematic piece of work to determine the net cost/saving implied by increasing the rate of donation and transplantation in the NHS including the capital and administrative costs associated.

Conclusions

The international published literature on solid organ transplantation finds that kidney (and pancreas), liver, heart and lung transplantation are generally cost-effective treatments for end-stage organ failure. The cost-effectiveness of these treatments may vary and international results are not directly applicable to treatment in the UK. However, the benefits are significant.

It is always likely that there will be a certain degree of publication bias associated with proving a treatment either cost-effective or not. This may exist in the transplant literature however, the quality and extent of evidence provided in each study is generally high and so it is unlikely that the cost-effectiveness of the treatments has been overstated.

Many economic issues associated with transplantation are yet to be faced, the introduction of new drugs, the expansion of supply, the cost implications for the NHS and the eligibility of patients for transplantation are all issues that will continue to require thought in the future.

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Net Costs of Transplantion - Assumptions

This section lists the assumptions that the Net Cost of Transplantation Model uses. This is discussed in the Benefits and Net Costs of Transplantion Section of this Report. The economic model was developed by ESOR.

General

- Additional percentage of transplant patients replaced on alternative treatment: 0% for kidney, lung, liver and heart
- HM Discount Rate: 3.5%

Kidney

Median survival time for transplanted patients	13	From Dave Collett at UKT
Median survival time for patients listed for a transplant	11	From Dave Collett at UKT
Median survival time for patients on dialysis but not listed	4	Estimated from renal registry data
Additional "listed" dialysis patients in year	3000	Arbitrary figure. Does not affect the net cost.
Additional "unlisted" dialysis patients in year	3000	Arbitrary figure. Does not affect the net cost.
Cost of Transplant Surgery	£42,025	Walker et al.
Annual cost of follow up for Tx patients	£6,500	Roderick et al. (confirmed by reference costs)
Annual cost of dialysis	£23,177	Reference costs

Liver

Median survival time for transplanted patients	18	UKT (Collett et al. 2007)
Median survival time for patients on medical management	1.5	UKT (Collett et al. 2007)
Cost of assessment	£7,130	Longworth et al. (2003)
Cost of candidacy	£5,532	Longworth et al. (2003)
Cost of Transplant Surgery	£35,527	Longworth et al. (2003)
Cost of follow-up for first 2 years	£20,639	Longworth et al. (2003)
Annual cost of follow up for 3rd & subsequent years	£4,000	Walker et al.
Additional number on medical management	1000	Arbitrary assumption. Does not affect the net cost
Annual cost of medical management	£18,179	Longworth et al. (2003)

Heart

Median survival time for transplanted patients	10	UKT (Collett et al. 2007)
Median survival time for patients on medical management	4	UKT (Collett et al. 2007)
Cost of first year	£100,000	Informed by NSCAG and Ref costs but mainly an assumption due to the poor quality of data out there.
Annual cost of follow up for Tx patients	£10,000	Survey of US literature

Cost of medical management	£18,179	Longworth et al. (2003) Note: this is assumed to be the same as liver medical management

Lung

Median survival time post transplant	5.5	UKT (Collett et al. 2007)
Median survival time on medical management	2	UKT (Collett et al. 2007)
Cost of first year post Tx	£130,000	Anyanwu et al.
Cost of follow up for Tx patients in year 2	£17,936	Anyanwu et al.
Cost of follow up for Tx patients in year 3	£7,130	Anyanwu et al.
Cost of follow up for Tx patients in year 4	£6,597	Anyanwu et al.
Annual cost in 5th & subsequent years	£3,685	Anyanwu et al.
Cost of medical management in year 1	£15,320	Anyanwu et al.
Cost of medical management in year 2	£11,102	Anyanwu et al.
Annual cost in 3rd & subsequent years	£7,775	Anyanwu et al.

Appendix 2: UK Demographics and Impact on the Need for Organ Transplantation

Objective : *To understand future demographic pressures on organ donation.*

Key Messages:

- The percentage of ethnic minorities in the UK is likely to increase. Given the traditionally lower rate of donation and high demand this is likely to raise the importance of addressing health inequalities.
- The size of the population in the UK is expected to increase. This is likely to increase the pressure on both the supply and demand for organ transplantation. This will put additional pressure on organ donation resources.
- Health related drivers differ from organ to organ. Specifically:
    - *Kidney*. ESRF, and by implication the need for kidney transplantation, is likely to increase at a rate of 2% a year.
    - *Pancreas*. The key driver is Type 1 diabetes. This has increased substantially over the past 10-20 years and looks set to continue.
    - *Heart*. The key driver is dilated cardiomyopathy. Over the last 5 – 10 years the numbers have increased.
    - *Lung*. The main drivers are emphysema and cystic fibrosis. Although figures for emphysema are not clear, hospital admissions for cystic fibrosis have trebled over the last ten years.
    - *Liver.* Drivers here include alcoholic cirrhosis, post Hepatitis C cirrhosis and primary biliary cirrhosis. Alcohol and Hepatitis C related illness have increased substantially over the last 10-15 years. If this continues, particularly for Hepatitis C, this will have a substantial effect on the demand of liver transplantation.

Contents:

- Demographic Change and the Need for Transplantation

Appendix Prepared by: Department of Health, Economics, Statistical and Operational Research

Demographic Change and the Need for Transplantation

Introduction and approach

The purpose of this paper is to illustrate how the expected changes in the age, ethnic and health profile of the population over the next 10 to 20 years may influence the need for transplantation. The focus is on solid organ transplants in the UK, where it is generally accepted that the demand for transplantation outstrips the supply of suitable organs.

The presence of a supply constraint means the observed number of transplants is unlikely to be an accurate indicator of the true need for transplantation, and that factors such as demographic change, which would be expected to affect the need for transplantation, may not be associated with a change in the number of transplants performed. Importantly, this means that historical data on actual transplant activity cannot be assumed to provide meaningful information about the influence of past demographic changes on the need for transplantation. It is therefore inappropriate to estimate the likely influence of future demographic changes by extrapolating from historical data on the number of transplants performed.

An alternative to focusing on the number of transplants is to focus on the number of patients added to the transplant waiting list. Even for a supply-limited system, the number of patients added to the waiting list could be a meaningful indicator of the need for transplantation. However, the validity of this indicator is crucially dependent on the extent to which the decision of whether to add a patient to the list is itself influenced by the supply constraint.

Figure 1 shows that, for heart, lung, liver and kidney transplants, there is a close temporal association between the annual total for patients added to the waiting list and that for the number of transplants performed. Viewed in the context of a limited supply of suitable organs, this close association could be interpreted as evidence that in deciding whether to add a patient to the waiting list clinicians take account of the (limited) probability of a suitable organ becoming available. Such an interpretation is thought to be appropriate for liver, heart and lung transplants. But for kidneys, it is generally felt that the vast majority of patients who would benefit from a transplant are added to the transplant waiting list.

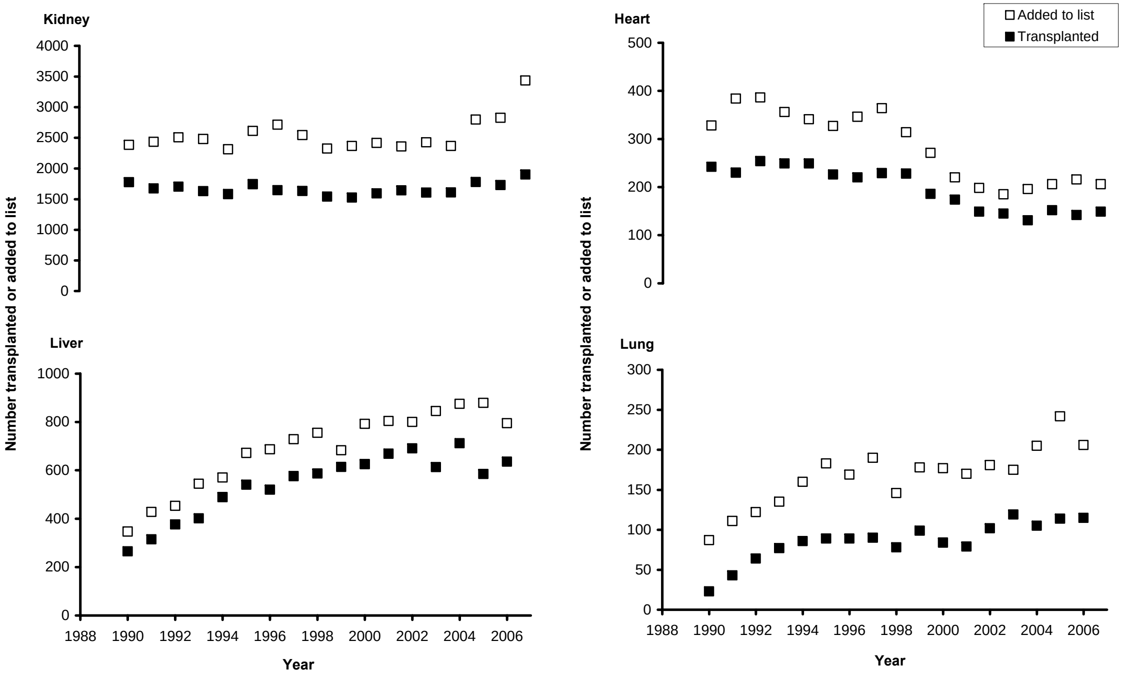

Figure 1. **Number of patients added to the waiting list (open symbols) and transplanted (closed symbols) each year (1990 to 2006; kidney, liver, heart and lung).**

The above arguments suggest that, for liver, heart and lung transplants, neither the number of transplants performed nor the number of patients added to the list is a valid indicator of the true need for transplantation. Historical data on the number of transplants performed or the number of patients added to the waiting list are therefore of limited value for estimating the influence of demographic change on the need for transplantation. There must however be such a true need, and the current level of transplant activity must be sufficient to meet this need *to some extent*.

The approach adopted in this paper is to identify the characteristics of current transplant recipients and estimate the likely future changes in the population distribution of these characteristics. Considering the relationship between demographic change and transplantation in this way puts the emphasis on the effect of demographic change in isolation. The focus is on attempting to quantify the theoretical change in need *due to demographic change alone.* Though the likely effect of demographic change on the supply of suitable organs is also considered, the aim is not to predict future transplant activity, or the likely future balance between the supply and demand for organs. Rather, it is to consider selected demographic drivers and illustrate how future changes in these drivers might influence both the need for transplantation and the supply of suitable donor organs.

Transplant activity since 1990

Though historical data on transplant activity may not provide useful information about the influence of past demographic changes, they do show the contribution of each organ to overall transplant activity and how this has changed over time. Considering these data therefore gives an idea of which organs are most likely to be most important as drivers of the overall need for transplantation.

Figure 2 shows transplant activity by organ for 1990 to 2006. The organs that currently contribute most to the overall level of activity are kidney and liver. Heart transplants have made a substantial contribution in the past but the level of activity has now decreased to the point where the contribution of heart transplants to the overall level of activity is low, as is that of lung transplants. The number of pancreas transplants is currently similar to that of heart or lung transplants. However there has been a substantial increase in pancreas activity over the last few years and it seems likely that the future contribution of this relatively new procedure to the overall level of transplant activity will be considerable. In contrast, the number of combined heart & lung transplants has declined to a very low level (there were just three in 2006). As this is thought to reflect changes in clinical practice (where those who would have received a combined heart & lung transplant in the past now typically receive a lung only transplant) rather than demographic changes, and the low level of activity observed in recent years makes it impossible to conduct a meaningful analysis of the characteristics of heart + lung transplant recipients, combined heart & lung transplants are not considered in the remainder of this paper.

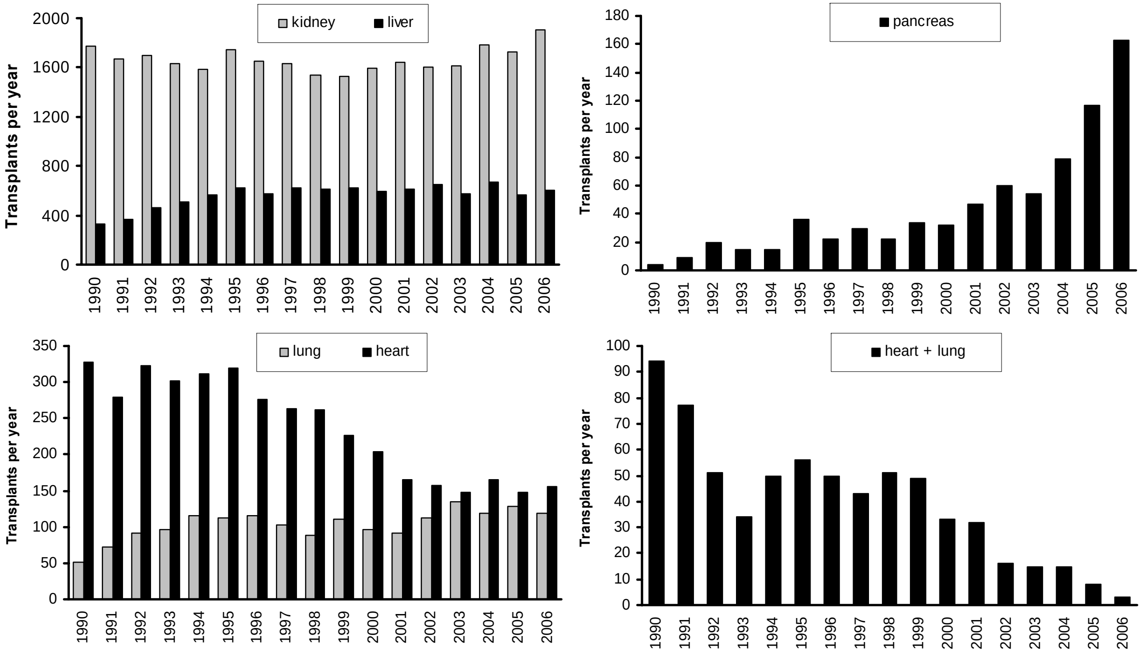

Figure 2. Number of kidney, liver, heart, lung, pancreas, and heart & lung transplants performed each year (UK, 1990 to 2006).

Potential drivers of the need for transplantation

1) Age

Figure 3 shows the age profile of transplant recipients. This figure compares the age profile of transplant recipients with that of the general population. If all transplant recipients had exactly the same age profile as the general population, the relative proportion would be 1 for all organs and all age bands. A relative proportion above 1 for a given age band indicates that people of that age are over-represented in the population of transplant recipients. Conversely, a relative proportion below 1 indicates that people of that age are under-represented in the population of transplant recipients. The only consistent observation from Figure 3 is that the relative proportion is low (for all organs) for those aged <25 or >65. For pancreas recipients, those aged 25 to 54 are over-represented; for kidney recipients, those aged 35 to 64 are over-represented; and for liver recipients, those aged 45 to 64 are over-represented.

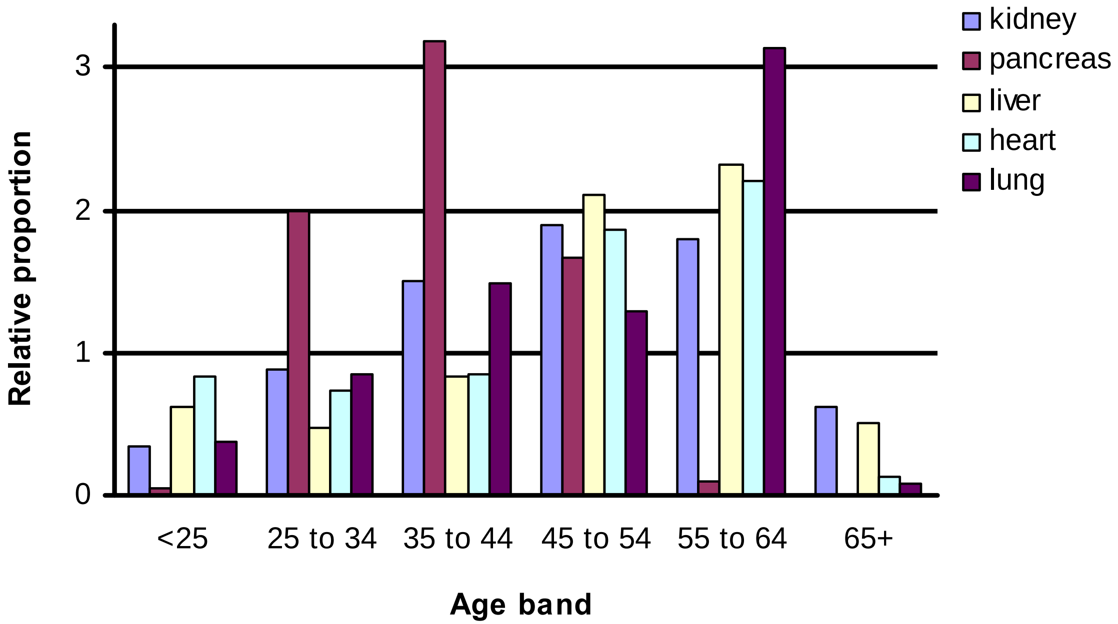

Figure 3. **Age profile of transplant recipients relative to that of the general population (see text for interpretation and Annex 1 for information on data sources).**

Figure 4 shows the age profile of the general population for 2005, and the projected profile for 2015 and 2025. The numbers for 2015 and 2025 are projections, based on a set of assumptions concerning the future patterns of fertility, mortality and migration. The error bars are included to give an indication of the uncertainty in these projections.[23]

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[23] The main bars show the values from the "principal" projection. The error bars show the highest and lowest values from the 12 "variant" projections. See Annex 1 for further information.

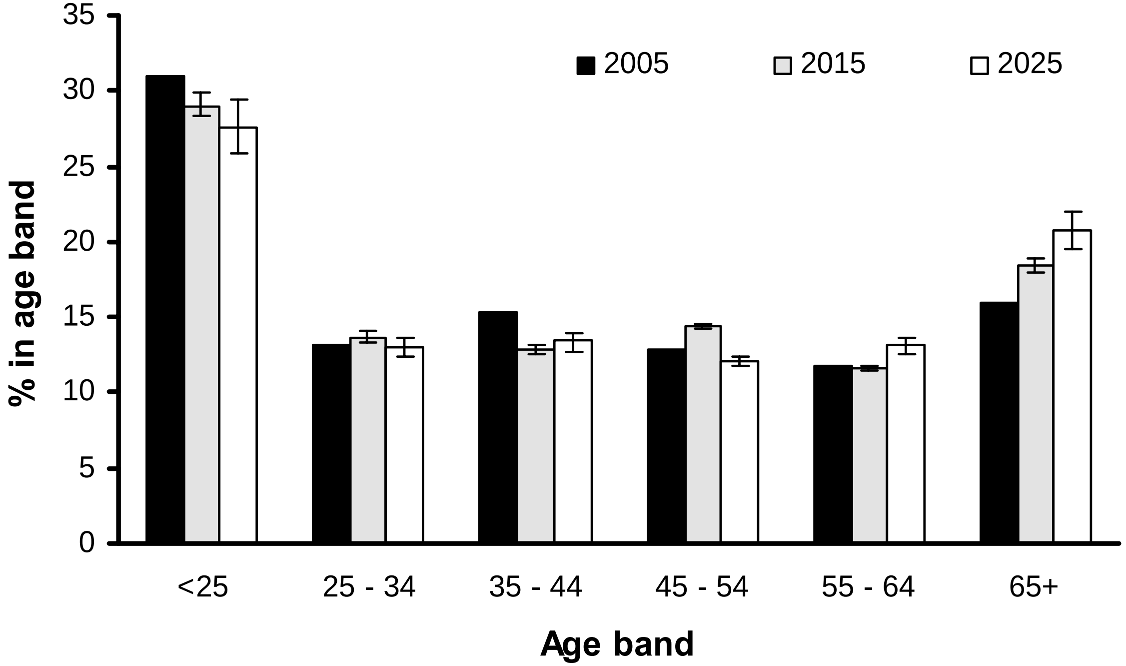

Figure 4. **Estimated age profile of the general population for 2005, 2015 and 2025.**

Considering the potential of future changes in the age profile of the general population to influence the need for transplantation involves interpreting the age profiles shown in figure 3 in the light of the projections shown in figure 4. The consistent observation from figure 3 was that those aged <25 or >64 are under-represented among transplant recipients. Figure 4 shows that the proportion aged <25 is expected to decrease, while the proportion aged >64 is expected to increase, from 2005 to 2025. These two changes will tend to cancel. Hence the net effect of changes in the proportion of the population aged <25 or >64 on the future need for transplantation is likely to be small. This trend for the proportion aged <25 to decrease and the population aged >64 to increase is the only clear trend that emerges from figure 4. There is a suggestion that the proportion aged 35 to 44 may decrease, and the proportion aged 55 to 64 may increase, from 2005 to 2025. However, the predicted changes are small for these age groups and the pattern of change is not consistent across the two intervals considered (2005 to 2015 and 2015 to 2025).

Figure 5 compares the age profile of kidney transplant recipients and the age profile of patients added to the kidney transplant waiting list with that of the general population. If both transplant recipients and waitlisted patients had exactly the same age profile as the general population the relative proportion would be 1 for both groups of patients across all age bands. A relative proportion above 1 for a given age band indicates that people of that age are over-represented in the population of transplant recipients or waitlisted patients, whereas a relative proportion below 1 indicates that people of that age are under-represented. The age profile of waitlisted patients is very similar to that of transplant recipients. Hence the observations that were made on figure 3 for transplanted patients (that those aged <25 or >65 are under-represented and those aged 35 to 64 are over-represented) apply equally to waitlisted patients.

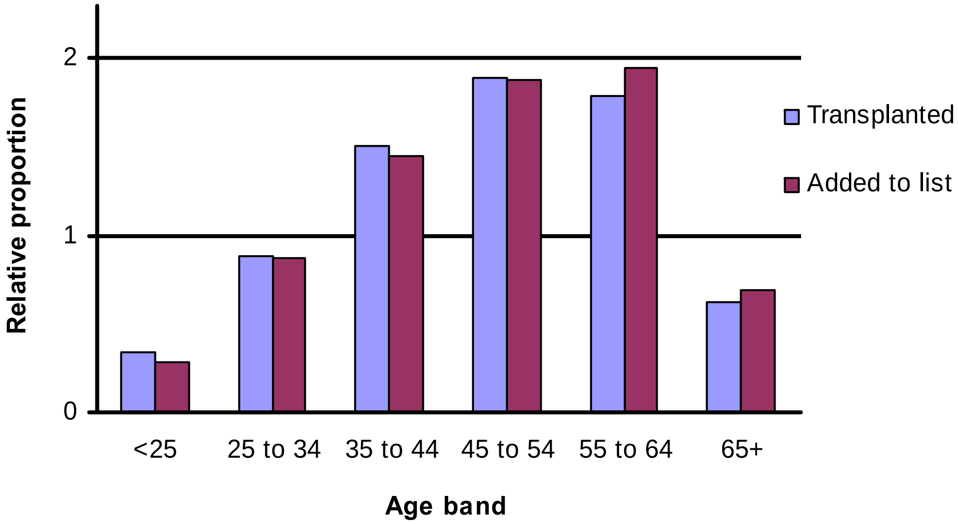

Figure 5. **Age profile of kidney transplant recipients and patients added to the kidney transplant waiting list relative to that of the general population.**

Figure 6 compares the age profile of donors with that of the general population, for deceased heartbeating, deceased non-heartbeating and living donors. If all donors had exactly the same age profile as the general population, the relative proportion would be 1 for all types of donor across all age bands. A relative proportion above 1 for a given age band indicates that people of that age are over-represented in the respective donor population, whereas a relative proportion below 1 indicates that people of that age are under-represented.

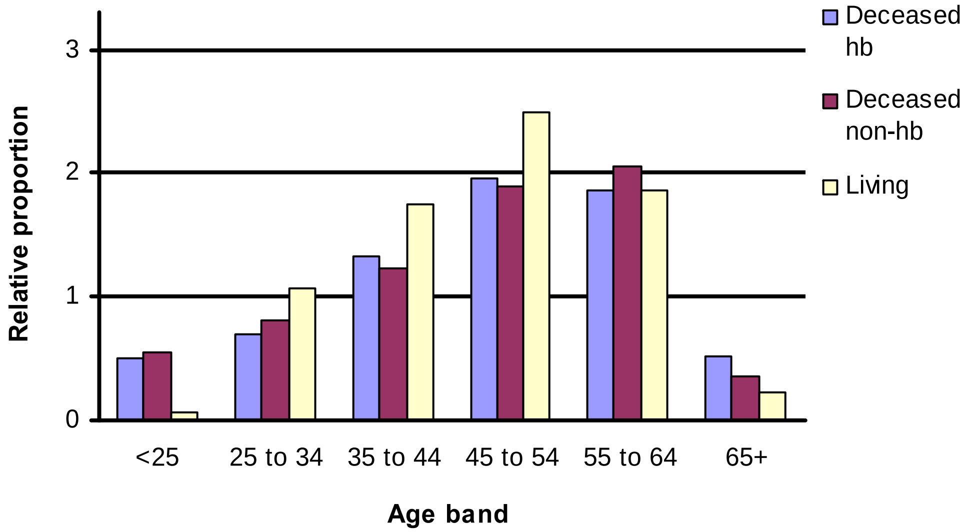

Figure 6. Age profile of solid organ donors relative to that of the general population, by type of donor.

The age profiles are broadly similar for the three types of donor. As is the case for transplant recipients, those aged <25 or >64 are under-represented among organ donors. This under-representation of those aged <25 or >64 is balanced by an over-representation of those aged 45 to 64, while for those aged 25 to 44 the donor population is broadly representative of the general population. These patterns are similar to those observed in both transplant recipients (figure 3) and patients listed for a kidney transplant (figure 5).

Figure 7 again compares the age profile of donors with that of the general population, but in this figure donors are grouped by whether they donate a given organ.[24] If all donors had exactly the same age profile as the general population, the relative proportion would be 1 for all age groups across all organs. A relative proportion above 1 for a given age band indicates that people of that age are over-represented in the respective donor population, whereas a relative proportion below 1 indicates that people of that age are under-represented.

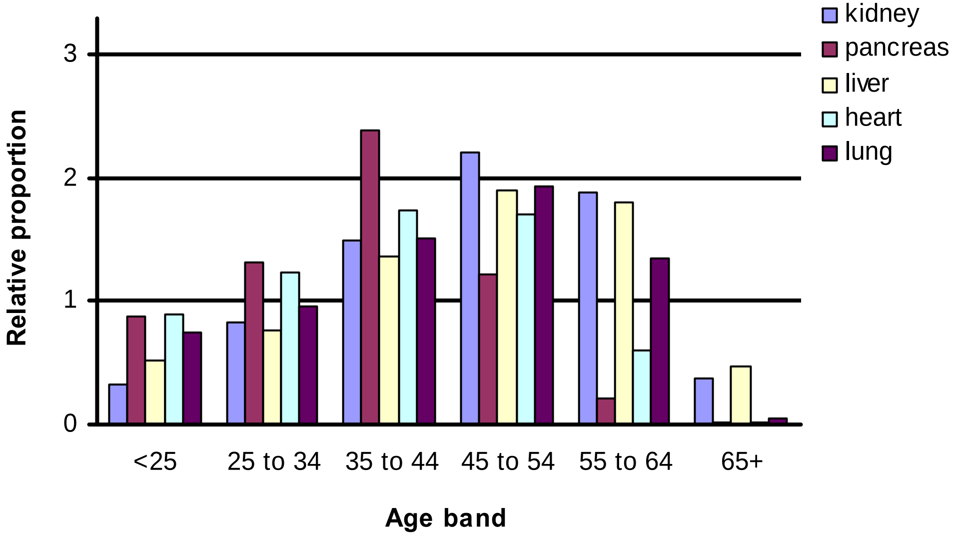

Figure 7. **Age profile of solid organ donors relative to that of the general population, by whether the donor donated a particular organ.**

The age profiles in figure 7 are similar to those for the corresponding organs shown for transplant recipients in figure 3. The implication of the age profile being similar for transplant recipients and organ donors is that the effect of future changes in the age profile of the population will be similar for both the need for transplantation and the potential supply of suitable organs. In both cases, the changes that are expected to occur in

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[24] Each deceased donor typically donated more than one organ. Hence the organ groups shown in figure 7 are not mutually exclusive.

the general population would have at most a minor impact because the increase in the proportion aged >64 would be counteracted by a decrease in the proportion aged <25.

2) Ethnicity

Figure 8 compares the ethnic profile of transplant recipients with that of the general population. If the profile was exactly the same for all transplant recipients as that of the general population, the relative proportion would be 1 for all organs and ethnic groups. A relative proportion above 1 for a given ethnic group indicates that people from that group are over-represented in the population of transplant recipients. Conversely, a relative proportion below 1 indicates that people from that group are under-represented in the population of transplant recipients.

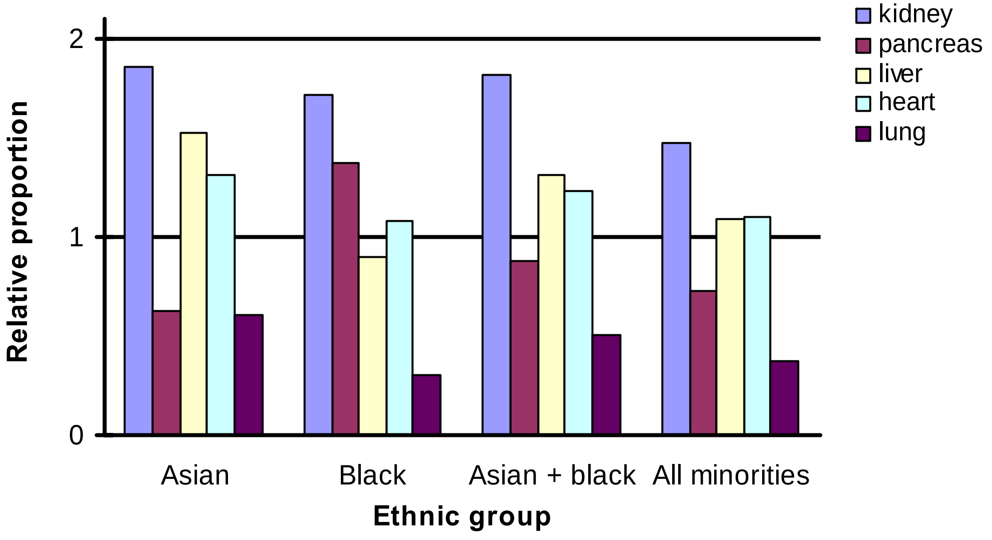

Figure 8. **Breakdown by ethnic group of transplant recipients relative to that of the general population (see text for interpretation and Annex 1 for information on data sources).**

For kidney recipients, both the Asian and black groups are over-represented, and this effect is reflected in the data for all ethnic minorities combined. In contrast, among recipients of a lung transplant, both the Asian and the black groups are under-represented. For the other organs the picture is less clear. There is a tendency for the Asian group to be over-represented among recipients of a liver or heart transplant and the black group to be over-represented among recipients of a pancreas transplant, but these effects are small relative to those observed for the black and Asian groups among kidney recipients.

Figure 9 shows the estimated size (as a proportion of the total population) of the Asian, black and Chinese ethnic groups, and of the total minority population, for 1991 to 2004.[25]

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[25] The ONS population projections do not consider ethnicity. Indeed, no national population projections by ethnic group currently exist for the UK. See Annex 1 for further information.

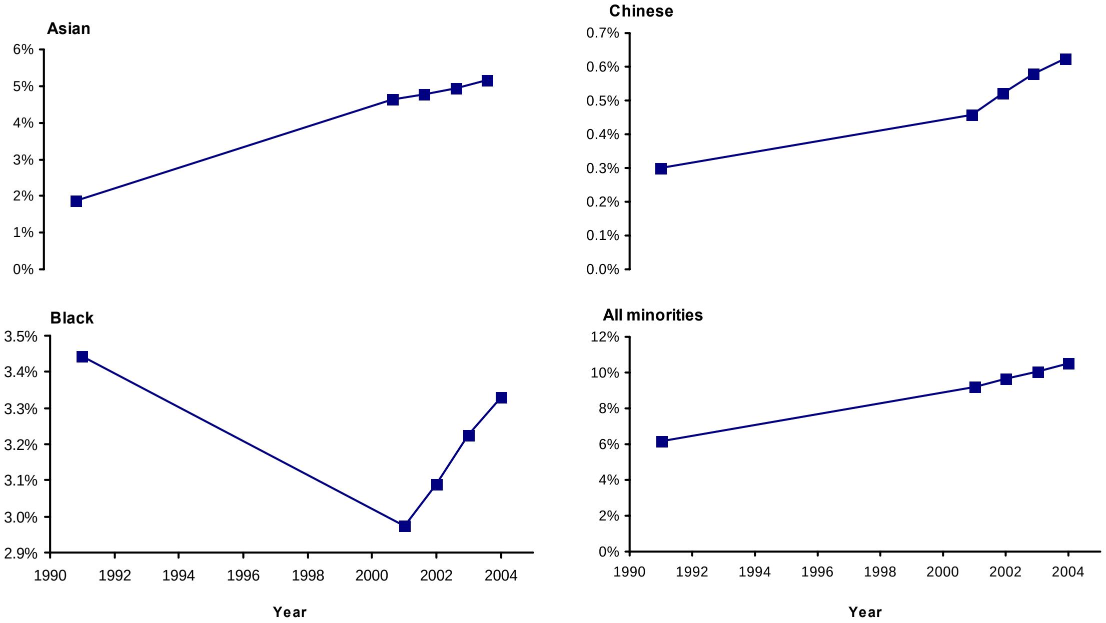

Figure 9. **Estimated size (as a proportion of the total population) of selected ethnic minority groups in England, 1991 to 2004.**

Using the data in figure 9 to make inferences about the likely future size of a given ethnic group is problematic. The data shown suggest that the overall size of the ethnic minority population has increased from 1991 to 2004, as has that of the Asian and Chinese groups. There is a suggestion that the size of the total minority population may have increased slightly faster after than before 2001. However, the data for 2001 onwards are from a different source to those for 1991 and the pattern seen in the total minority population is not seen in some of the larger component groups. Any trends in the mid-year estimates for 2001 to 2004 may simply reflect short term fluctuations in fertility, mortality or net migration. The annual level of migration has historically been particularly volatile and is a substantial component of the year-to-year change in the size of each ethnic group. It is clear from census data that the size of the total minority ethnic population increased between 1991 and 2001, and it seems likely that it is still increasing and will continue to increase over the subsequent decade. However, given the data currently available, it is not possible to quantify the likely future rate of increase.

Figure 9 suggests that the relative size of the Asian ethnic group is increasing, as is that of the total minority population. The Asian group is over-represented among the recipients of a kidney transplant, and to a lesser extent among recipients of a liver or heart transplant, while all ethnic minority groups are under-represented among lung transplant patients (see figure 8). If the trends shown in figure 9 continue into the future, this will lead to an increased need for kidney transplants, a slightly increased need for both liver and heart transplants, and a reduced need for lung transplants.

Figure 10 compares the ethnic profile of kidney transplant recipients and the ethnic profile of patients added to the kidney transplant waiting list with that of the general population. If both transplant recipients and waitlisted patients had exactly the same ethnic profile as the general population, the relative proportion would be 1 for both groups of patients across all ethnic groups. A relative proportion above 1 for a given group indicates that people from that group are over-represented in the population of transplant recipients or waitlisted patients, whereas a relative proportion below 1 indicates that people from that group are under-represented.

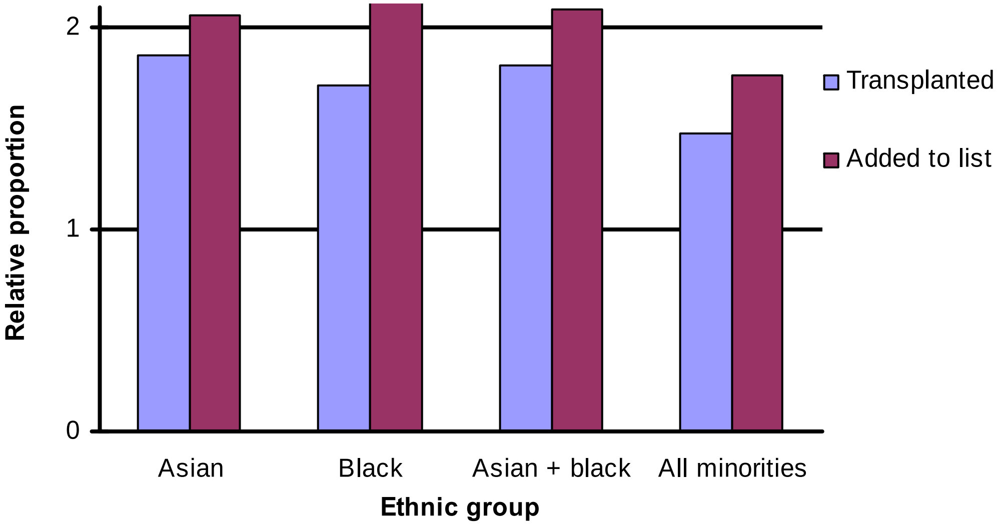

Figure 10. **Ethnic profile of kidney transplant recipients and patients added to the kidney transplant waiting list relative to that of the general population.**

The ethnic profile of waitlisted patients is similar to that of transplant recipients, but the extent to which the black and Asian groups are over-represented is greater for patients on the waiting list. The observations that were made on Figure 8 for transplanted patients (that the black and Asian groups are over-represented) are strengthened by the data in figure 10 on waitlisted patients.

Figure 11 compares the ethnic profile of donors with that of the general population, for deceased heartbeating, deceased non-heartbeating and living donors. If all donors had exactly the same ethnic profile as the general population, the relative proportion would be 1 for all types of donor across all ethnic groups. A relative proportion above 1 for a given group indicates that people from that group are over-represented in the respective donor population, whereas a relative proportion below 1 indicates that people from that group are under-represented.

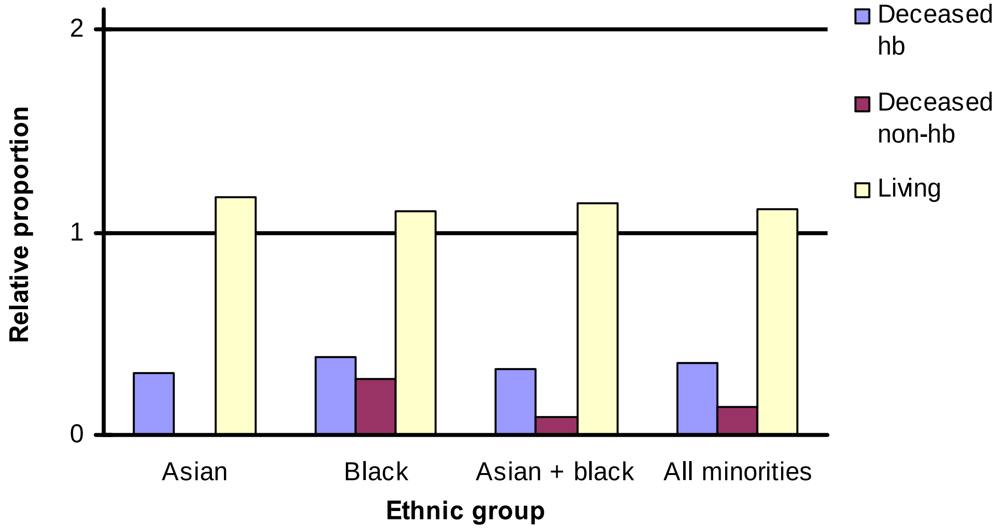

Figure 11. **Ethnic profile of solid organ donors relative to that of the general population, by type of donor.**

The above figure shows that ethnic minorities are substantially under-represented among deceased solid organ donors. The living donor population is broadly representative of the general population. However, the number of living donors is substantially smaller than the number of deceased donors. Hence the overall trend is for ethnic minorities to be under-represented among donors. This is a very different picture to that painted by figure 8, which shows that, with the exception of lung transplant recipients, at least one ethnic minority is over-represented among each group of transplant recipients.

Figure 12 again compares the ethnic profile of donors with that of the general population, but in this figure donors are grouped by whether they donate a given organ. If all donor populations had exactly the same ethnic profile as the general population, the relative proportion would be 1 for all ethnic groups across all organs. A relative proportion above 1 for a given ethnic group indicates that people from that group are over-represented in the respective donor population, whereas a relative proportion below 1 indicates that people from that group are under-represented.

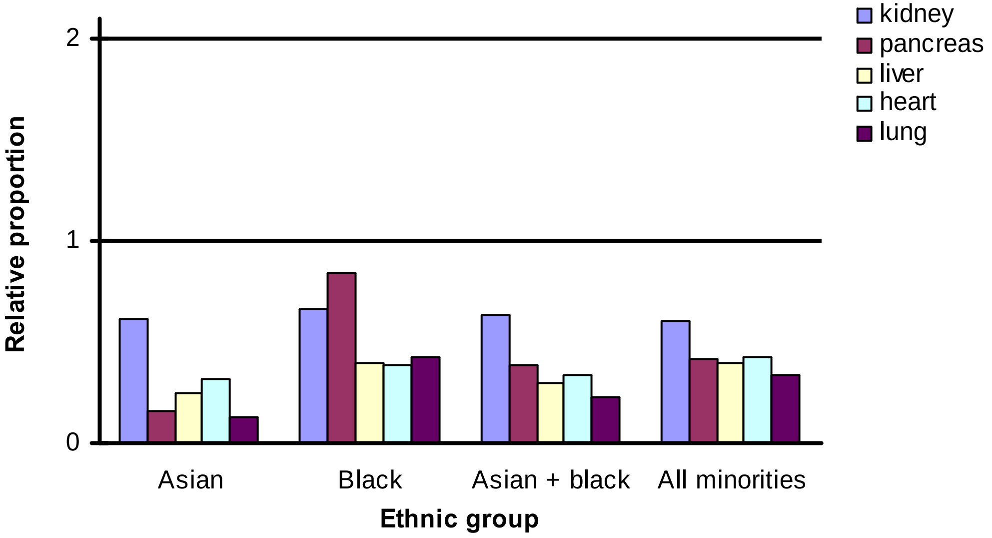

Figure 12. Ethnic profile of solid organ donors relative to that of the general population, by whether the donor donated a particular organ.

The ethnic profiles in figure 12 are very different to those shown in figure 8 for transplant recipients or figure 10 for waitlisted patients. Whereas ethnic minorities tend to be over-represented among transplant recipients or waitlisted patients, they are under-represented among the donor population. If the size of the ethnic minority population increases, that of the white majority population will decrease, and so will the potential supply of donor organs. Hence an increase in the size of the ethnic minority population would tend to increase the imbalance between the need for, and the potential supply of, donor organs. For example, suppose the trend shown in figure 9 for the size of the Asian population to increase continues into the future. This would lead to 1) an increased need for kidney transplants, and a slightly increased need for both liver and heart transplants (see commentary on figure 8), and 2) a reduced supply of suitable donor organs (see above).

3) Health-related drivers

Approximately 85% of patients added to the kidney transplant waiting list are already receiving renal replacement therapy (RRT) when they are added.[26] Trends in the take up of RRT are therefore of interest for estimating the likely future need for kidney transplants. Roderick et al. used a simulation model to estimate the likely future demand for RRT in England.[27] From a starting point in 2000, they predicted the average annual increase to 2010 in the take-on rate for RRT. In making these predictions, they attempted to account for the likely future changes in 1) the age and ethnic profile of the population and 2) the incidence of diabetes. With the level of transplant activity held constant at the 2000 level, their model predicted an annual increase of ~1% in the take-on rate for RRT. Including a 50% increase in the incidence of diabetes increased this estimate to 2% per year. Historical data from the Renal Registry suggest an actual increase of 8% from 2000 to 2004[28], or an average annual increase of ~2%. Thus Roderick et al.'s higher estimate of 2% for the average annual increase in the take-on rate for RRT is supported by the available data. If the proportion of incident RRT patients that are suitable for transplantation remains constant, this increase in RRT will translate to an equivalent increase in the need for kidney transplants.

Of the patients who received a pancreas transplant in the 3 year period from 2003 to 2005, 90% had a primary diagnosis of type 1 diabetes. Trends in the incidence or prevalence of type 1 diabetes are therefore of interest for estimating the likely future need for pancreas transplants. Recent findings from a study of 2.6 million people in the Oxford area show a five-fold increase in the prevalence of type 1 diabetes among

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[26] http://www.renalreg.com/Report%202005/chap-05.pdf

[27] Roderick P et al. Simulation model of renal replacement therapy: predicting future demand in England. Nephrol Dial Transplant 2004 19(3): 692-701.

[28] http://www.renalreg.com/Report%202005/chap-03.pdf

children aged <5, and a two-fold increase among children aged <15, from 1985 to 2004.[29] Though it remains to be confirmed that these findings are representative of the country as a whole, there are data showing a worldwide increase in the incidence of diabetes over the later part of the 20th century[30]. The general picture is of an increasing prevalence of type 1 diabetes, and therefore also of an increasing need for pancreas transplants.

The four most common diagnoses among liver transplant recipients are alcoholic cirrhosis, post hepatitis C cirrhosis, primary biliary cirrhosis (PBC) and sclerosing cholangitis. Figure 13 shows data from 1995 to 2005 on the number of hospital admissions for alcoholic cirrhosis, PBC and cholangitis. For PBC, the annual number of admissions has remained essentially constant from 1995 to 2005. However, for both alcoholic cirrhosis and cholangitis the number of admissions has increased over this period. For alcoholic cirrhosis, the rate of increase has been greater after than before 2001.

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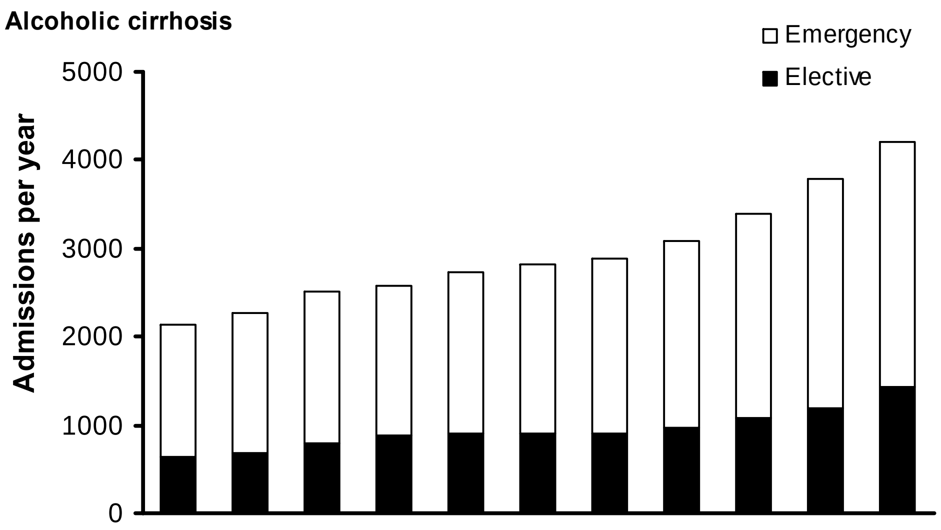
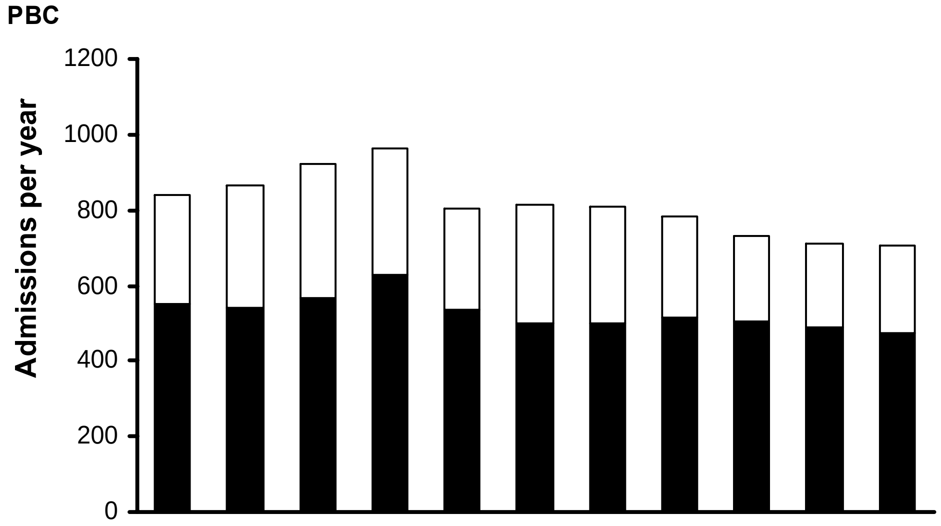
[29] See http://www.bristol.ac.uk/news/2007/5349.html

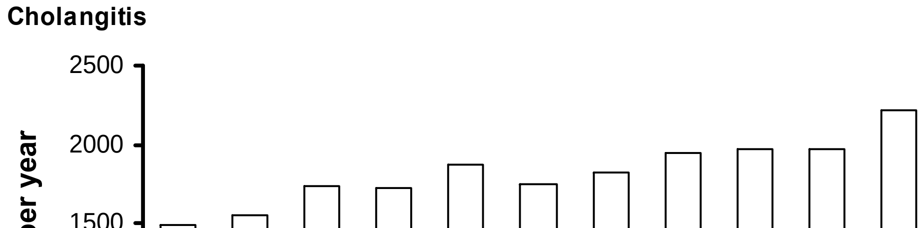
[30] Onkamo P et al. Worldwide increase in incidence of Type I diabetes: the analysis of the data on published incidence trends. Diabetologia (1999) 42: 1395-1403.



Alcoholic cirrhosis



PBC



Cholangitis

Figure 13. **Hospital admissions (emergency and elective) for alcoholic cirrhosis, PBC, and cholangitis (England, 1995 to 2005).**

Figure 14 shows data for 2001 to 2005 on the number of deaths for which the underlying cause was recorded as alcoholic cirrhosis, PBC or cholangitis.

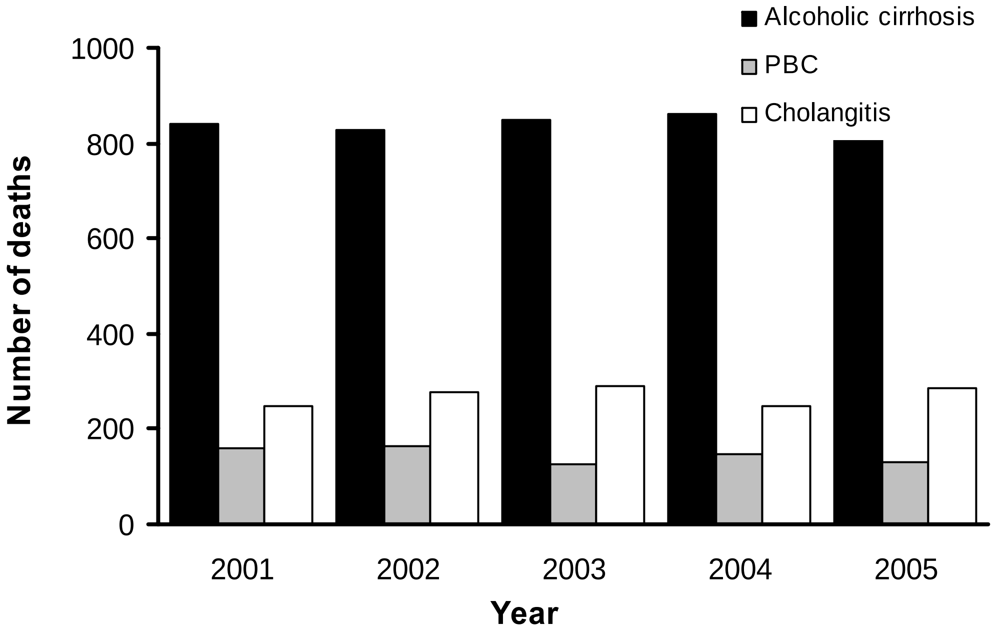


Figure 14. **Number of deaths with a recorded underlying cause of alcoholic cirrhosis, PBC, or cholangitis (England & Wales, 2001 to 2005).**

The mortality data in figure 14 do not show any clear patterns: the general picture is of an essentially constant number of deaths for each of the selected underlying causes. Investigation of a longer time series may be more informative, but would be complicated by the change from ICD-9 to ICD-10 coding that was implemented in 2001 (see Annex 1).

Figure 15 shows the annual number of alcohol-related deaths from 1991 to 2005.[31] The number of deaths has increased considerably over this period, in both males and females. These data are not specific. They do however suggest an increasing burden of alcohol-related disease.

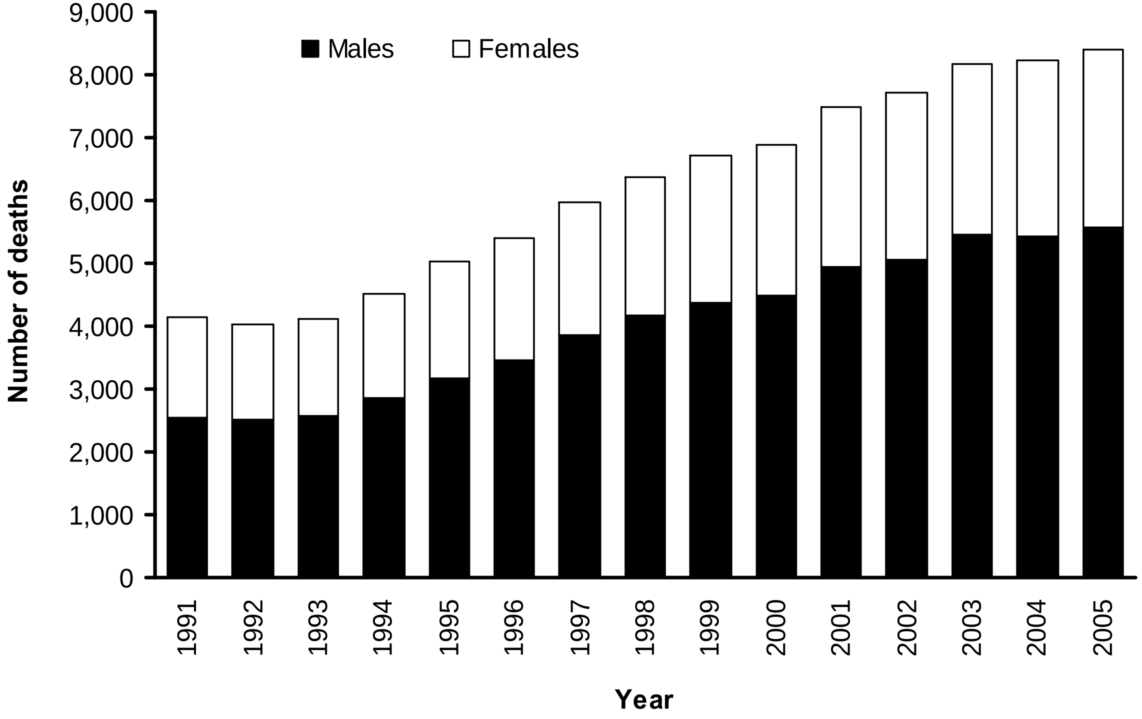


Figure 15. Annual number of alcohol-related deaths (UK, 1991-2005).

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[31] See http://www.statistics.gov.uk/CCI/nugget.asp?ID=1091&Pos=2&ColRank=1&Rank=192

Figure 16 shows data for 1993 to 2002 on the mean number of alcohol units consumed per week. The average amount of alcohol consumed has increased slightly over this 10 year period, but it is not clear from these data how alcohol consumption has changed in particular age groups.

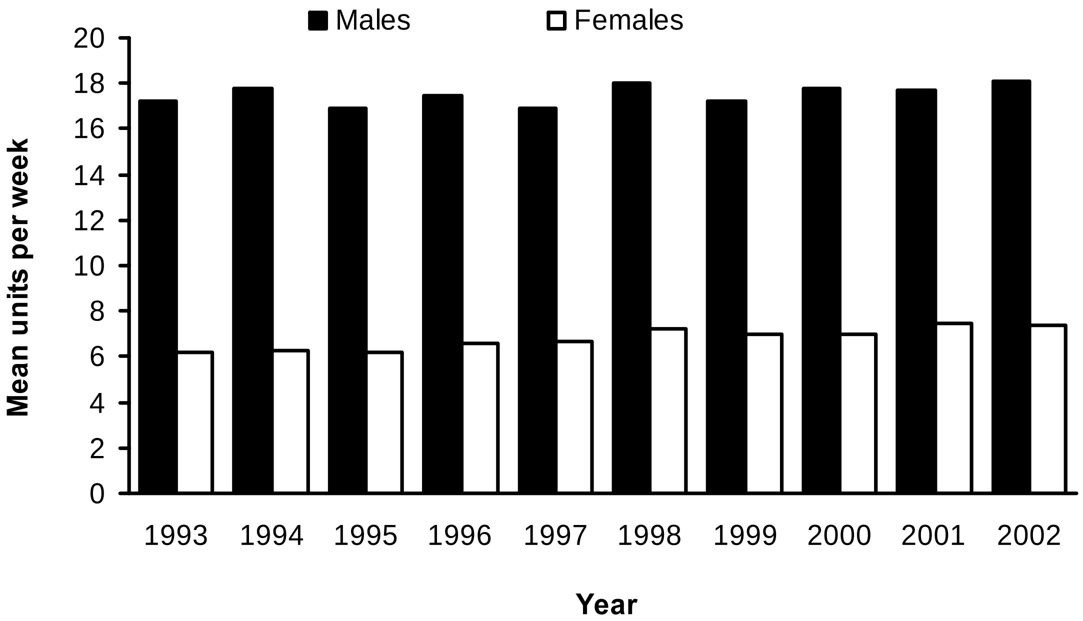

Figure 16. Mean number of alcohol units consumed (Health Survey for England, 1993 to 2002)

Figure 17 shows data, again for 1993 to 2002, on the proportion in each age group who drink more than the recommended upper limit of alcohol per week (21 units for females, 28 units for males). The proportion of the population who drink above this limit has remained essentially unchanged in most age groups, but in those aged 16-24 it has increased substantially. The general pattern is the same for males and females, but the increase observed in the 16-24 age group is particularly marked for females.

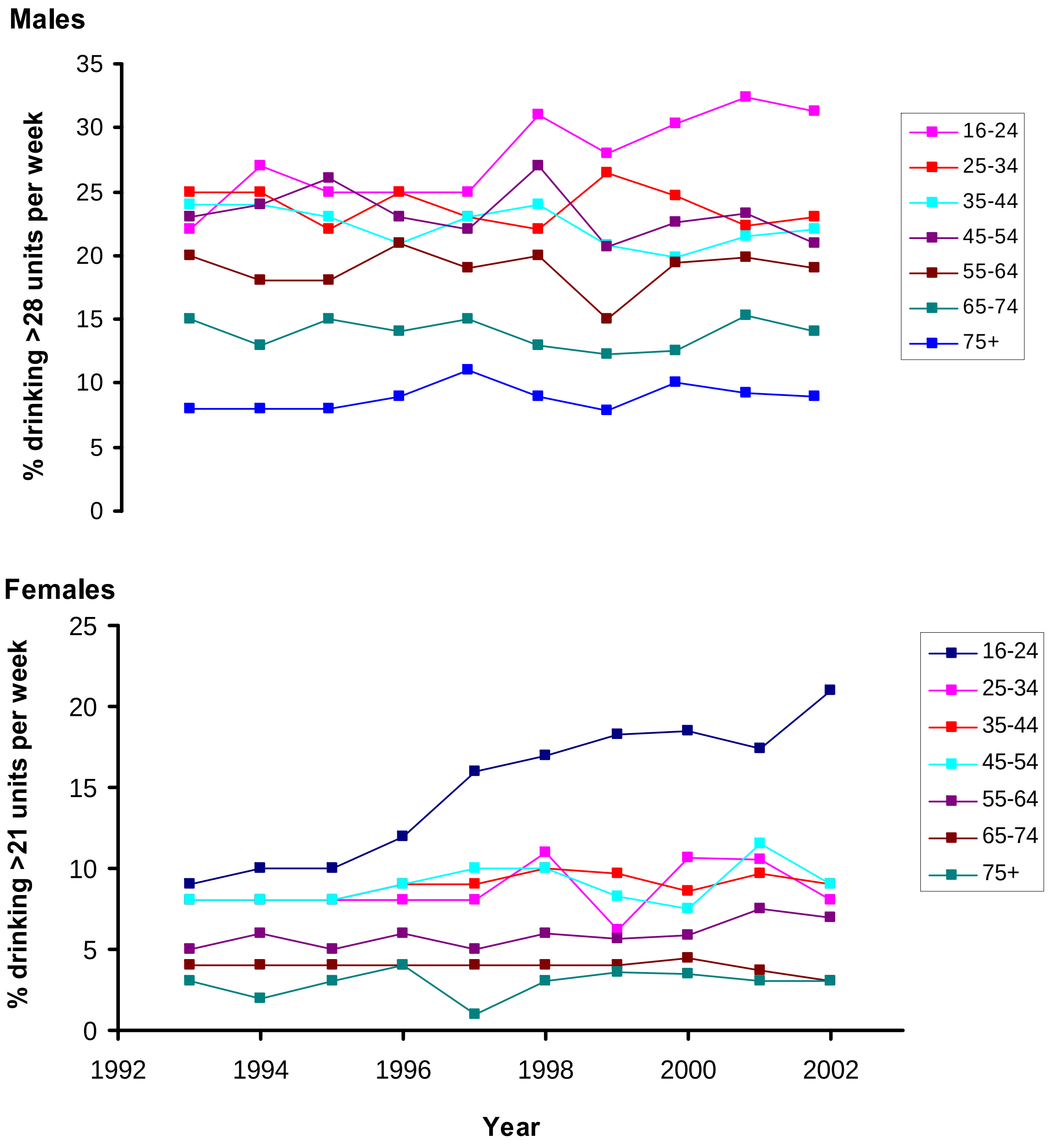
Males
% drinking >28 units per week
35
30
25
20
15
10
5
0
16-24
25-34
35-44
45-54
55-64
65-74
75+
Females
% drinking >21 units per week
25
20
15
10
5
0
1992
1994
1996
1998
2000
2002
Year
16-24
25-34
35-44
45-54
55-64
65-74
75+

Figure 17. Proportion by age drinking more than the recommended upper limit of alcohol per week (Health Survey for England, 1993 to 2002).

The epidemiology of hepatitis C is complex, and statistics on events such as hospital admissions or deaths do not necessarily capture the full burden of the disease. Modelling studies suggest, however, that the burden of Hepatitis C disease is increasing and will continue to increase for the foreseeable future (see Figure 18 below).

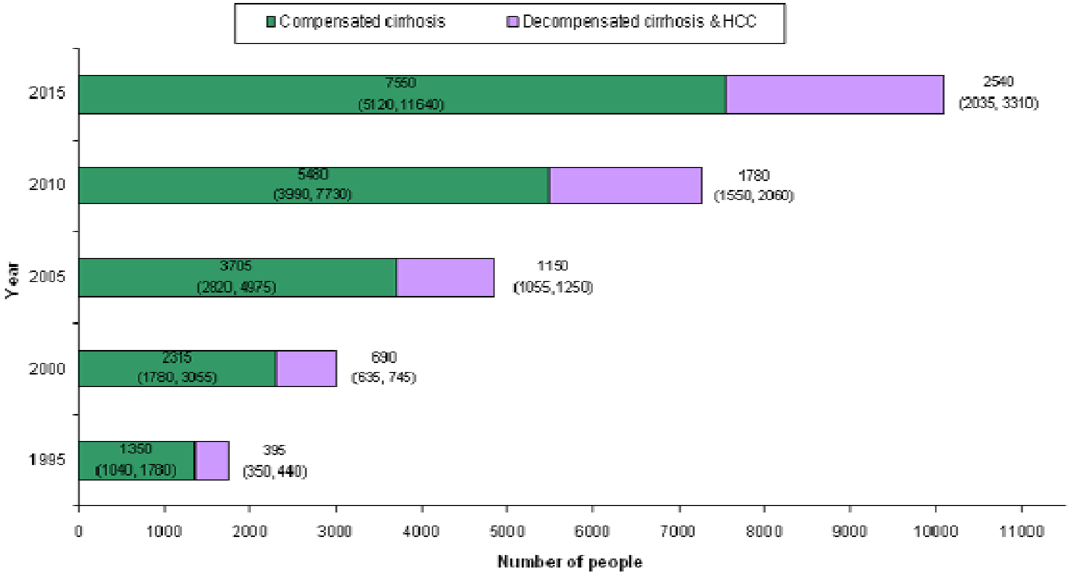

Figure 18. HPA estimates of the number of people living with HCV-related cirrhosis or decompensated cirrhosis / hepatocellular carcinoma (HCC) in England, 1995-2015.[32]

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[32] From http://www.hpa.org.uk/publications/2006/hepc_2006/Hepatitis_C2.pdf

The most common diagnosis among heart transplant recipients is dilated cardiomyopathy. Figure 19 shows data from 1995 to 2005 on the annual number of hospital admissions for dilated cardiomyopathy, which has increased progressively over this period.

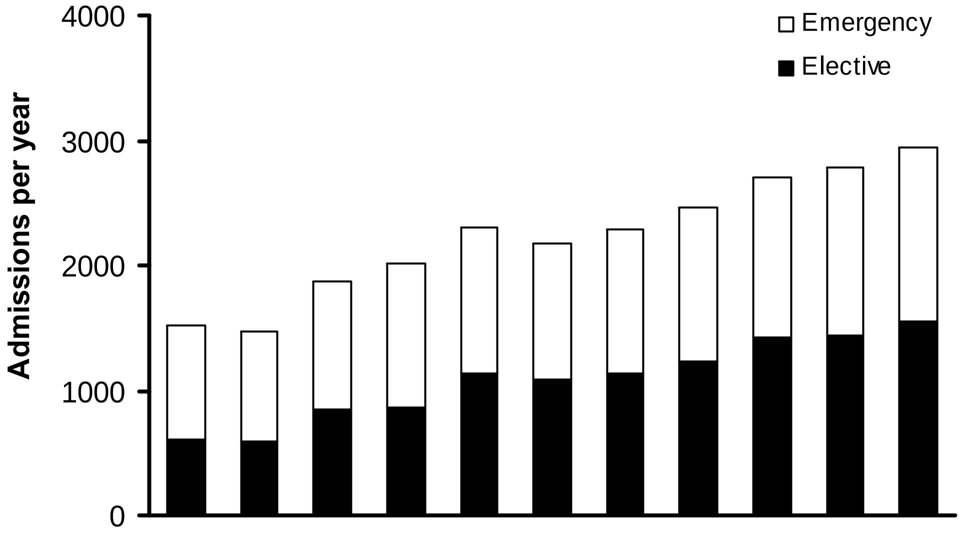

Figure 19. **Hospital admissions (emergency and elective) for dilated cardiomyopathy (England, 1995 to 2005).**

Figure 20 shows data for 2001 to 2005 on the annual number of deaths with a recorded underlying cause of dilated cardiomyopathy, which has increased ~20% over this period.

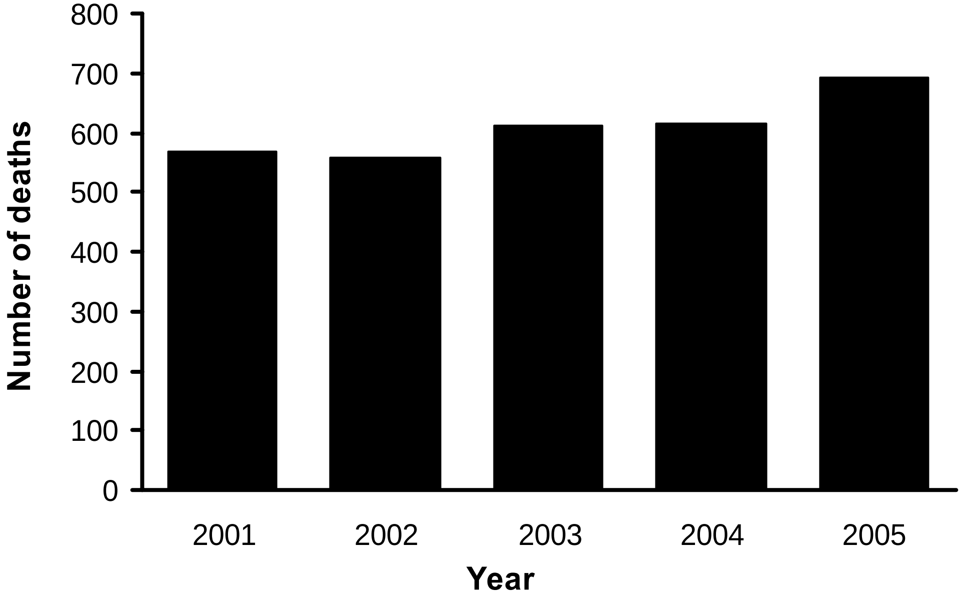

Figure 20. **Annual number of deaths with a recorded underlying cause of dilated cardiomyopathy (England & Wales, 2001 to 2005).**

The two most common diagnoses among lung transplant recipients are emphysema and cystic fibrosis. Figure 21 shows data from 1995 to 2005 on the number of hospital admissions for 1) emphysema and 2) cystic fibrosis.

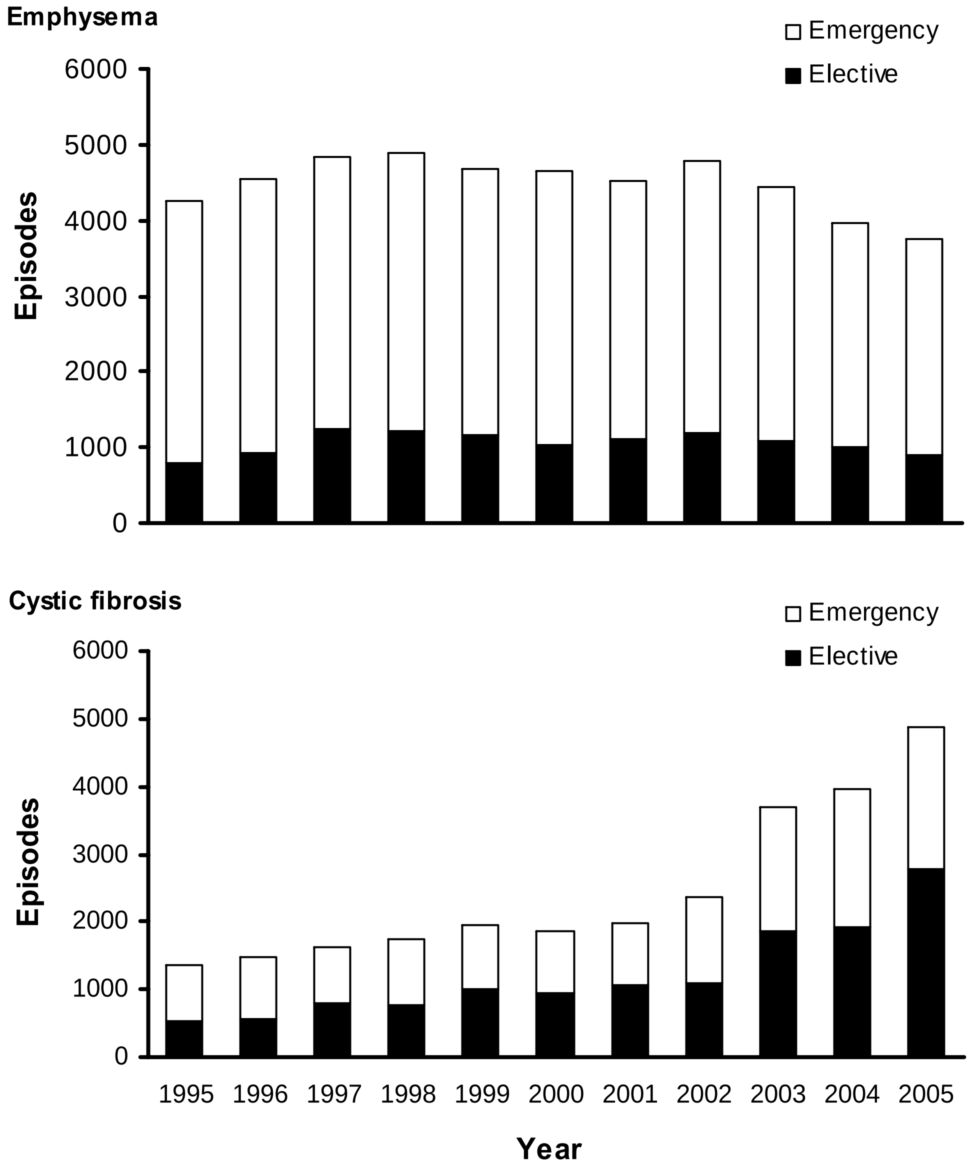
Emphysema
Emergency
Elective
Episodes
6000
5000
4000
3000
2000
1000
0
Cystic fibrosis
Emergency
Elective
Episodes
6000
5000
4000
3000
2000
1000
0
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
Year

Figure 21. **Hospital admissions (emergency and elective) for 1) emphysema and 2) cystic fibrosis (England, 1995 to 2005).**

For emphysema, the annual number of admissions has remained essentially constant from 1995 to 2005. However, for cystic fibrosis the number of admissions has increased, at a rate that appears to be higher after than before 2002.

Figure 22 shows data for 2001 to 2005 on the number of deaths with a recorded underlying cause of emphysema or cystic fibrosis.

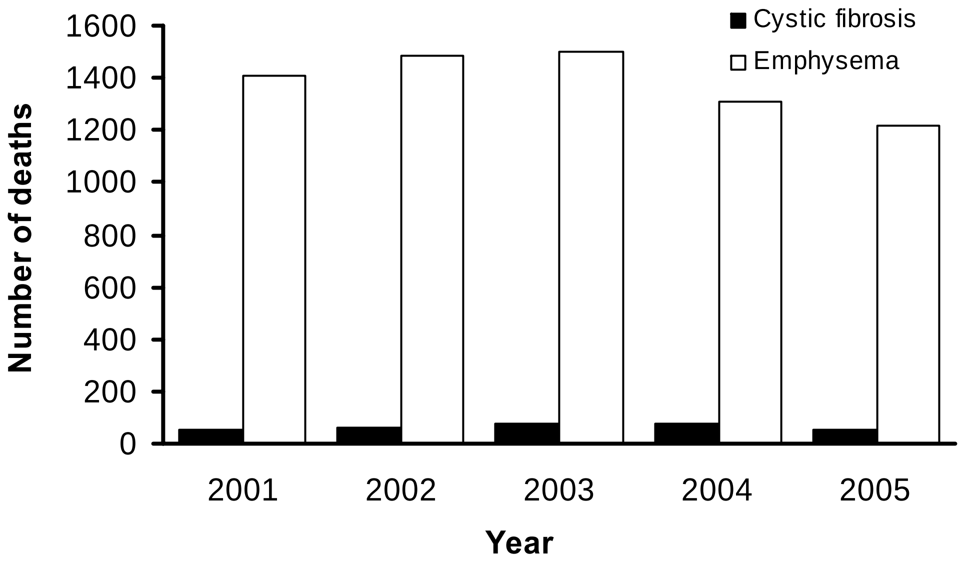

Figure 22. **Number of deaths with a recorded underlying cause of emphysema or cystic fibrosis (England & Wales, 2001 to 2005).**

The mortality data in figure 22 do not show any clear patterns: the general picture is of an essentially constant number of deaths for each of the selected underlying causes. The marked increase in hospital admissions for cystic fibrosis observed since 2001 may indicate that the disease is being increasingly actively managed.

Summary and conclusions

This paper considers the likely effect on the future need for transplantation of changes in the age, ethnic and health profile of the UK population.

The age profile is similar for waitlisted patients or transplant recipients and organ donors (see figures 3 and 7 respectively). Hence the effect of future changes in the age profile of the population will be similar for both the need for and the potential supply of donor organs. In both cases, the changes that are expected to occur in the national population would have at most a minor impact because the increase in the proportion aged >64 would be counteracted by a decrease in the proportion aged <25.

The ethnic profiles of waitlisted patients or transplant recipients are very different to those of organ donors (see figures 8 and 12 respectively). Whereas ethnic minorities tend to be over-represented among waitlisted patients or transplant recipients, they are under-represented among the donor population. If the size of the ethnic minority population increases, that of the white majority population will decrease, and so will the potential supply of donor organs. Hence an increase in the size of the ethnic minority population – as seems likely to occur over the next 10 or 20 years (see figure 9) – would tend to increase the imbalance between the need for, and the potential supply of, donor organs. This is particularly the case for kidney recipients or donors but it is also the case (albeit to a lesser extent) for the recipients or donors of a liver, pancreas or heart. The exception is lung transplants, where all ethnic minorities are under-represented among recipients. The annual number of lung transplants is however low relative to that of kidney or liver transplants.

The nature of the health-related drivers of the need for transplantation differs from organ to organ. For *kidney transplants*, the key health-related driver is the incidence of end-stage renal failure, of which the best indicator is arguably the take-on rate for renal replacement therapy (RRT). Trends in, and modelling studies of, the take-on rate for renal replacement therapy suggest a modest increase of the order of 2% per year in this take-on rate, and therefore presumably in the need for kidney transplants.

For *pancreas* transplants, the key driver is the incidence of type 1 diabetes, which recent data suggest has increased substantially over the last 10 or 20 years. If this increase continues over the next 10 or 20 years, so too will the need for pancreas transplants.

For *liver* transplants, the health-related driver is a function of the incidence of those conditions that most commonly lead to transplantation, such as alcoholic cirrhosis, post hepatitis C cirrhosis, primary biliary cirrhosis (PBC) and sclerosing cholangitis. Of these, alcoholic cirrhosis and post hepatitis C cirrhosis are of particular concern. Hospital admissions for alcoholic cirrhosis, alcohol-related deaths, and alcohol consumption have all increased substantially over the last 10 to 15 years, as has the estimated prevalence of hepatitis C. If these trends continue over the next 10 or 20 years – as has been predicted, at least for hepatitis C – the effect will be a substantial increase in the need for liver transplants.

For *heart* transplants, a key driver is the incidence of dilated cardiomyopathy, for which both the annual number of hospitalisations and the annual number of deaths have increased over the last 5 to 10 years.

Finally, for *lung* transplants, the health related driver is a function of the incidence of conditions such as emphysema and cystic fibrosis. Though there are no clear trends for emphysema, the annual number of hospital admissions for cystic fibrosis has trebled over the last 10 years.

Overall, the analyses reported in this paper suggest that the need for transplantation will increase over the next 10 or 20 years. The analysis presented suggests that age is not an important driver of this increase. However, these analyses were based on national, rather than regional or local, data. For areas where the expected future changes in the age profile of the population differ from those for the country as a whole, age may be an important driver of the future need for transplantation. Similarly, for areas where the ethnic profile of the population is changing more rapidly than that of the country as a whole, the need for transplantation may increase to a greater or lesser extent than the analyses presented here suggest. In particular, if the size of the Asian or black ethnic groups is increasing more rapidly in a given area than in the country as a whole, the need for transplantation, and the potential imbalance between the need for and supply of donor organs, may increase considerably in that area. A similar argument applies to those areas where the incidence of a particular condition that commonly leads to transplantation (such as type 1 diabetes for pancreas transplants or hepatitis C for liver transplants) is increasing at an unusually rapid rate.

Throughout this report, the focus has been on the *per capita* need for transplantation (or the *per capita* potential to supply suitable donor organs). It should however be kept in mind that the total population is expected to increase over the next 10 or 20 years. Indeed, as figure 23 shows, the UK population is expected to increase by ~5% between 2005 and 2015 and by a further ~5% between 2015 and 2025.

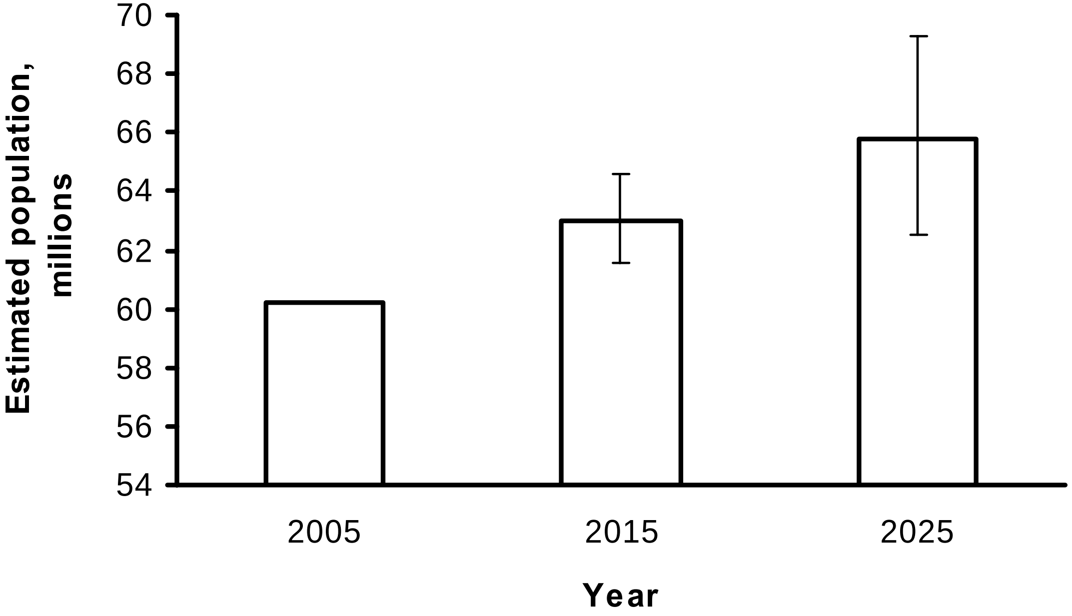

Figure 23. Estimated size of the UK population in 2005, 2015 and 2025.[33]

An increase in population size will not affect the relative balance between the need for transplantation and the potential supply of organs. It will however increase the absolute need, and the absolute size of any imbalance between the need for and the potential supply of donor organs.

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[33] The number for 2005 is the ONS mid-year estimate. The main bars for 2015 and 2025 are the “principal” projections, while the “error bars” for these years are the minimum and maximum values from the 12 “variant” projections. See Annex 1 for further information.

Annex 1: Information Sources

Population projections

Detailed information on the population of the UK is collected once every 10 years via the census, the most recent of which was in 2001. The Office of National Statistics (ONS) uses information from the census to derive estimates of the usual resident population, broken down by age, sex and, from 1991, ethnicity[34]. Between censuses, ONS uses data on births, deaths and net migration to derive mid-year estimates of the resident population. These are in turn used by ONS to derive projections of the future population, the most recent of which were based on the mid-year estimates for 2004. These are presented as projections of the usual resident population, broken down by age and sex. The latest (2004-based) projections include figures for every year from 2004 to 2029, and longer term projections for selected years up to 2074. For this report, the focus is on relatively short term projections – to 2015 and 2025.

In making these projections ONS demographers make assumptions about future levels and patterns of fertility, mortality and migration. The assumptions adopted are based on analysis of historical data and on expert judgement. A range of projections is published, covering a range of plausible scenarios in terms of fertility, mortality and migration. The “best estimate”, termed the Principal projection, is published along with a set of “variant” projections.[35]

Table A1 below shows the projected size of the UK population, and the percentage in each age band, for 2015 and 2025 (with the mid-year estimate for 2005 included for comparison). The single figures are those from the Principal projection; the ranges in brackets are the minima and maxima from the 12 “standard variant” projections. (The percentage breakdowns were presented graphically in figure 4 of the main report.)

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[34] Before 1991, respondents were asked about their country of birth; from 1991, they have been asked to select, from a pre-defined list, the ethnic group with which they most closely identify.

[35] For further information on the ONS population projections, see http://www.statistics.gov.uk/downloads/theme_population/PP2_No25.pdf

Table A1. Projections of the UK population (size and age distribution) for 2015 and 2025.

	2005	2015	2025
Total population (000s)	60,200	63,000 (61,600 - 64,600)	65,800 (62,500 - 69,300)
% aged:			
<25	31.0	29.0 (28.3 - 29.9)	27.6 (25.8 - 29.5)
25 - 34	13.1	13.7 (13.3 - 14.1)	13.0 (12.4 - 13.6)
35 - 44	15.4	12.8 (12.6 - 13.1)	13.4 (12.7 - 14.0)
45 - 54	12.8	14.4 (14.2 - 14.6)	12.1 (11.7 - 12.4)
55 - 64	11.7	11.6 (11.4 - 11.8)	13.2 (12.6 - 13.7)
65+	16.0	18.4 (17.9 - 18.9)	20.8 (19.5 - 22.0)

The figures in table A1 indicate that:

1) The population of the UK is expected to increase in size by ~5% between 2005 and 2015 and by ~10% between 2005 and 2025[36]
2) The UK population is expected to continue to age over the next 20 years, with a decrease in the proportion aged under 25 and an increase in the proportion aged 65 and over.

Although it is not evident from the table above, none of the ONS population projections suggest a change from the current sex distribution of 49% male and 51% female.

Ethnicity data

The ONS population projections do not consider ethnicity: the projected figures are broken down by age and sex, but not by ethnic group. No national population projections by ethnic group currently exist for the UK.

An ethnic group question was included in both the 1991 and 2001 censuses but it was not the same question. Table A2 below presents the categories used to collect ethnic group information in the 1991 census together with those used in the 2001 census, arranged in a way that highlights the difficulties involved in mapping ethnic group data from one set of categories to the other.

Table A2. Ethnic group categories from the 1999 and 2001 censuses.

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[36] The vast majority of this increase is predicted to occur in England. The proportional increase in total population size is greater for England than for Wales or Northern Ireland, while the population of Scotland is predicted to remain essentially constant over the next 20 years.

2001 category	Equivalent 1991 category?
White: British	White
White: Irish	
White: Other White	
Black or Black British: Black Caribbean	Black Carribean
Black or Black British: Black African	Black African
Black or Black British: Other Black	Black other
Asian or Asian British: Indian	Indian
Asian or Asian British: Pakistani	Pakistani
Asian or Asian British: Bangladeshi	Bangladeshi
Asian or Asian British: Other Asian	Other Asian
Chinese or Other Ethnic Group: Chinese	Chinese
Chinese or Other Ethnic Group: Other	Other
Mixed: White and Black Caribbean	
Mixed: White and Black African	
Mixed: White and Asian	
Mixed: Other Mixed	

The principal problem here is the addition in 2001 of the “mixed” category. While some respondents who selected the mixed category in 2001 would have selected “other” in 1991, others would have selected “white”, “Chinese”, or one of the “Asian” or “black” categories in 1991. Studies in which individuals have been asked to categorise themselves using both schemes[37] show, *inter alia*, that the majority of those who categorise themselves as “mixed” in the 2001 scheme select the “other” category from the 1991 scheme. The results of such studies have been used to devise strategies for mapping the 16 ethnic groups from the 2001 census onto those from the 1991 census, which in turn have been used to derive the figures shown below and those in figure 9 of the main report.

Table A3 below compares data for England from the 1991 and 2001 censuses to show how the population of each ethnic group changed between 1991 and 2001. Though the overall population grew between 1991 and 2001, the ethnic minority population grew at a greater rate than the white population, leading to a decrease in the relative size of the white group from ~94% to ~91%. Of the broad ethnic minority groups considered in Table 3, only the black group decreased in size from 1991 to 2001. All the other groups increased in size, with the largest increase (both in absolute numbers and as a percentage of the 1991 size) in the Asian group.

Table A3. Estimated resident population by broad ethnic group (England, 2001 vs. 1991)

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[37] Simpson L and Akinwale B. Quantifying Stability and Change in Ethnic Group. Journal of Official Statistics, in press. Available from http://www.ccsr.ac.uk/publications/working/2006-05.pdf.

	1991	2001
All Groups	47,055 (100%)	49,450 (100%)
White	44,144 (93.8%)	44,897 (90.8%)
Asian	875 (1.9%)	2,291 (4.6%)
Black	1,621 (3.4%)	1,471 (3.0%)
Chinese	142 (0.3%)	227 (0.5%)
Other	274 (0.6%)	564 (1.1%)

Table A4 shows the estimated age breakdown of the white, Asian, black and total ethnic minority populations for 1991 and 2001.[38] It is clear from table A4 that:

1) The ethnic minority populations are considerably younger than the white population
2) The differences between 1991 and 2001 are small relative to those between the white and ethnic minority groups.

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[38] The total ethnic minority population was obtained by summing across the Asian, black, Chinese and other groups.

Table A4. Age breakdown of the population for selected ethnic groups (England, 2001 vs. 1991).

	White		Asian		Black		All ethnic minorities	
	1991	2001	1991	2001	1991	2001	1991	2001
% aged:								
<25	31.7%	29.5%	45.5%	45.4%	50.4%	45.1%	49.1%	45.8%
25 to 34	15.0%	14.1%	23.1%	19.1%	16.9%	18.1%	19.2%	18.8%
35 to 44	14.0%	14.9%	10.1%	13.9%	14.8%	18.5%	13.3%	15.5%
45 to 54	11.8%	13.5%	9.5%	10.4%	9.1%	7.2%	8.9%	9.3%
55 to 64	10.5%	11.1%	8.0%	6.0%	5.9%	5.5%	6.3%	5.6%
65+	16.9%	16.9%	3.8%	5.3%	3.0%	5.6%	3.2%	5.1%

In 2006, ONS produced, for the first time, mid-year population estimates broken down by ethnic group. These were released as, and remain, “experimental statistics”, indicating that they do not yet meet the rigorous quality standards of official National Statistics. The labelling of these statistics as experimental by ONS reflects the technically challenging nature of attempting to estimate fertility, mortality and net migration by ethnic group.[39] The publication of these statistics is nevertheless an important step, as it paves the way for the subsequent production of population projections by ethnic group.

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[39] For a discussion of the methodological challenges associated with producing population estimates or projections by ethnic group, see http://www.statistics.gov.uk/downloads/theme_population/SMPS_67_v2.pdf

The experimental mid-year estimates are based on the same 16 category ethnic group classification as was used in the 2001 census (see table A2 above). However, for comparison with earlier data (namely those from the 1991 census) or data from sources other than ONS (such as the ethnic group information collected by UK Transplant), it is necessary to merge some of these categories (as discussed above).

Figure 9 of the main report combines data from the 1991 census with mid-year estimates from 2001 to 2004 to show the estimated change in the proportion of the population represented by each of four ethnic groups (White, Asian, Black, and Chinese) from 1991 to 2004.[40] Probably the most robust of the trends from this figure is that shown by the White ethnic group, the relative size of which appears to have decreased at a faster rate between 2001 and 2004 than between 1991 and 2001. However, even this trend should be interpreted with caution. Any trends in the mid-year estimates for 2001 to 2004 may simply reflect short term fluctuations in fertility, mortality or net migration. The annual level of migration has historically been particularly volatile and is a substantial component of the year-to-year change in the size of each ethnic group.

It is clear from census data that the size of the total minority ethnic population increased between 1991 and 2001, and it seems likely that it is still increasing and will continue to increase over the subsequent decade. However, given the data currently available, it is not possible to quantify the likely future rate of increase.

Morbidity and mortality data

In addition to changes in the overall size of the population and its age and ethnic profile, changes in the incidence of certain conditions could have important effects on the future need for transplantation. (For example, an increase in the incidence of type 1 diabetes would potentially increase the need for pancreas transplants.) Comprehensive data on the incidence of a particular condition are rarely available. It is however often possible to use proxy measures (such as the number of consultations, hospital admissions or deaths), or survey data, to paint a general picture of the impact of the condition. Relevant data sources are:

> GP consultations:
> GP consultation data can provide useful information about the impact of a particular condition on primary care. However, access to these data is controlled by the research groups who collate the information, who typically operate on a commercial basis. Such data have been used in various research studies (such as the Royal College of General Practitioners' series of morbidity surveys[41]), but are not routinely available.

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[40] 2004 is the latest year for which mid-year estimates by ethnic group are available.

[41] See http://www.statistics.gov.uk/statbase/Product.asp?vlnk=616

Hospital episode statistics:
Data on hospital activity associated with a particular condition can be extracted from the Hospital Episode Statistics (HES) database. These data are available from 1989-1990 onwards. As is the case for mortality statistics (see below), the methods used to collect and code HES data have changed over the years. However, the change from the 9th to the 10th revision of the International Classification of Diseases (ICD) was made earlier for HES than for mortality data (1995 for HES vs. 2001 for mortality). For HES, there are 11 years (1995 to 2005 inclusive) for which the statistics are based on the latest revision of the International Classification of Diseases.

Mortality statistics:
Counts of the annual number of deaths, broken down by age and underlying cause, are published by ONS. These data have been published for many years, but the methods used to code the underlying cause have changed over this period, making it difficult to interpret any trends in longitudinal data. One such change was the change, in 2001, from ICD-9 to ICD-10.[42] Data are not yet available for 2006. There are, therefore, just 5 years (2001 to 2005 inclusive) for which mortality statistics based on the latest revision of the International Classification of Diseases are available.

Other relevant sources of information include the Renal Registry[43], and modelling studies on topics such as the future demand for renal replacement therapy[44] or the likely future prevalence of particular diseases such as Hepatitis C[45]. Data from each of these sources have been presented in the main report.

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[42] See http://www.statistics.gov.uk/about/classifications/icd10/default.asp for further information on the impact of this change

[43] See http://www.renalreg.com/ for further information

[44] Roderick P et al. Simulation model of renal replacement therapy: predicting future demand in England. Nephrol Dial Transplant 2004 19(3): 692-701.

[45] http://www.hpa.org.uk/publications/2006/hepc_2006/Hepatitis_C2.pdf

Appendix 3: The Ethical Dimension of Organ Donation and Transplantation

Objective: *To map out and to appreciate the ethical issues of transplantation that lie beyond the immediate concern of intensivists and others in ICUs*

Key Messages:

- There are unresolved ethical and legal issues with organ donation, these centre around NHBD and the assessment of 'best interest', namely continuing with treatment when there is no hope for recovery in order to maintain the option for organ donation. These cause significant concern to clinicians in ICU and require attention.
- In addition to the main ethical issues above there are other ethical issues.
- The unresolved ethical issues and the lack of a suitable forum for resolution indicates the need for the establishment of an independent forum where these can be discussed and resolved.

Contents:

- Ethical Dimension to Organ Donation in the UK

Appendix Prepared by: UKT Review Group

Ethical Dimension to Organ Donation in the UK

Context

1. Heading: Societal Attitudes

Issues clustered under this heading:

- Peoples’ inability to deal and think about death. How explicit are we about death and how important is this in moving people from the ODR to becoming a donor (Also: 6, 13 and 14).
- Consent/authorisation issues and the rights of Next of Kin over the donors wish in life (Also: 2 & 3).
- How do we know what is ethically relevant, what “test” do we need to apply to decide what question to address and what not to.
- Gender issues in live donation.

2. Heading: Health Inequalities

Issues clustered under this heading:

- Wide issues including racism, sexism, culture, ageism, disability, mental capacity. These issues affect both sides of the pathway (i.e. being a donor and patient), often in very different ways.
- Health inequalities could become more important with increased transparency and robustness of the organ donation process.
- Increasing Black, Minority &Ethnic (BME) groups knowledge of donation.
- Increasing transplantation of organs in BME groups without corresponding increase in supply from those communities
- Developing a “culturally competent” approach to BME groups that may lie outside wider “norms”
- Should anonymity between donor family and recipient be relaxed to increase cultural relevance amongst BME groups? How best we make the connection between the gift and the patient in a culturally appropriate manner? (Also: 1, 10 and 12)

3. Heading: Health Care Professionals and the use of their discretion

Issues clustered under this heading:

- Validating consent; how much detail should be provided to the family? How "ethically rigorous" is appropriate?
- Making overall policy decisions about consent implies there is a base understanding and knowledge of what happens during organ retrieval. (Also: 1)
- Challenging and changing the culture of the medical profession to remove barriers for donation, to what extent is this appropriate?
- Is it satisfactory for doctors NOT to actively support organ donation?

4. Heading: Health economics

Issues clustered under this heading:

- Non identified during workshop

5. Heading: Advances in healthcare and new procedures

Issues clustered under this heading:

- Artificially "grown" organs
- Xeno-transplantation
- Ethical challenges in therapeutic advances and research
- New body parts and organs for transplantation, both intern of the donor, consent and the patient (Also: 9)
- Cloning (Also: 1)
- Saviour siblings (Also: 1)

6. Heading: Media / publicity / public perception

Issues clustered under this heading:

- Separating fact from fiction in the public's mind
- What could the trigger be for a fundamental attitude or policy shift? Can this be anticipated?

7. Heading: NHS “politics”

Issues clustered under this heading:

- Increasing tensions between disciplines e.g. as more information on health economics becomes apparent it may affect the case for increasing transplantation amongst older people and possibly poorly matched grafts to BME groups. (Also: 13)
- Could an increase in donation and transplant affect initiatives in health promotion? Transplant could be seen as a “cure” rather than moving an acute problem to a chronic one.

8. Heading: Intra organisational issues

Issues clustered under this heading:

- The increasing role of “multi-professionalism”, including the spread of roles to other professional groups.

9. Heading: Long term implications of improved donation rates

Issues clustered under this heading:

- How does transplantation affect long term medical planning and provision?
- Reconciliation between transplantation and wider healthcare.

10. Heading: Inter organisational issues

Issues clustered under this heading:

- Who owns ethical issues?
- Tensions between organisational responsibility and clinical accountability, particularly with respect to the tolerance of risk.

11. Heading: Globalisation

Issues clustered under this heading:

- “Organ Tourism”; the ethical implications for UK healthcare of individuals going overseas for organs. The political risk of “vicarious moral responsibility” in overseeing a healthcare system that necessitates individual “offshoring” of their demand for organs to ethically ambiguous countries. (Also: 2 and 6)
- Organ trafficking. (Also: 2 and 6)

12. Heading: Unconditional vs. directed donation

Issues clustered under this heading:

- How much control should the donor family have as to who should receive the gift or donation? I.e. conditional or directed donation. (Also: 2)

13. Heading: Attitudes of healthcare professionals

Issues clustered under this heading:

- Deciding who should and who should not receive a transplant.
- Balancing the needs and the rights of the donor and the patient who needs a transplant. The recognition that a decision for one has an ethical impact on the other.

14. Heading: Underlying moral principles

Issues clustered under this heading:

- Is the definition of altruism too narrow and how this affects the attitude towards reimbursement and living donation? (Also: 1 and 4)

15. Heading: Other

Issues clustered under this heading:

- As organs are not readily available to all, should we offer them to anyone? Not a serious question but challenges the notion of allocation.
- Blame; how healthcare and society “blames people”, particularly how this is reflected, amongst, for example:

  - People who may have chaotic lives and may find it hard to keep up-to-date with their anti-rejection drugs
  - Alcoholics who need a liver transplant
  - Smokers who may need a lung transplant
  - Groups that may have low donation rates, but have high demand (Also: 1, 2 and 3)
- Payment and reward for gifting
- How an organisation deals with “ethical whistle blowing”
- Accessibility and prioritisation for waiting lists

Pathway

1. Heading: Donor identification; including consent/authorisation, incentives, accountability and early intervention.

Issues clustered under this heading:

- Why aren’t all organs automatically available for donation?
- The impact of “avoidable waste” i.e. organs not being used because of a lack of capacity in the healthcare system, on consent/authorisation and willingness to donate
- Need to understand the range of ethical issues and where the conflict is.
- Ethical issues surrounding marketing, publicity and informed choice
- Identifying who has “primacy” over consent/authorisation – the family or the donor’s wish in life, or wider societal benefit
- Building and improving the legislative framework e.g. Acts, Codes of Practice/Explanatory Notes and practice.
- Duty of care to the family – how hard should this be pushed? There are different international approaches.
- Point at which the Donor Transplant Co-ordinator gets involved.
- The change in mindset towards a “presumption of consent”.
- Should people’s wish to donate be on the summary of their Connecting for Health record?
- Can children or those with learning difficulties register themselves on the ODR?
- The “unidentified”; Donation of organs amount, those without relatives or readily available identity.
- To what extent should those involved try to resolve disputes in families?
- To what, if any, extent can a person on the ODR expect to be pushed up the waiting list if they need an organ?
- To what extent should donor families expenses be paid (e.g. funeral) to support donation?

2. Heading: Resourcing; including prioritisation of scarce resources/ ICUs / staff etc

Issues clustered under this heading:

- Is the use of ICU capacity, to support transplantation, the best use of healthcare resource?
- Should there be reimbursement of costs for the ICU and for live donation?

3. Heading: Definition of death; including information and agreement on cardiac death

Issues clustered under this heading:

- What information should be given to families and those who are signing up for the ODR?
- How much information do people need to know?
- Why should a lay person accept a medical definition of death?
- Although the family accepts the definition of brain death, some want to see cardiac death.
- Uncertainty about the certification of death
- Professional concern about ethical and legal ramification of death amongst doctors.

4. Heading: “Best Interest” of the donor during death and possible tension in respecting individual’s wish to donate. Also professional uncertainty over Non Heart Beating Donors and perceived conflict of interest.

Issues clustered under this heading:

- What interventions are appropriate to preserve organs and the options to donate:
- Continuing with fluids
- Providing care
- Keeping/taking the potential donor to ICU
- Possible conflict of interest between the donor’s wish, as expressed on the ODR, and extending care to organ retrieval (i.e. futility of care).
- After cardiac death could the clinician be accused of not doing all that was possible for the patient?

5. Heading: Testing; including which tests to be carried out and to whom information is given

Issues clustered under this heading:

- Should “contentious” results of the donor be communicated to the donor’s family, how far does the duty to inform people go?
- What is the basis to decide what tests are appropriate and not appropriate e.g.:
- Directly affect the clinical outcome of the transplant
- General health
- Availability of the test (speed and access)
- What can or should be done to collect samples prior to consent?

6. Heading: New Technologies; including new forms of technologies and alternatives to transplantation.

Issues clustered under this heading:

- What will the implications be of new technologies?
- What are the implications for new transplants (e.g. face transplants) for the ODR?
- Implications of sibling donors and stem cell technologies

7. Heading: Allocation; including equality of access (waiting lists) and criteria for allocation

Issues clustered under this heading:

- Implications of patients going overseas for organs, particularly with respect to follow up care.
- To what extent should account be taken of social and lifestyle factors in the allocation of organs?
- To what extent should account be taken on the destination of organs?
- With increased number of organs, what will be the implications for who will now go on the waiting lists?
- What would the implications be if there were changes to the “rules” on ICU admission e.g. during pandemic flu?

Appendix 4: Inequalities in Organ Donation and Transplantation Affecting Black and Minority Ethnic Groups in the UK

Objective: *To understand the main reasons behind the disparity between the supply and demand of organs for BME groups compared to others sections of UK society.*

Key Messages:

- Tackling health inequalities, particularly amongst BME, groups is a major political objective.
- The number of organs being donated amongst BME groups is less than other sectors of society. However, their need for organ transplantation, particularly for kidney transplantation, is substantially higher.
- There is little understanding of the notion of “gift” amongst BME groups, namely what are the key factors that will make bereaved families from BME groups give consent for organ donation.
- Although a considerable amount of work has been done to engage BME groups this has had little effect on increasing the number of organs from BME groups.
- Although outside the direct remit of the Taskforce, it is relevant to point out that both disease prevention and live donation have a substantial role to play in narrowing the differential between the number of organs donated and the need for transplantation.
- It will be relevant to work to unpack the cultural concerns over organ donation from religious beliefs amongst BME Groups.
- In order to get more meaningful information it is relevant to include more demographic information on the ODR.

Contents:

- Inequalities in Organ Donation and Transplantation Affecting Black and Minority Ethnic Groups in the UK

Appendix Prepared by: Gurch Randhawa (Taskforce Member) and the UKT Group

Introduction

Inequalities do currently exist in transplant services and the solutions to rectifying this situation are complex and which require a holistic approach that considers both the short-term requirement to increase the number of organ donors from black and minority ethnic groups, and the longer term focus to decrease the number of black and minority ethnic patients requiring a transplant via preventative strategies. It is recognised that work concerning disease prevention is not strictly within the remit of the Taskforce. However, it is felt that the financial and human burden of not addressing these inequalities utilising a ‘whole-systems’ care-pathway approach should be considered.

The Government’s Cross Cutting Review of Health Inequalities published earlier this decade reminded us not only do health gaps still exist in the UK but, in some cases, are growing ever wider.

> *“There are wide geographical variations in health status, reflecting the multiple problems of material disadvantage facing some communities. These differences begin at conception and continue throughout life. Babies born to poorer families are more likely to be born prematurely, are at greater risk of infant mortality and have a greater likelihood of poverty, impaired development and chronic disease in later life. This sets up an inter-generational cycle of health inequalities.”* (DH, 2002a).

This statement reflects the shift in focus of policy during the last 20 years in which there has been a growing interest in the health of minority ethnic populations in the UK.

Throughout this period, the provision of transplant services for minority ethnic groups has become a particularly important area of debate. This is in part due to the observation of high rates of end stage renal failure (as a result of diabetic nephropathy) among South Asian and African-Caribbean populations in the UK and the disproportionately higher numbers of South Asians and African-Caribbeans represented on transplant waiting lists.

Background

South Asians (those originating from the Indian subcontinent) and African-Caribbean communities have a high prevalence of Type 2 diabetes: recent studies indicate a prevalence rate four times greater than Whites. It has been reported that 20% of South Asians aged 40-49 have Type 2 diabetes, and by the age of 65 the proportion rises to a third (Raleigh, 1997).

A further complication is that diabetic nephropathy is the major cause of end stage renal failure [ESRF] in South Asian and African-Caribbean patients receiving renal replacement therapy [RRT], either by dialysis or transplantation. Nationally, this higher relative risk, when corrected for age and sex, has been calculated in England as 4.2 for the South Asian community and 3.7 for those with an African-Caribbean background (Roderick et al, 1996). Data from Leicester shows that South Asians with diabetes are at 13 times the risk of developing ESRF compared to ‘White’ Caucasians (Burden et al, 1992). Thus, not only are South Asians and African-Caribbeans more prone to diabetes than Whites, they are more likely to develop ESRF as a consequence.

Importantly, the South Asian and African-Caribbean populations in the UK are relatively young compared to the White population. Since the prevalence of ESRF increases with age, this has major implications for the future need for RRT and highlights the urgent need for preventive measures (Randhawa, 1998a). The incidence of ESRF has significant consequences for both local and national NHS resources. The National Renal Review estimated an increase over the next decade of 80% in the 20,000 or so patients receiving RRT and a doubling of the current cost, about £600m a year of providing renal services (Raleigh, 1997).

Kidney transplantation is the preferred mode of RRT for patients with end-stage renal failure. There are currently over 5,500 people on the transplant waiting list in the UK – the majority waiting for kidney transplants, but substantial numbers also waiting for heart, lung, and liver transplants. However, a closer examination of the national waiting list reveals that some minority ethnic groups are greater represented than others. 14% of people waiting for a kidney transplant are South Asian and over 7% are African-Caribbean even though they compromise only 4% and 2% respectively of the UK general population. South Asians are also greater-represented on the liver transplant and heart transplant waiting lists. South Asians and African-Caribbeans have to wait on average twice as long as a white person for a kidney transplant. White patients wait on average 722 days, South Asian patients wait 1496 days, and African-Caribbean people wait 1389 days.

The situation is clear, there is an urgent need to address the number of African-Caribbean and South Asian patients requiring a kidney transplant otherwise the human and economic costs will be very severe. In the short term there needs to be a greater number of donors coming forward from these communities to increase the pool of suitable organs (Randhawa, 1998a; Exley et al, 1996a). In the long term, there needs to be greater attention on preventive strategies to reduce the number of African-Caribbeans and South Asians requiring RRT. The latter can only be achieved if we begin to address the problem of poor access to services for minority ethnic groups (Randhawa, 2003).

Improving access to services

The Diabetes National Service Framework highlights the importance of access to services, in particular to meet the needs of minority ethnic groups (DoH, 2002b). The Renal Services NSF also focuses on ‘renal disease complicating diabetes’ and emphasises inequalities experienced by minority ethnic groups (DoH, 2004). However, there is evidence that knowledge of diabetes and its complications is poor among South Asians and African-Carribeans (Nazroo, 1997; Johnson et al, 2000). Preliminary evidence also suggests that quality of health care for South Asians and African-Caribbeans is inadequate and compliance poor (Johnson et al, 2000; Raleigh, 1997). There is also a low-uptake of hospital-based diabetes services, with growing evidence that South Asians are subsequently referred later for renal care, and are more likely to be lost to follow-up (Jeffrey et al, 2002). Late referral may reduce opportunities to implement measures to slow progression of renal failure, or to prepare adequately for RRT, adding to morbidity and mortality.

The World Health Organisation (WHO) study group on diabetes notes that resources should be directed to improving the quality of preventive care in primary care settings and to public health interventions for controlling diabetes. Education, early diagnosis, and effective management of diabetes are important for safeguarding the health of susceptible populations and for long term savings for the NHS (Raleigh, 1997). Most encouragingly, recent studies from the US and Finland have demonstrated that modest lifestyle changes can reduce the risk, by more than 58%, of developing overt Type 2 diabetes in susceptible groups (DPPRG, 2002; Tuomilehto et al, 2001). Furthermore, various interventions, such as tight blood pressure control, effective use of angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor (ATR) blockers, and tight blood sugar control can significantly delay the progression of diabetic nephropathy (UKPDS, 1998; Feest et al, 1999; Brenner et al, 2001; Cinotti & Zucchelli, 2001; Lewis et al, 2001; Lightstone et al, 2001).

Recommendation 1: 'reducing inequalities' is a cross-cutting theme in the diabetes NSF, renal NSF, Coronary Heart Disease NSF, and the Organ Donation Taskforce. There be should collaboration with the respective NSF 'czars' to ensure the best use of resources so that future rates of renal failure and heart failure are reduced among black and minority ethnic groups.

Improving transplantation rates

Unfortunately, the transplant option may be medically and economically favourable but in reality is not as forthcoming due to constraints around the severe lack of donors from the African-Caribbean and South Asian population. This could be attributed to 2 main reasons – a lack of awareness concerning organ donation and transplantation; and potentially low referral rates to the Intensive Care Unit (Exley et al, 1996a; Darr & Randhawa, 1999). It must be stressed that these factors are not unique to the African-Caribbean and South Asian population and have relevance to other members of the UK's public. Furthermore, it is extremely important to recognise that the African-Caribbean and South Asian communities in the UK are heterogeneous and thus it is important to familiarise oneself with the demographics of the local population (Khan & Randhawa, 1999).

Increasing awareness of the need for organ donors among the African-Caribbean and South Asian communities

Unfortunately, very little research has been devoted to this area. The relatively few studies which have been carried out consistently show that African-Caribbeans and South Asians are supportive of organ donation and transplantation, but are simply not aware of the specific needs for organs from their community (Exley et al, 1996a; Darr & Randhawa, 1999; Hayward & Madhill, 2003; Alkhawari et al, 2005; Davis & Randhawa, 2006; Morgan et al, 2006). These studies, however, do not identify what would motivate these communities to come forward as potential organ donors. Pertinently, Titmuss (1973) famously viewed the NHS which had been created in the post-war period as a vehicle for institutionalising altruistic practices, notably the voluntary 'gift' of blood to strangers represented by the transfusion service. More recent advances in medical technology have made new forms of bodily tissue donation possible, including organs, gametes, eggs, stem cells, embryos, etc. The limitation of Titmuss's analyses was an implicit assumption that all individuals would feel a belonging to 'society' and would therefore wish to contribute to a 'societal problem'. Within the main South Asian religions namely, Hinduism, Sikhism and Islam, the concept of gifting to assist society is a highly-valued virtue, 'Sewa', 'Sewa', and 'Zakat' respectively. This issue needs careful examination within the context of an increasingly diverse UK population.

Recommendation 2: research is required to identify what would make the "gifting of organs" relevant to a multi-ethnic & multi-faith UK society

A growing amount of literature has shown that the role of religion has been known to play an important part in the decision to donate organs (Randhawa, 1998b; Hayward & Madhill, 2003; Alkhawari et al, 2005; Davis & Randhawa, 2006). The religious beliefs of the major faiths of the

UK's African-Caribbeans and South Asians namely Islam, Hinduism, Sikhism, Buddhism, and Christianity have been scrutinised in the literature. None of the religions object to organ donation in principle although in some there are varying schools of thought. What is interesting, however, is that the position of one's religion is used by many people in informing their decision as to whether to donate or not (Randhawa, 1998b). This has been highlighted in several studies conducted abroad (Callender, 1989; Kyriakides et al, 1993; Spina et al, 1993). Unfortunately, this issue has not been prominent in research carried out in the UK but the findings of a pilot study to examine the attitudes towards organ donation and transplantation among a cross-section of the UK's South Asian population have shed some light on the matter (Randhawa, 1998b). It was found that far from being a barrier to organ donation, the respondents were more supportive of donation and, transplantation, in general, when they were aware of the position of their religion with regards to these issues. This highlights the importance of education and raising awareness among the South Asian public (Exley et al, 1996a; Darr & Randhawa, 1999).

In recent years, the Department of Health and UK Transplant have produced a range of educational material (including leaflets, posters, and videos) in the main South Asian languages to increase awareness of transplant related issues. Additionally, materials have been produced that set out the position of each religion regarding organ donation. However, current evidence shows that further thought is required to the dissemination of this literature among African-Caribbean and South Asian populations Unit (Exley et al, 1996a; Randhawa, 1998b; Darr & Randhawa, 1999). Namely, care needs to be taken in specifying the target population, selecting the persons who will communicate the campaign appeal, designating the methodology of appeal delivery, and deciding upon the content of the appeal. There are indications from pilot work in the UK and research overseas involving minority ethnic groups, that appeals for African-Caribbean and South Asian donors may be more effectively communicated by employing a grassroots, community networking approach Unit (Exley et al, 1996a; Darr & Randhawa, 1999; Khan & Randhawa, 1999).

Recommendation 3: there is a need to identify how best to engage local religious 'stakeholders' with agreed religious opinion.

Recommendation 4: furthermore, there is a need to identify how best to encourage religious 'stakeholders' to engage with their local community concerning the issue of organ donation & transplantation

Low referral rates to the Intensive Care Unit (ICU)

The vast majority of organs are procured from ventilated patients in the ICU who have suffered some form of cerebrovascular accident (Gore et al, 1992; Randhawa, 1997). Thus, an important point to consider is whether African-Caribbean and South Asian patients are reaching the ICU so that the may be considered to be potential donors. It may be that the African-Caribbean and South Asian population are simply not dying of the relevant cause or being referred to the ICU rather than an unwillingness to become donors (Exley et al, 1996b).

Again, there is very little research in this area. Gore et al (1992) carried out a comprehensive audit of all ICU deaths in the UK and the suitability to become organ donors. However, the main drawback to this study was that the ethnic group of patients was not recorded. A pilot study in Coventry was carried out which sought to determine admission rates of South Asian and non-South Asian patients to ICUs (Exley et al, 1996b). The results indicate that South Asians were less than half as likely to be admitted to an ICU than non-South Asians. These findings have serious implications, as it indicates that there are less instances where the health professional has an opportunity for making a request for organs from South Asian families. Another important finding of this study was that the rates of referral from the ICU to the transplant unit were the same for South Asians and non-South Asians, as were subsequent donation rates (Exley et al, 1996b) Thus, the results of this preliminary study suggest that lower rates of organ donation among the South Asian population are related to the initial low admission rates to the ICU. Related to this, there is preliminary evidence emerging to suggest that the number of brainstem deaths is lower among minority ethnic groups. It is acknowledged that the more recent work of the UK Transplant led Potential Donor Audit may have begun to address these issues. However, presently there is no firm evidence to support the view that access to ICUs is equitable across all ethnic groups.

Recommendation 5: identify whether black & minority ethnic groups have the same likelihood to become potential organ donors as their 'white' counterparts

The Potential Donor Audit has highlighted the fact that families and friends of African-Caribbean and South-Asian potential donors are more likely to withhold consent for donation to take place than for white donors. Indeed, the refusal rate for non-white potential donors is 69%, compared with 35% for white potential donors. UK Transplant have previously commissioned research to identify why families refuse a request for organ donation. However, this research did not include non-white families.

Recommendation 6: commission research to understand why non-white families have a higher refusal rate than white families

Looking to the future

It is clear that black and minority ethnic groups are disproportionately affected by renal health problems both in terms of access to appropriate services and the higher prevalence of renal complications, reduced likelihood of a transplant, and longer waiting times on the transplant waiting list.

A major undertaking for researchers and clinicians in the UK will be to explore *access* to and the progression through the diabetes and 'renal disease complicating diabetes' care pathways; and identify health beliefs and experiences associated with diabetes and diabetic renal complications among African-Caribbean and South Asian groups. A systematic exploration of these would provide a valuable resource for health professionals working with these groups and allow for the development of a culturally competent diabetic and renal service, which is sensitive to the needs of minority ethnic groups (Randhawa, 2000).

Specifically, gaps are:

- Identification of cultural beliefs and practices relevant to diabetes and diabetic renal disease self-management, including attitudes to medication and attendance to - GPs, diabetic services and nephrology services - for routine monitoring;
- Examination of referral patterns to hospital-based diabetic services, and subsequent attendance;
- Exploration of referral patterns to nephrology services;

- Exploration of the relevance of current renal complications education programmes for minority ethnic groups.

Kidney Research UK have recently launched the ABLE – “A better life through education and empowerment” – campaign which aims to redress some of the above issues by education and raising personal awareness of kidney health issues among minority ethnic groups. Professor Randhawa is leading a national pilot study (with colleagues from Imperial College and the University of Leicester) to explore the above issues and the study is due to be completed in September 2008.

Concomitantly, there needs to be an increase in the supply of organs from the African-Caribbean and South Asian population to alleviate the burden on current waiting lists and for those patients on dialysis. This process can only begin if the public are in an informed position to consider and debates the issues surrounding organ donation and transplantation. Central to attaining this goal is increased levels of health education and awareness of the specific problems within the African-Caribbean and South Asian population. This is a difficult challenge as many of these communities live within the most deprived (and hard-to-reach) communities in the UK.

Recommendation 7: should we engage the public with the discourse of “disease prevention” as well as “organ donation”?

Recommendation 8: there is a need to identify whether the social class of a patient and/or their family influences live donation as this may have implications for current reimbursement arrangements. This issue may have particular relevance to black and minority ethnic groups who experience the greatest levels of deprivation in the UK.

It has been suggested previously by commentators that religion acts as a prohibitor to organ donation among the South Asian population but empirical research however seems to suggest otherwise. The position of one's religion towards donation is used by individuals as a helpful guide in reaching their decision as to whether to donate or not (Randhawa, 1998b). The introduction of community based information programmes need to be evaluated to assess whether this impacts upon the number of African-Caribbeans and South Asians on the Organ Donor Register.

Recommendation 9: all public organ donor campaigns should be formally evaluated to identify which members of the public benefit from such campaigns and to identify which members of the public are still not being reached.

Recommendation 10: research should be commissioned to identify how best to unravel public concerns that are ‘cultural’ as opposed to ‘religious’.

Attention also needs to be given to the number of South Asian patients who are eligible to become organ donors in the ICU. The limited research conducted so far suggests that low rates of organ donation by South Asian people may be related to factors pertaining to the low admission to ICUs rather than by those relating to the donation of organs (Exley et al, 1996b). There is a clear need for extensive research in this area. Preliminary evidence also suggests that the number of brainstem deaths is lower among minority ethnic groups (Exley et al, 1996b). An audit of potential donors identifying ethnicity is urgently required to substantiate this (it is recognised that the Potential Donor Audit is beginning to address this issue). Within the ICU also, there needs to be clear guidelines on how to approach patients for making a request for their loved one's organs with specific training and counselling in a multicultural environment (Randhawa, 1997). Alongside these initiatives, efforts to promote living related kidney donation among Asian families need to be implemented. Especially in the light of potentially lower admission rates to ICUs and the subsequent lower cadaveric donation rates.

Conclusion

There has been substantial recognition of the need to improve organ donation rates among black and minority ethnic groups in the UK as evidenced by the plethora of initiatives led by UK Transplant (see Section A). Many of these initiatives are recognised to be at the forefront worldwide in the development of culturally-competent organ donation education materials. However, the success of these initiatives has been limited by the lack of a focussed strategy that brings together the various strands of a multi-faceted problem that would lead to a coherent implementation plan. It is hoped that this paper contributes to beginning and shaping this process.

On a final note, it is worth noting that debates concerning organ donation and ethnicity are relatively new and are limited by the quality of data available not just in the UK but also worldwide. In future, it is imperative that data is collected on a wide range of variables including age, ethnicity, social class, gender, and religion. The potential interaction of these variables will be an important area of research in future to identify potential organ donors.

Recommendation 11: donor data and organ donor register data should collect age, ethnicity, social class, gender, and religion. The potential interaction of these variables should be analysed to inform future strategies.

It is only when these issues are addressed adequately will we begin to see a transplant service that truly meet the needs of a multi-ethnic and multi-faith population within the UK.

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Section A: Work already done or supported by UK Transplant

2000 - A multi faith symposium organised by Donor and transplant professionals aimed at the 8 major faiths in the UK supported by the Department (Lord Hunt). And senior religious leaders (Bradford 250 delegates from all major faiths).

2001 - Arranged a debate for Muftis and Imams in the Muslim school. Unable to go forward with this project due to political reasons.

2002 - Appointment of project worker by UKT, to look at organ donation and ethnicity. Leaflets and booklet produced and another seminar (in Birmingham 200 delegates).

2003 - UKT take over running of all Black and Asian donor campaigns developed by the Department of Health, using black and Asian celebrities to highlight the importance of organ donation and transplantation.

2005 - Developed training for Donor Transplant Co-ordinators and clinicians (Hospital development, breaking bad news) with a significant component of the training applied to cultural differences.

2006 - Research into attitudes of Ethnic Minority groups to organ donation run and commissioned by UKT.

2006 - Developed cultural guide for Health Care Professionals as aid for use in interviews when speaking to families with differing and diverse cultural backgrounds.

Appendix 5: Key messages from the Potential Donor Audit

Objective: *To show the significant variation in performance amongst in key steps along the donation pathway.*

Key Messages:

- A 36 month analysis of the PDA is able to provide an understanding of deaths in ICUs and how they may, or may not, result in becoming organ donors.
- There are a number of key steps that occur in ICUs where the opportunity for organ donation can be substantially improved. These include:
  - Identification of potential organ donors
  - Carrying out brainstem death testing (BSD)
  - Obtaining consent/authorisation from families of the bereaved
- The PDA, or something similar, provides a useful way to identify areas for improvement in hospitals.
- There is significant variation in performance and particularly the rate of consent/authorisation

Contents:

- Potential Donor Audit 36-Month Summary Report 1 April 2003 – 31 March 2006

Appendix Prepared by: UKT, Statistics and Audit Directorate

Potential Donor Audit 36-Month Summary Report 1 April 2003 – 31 March 2006

Introduction

This section presents fully validated data from the Potential Donor Audit (PDA) covering the 36-month period from 1 April 2003 to 31 March 2006. The dataset used to obtain the results for this report comprises data for all audited patient deaths in UK Intensive Care Units (ICUs) over the period 1 April 2003 to 31 March 2006, as recorded on the National Transplant Database (NTxD). It is based on PDA forms received and validated by UK Transplant on or before 20 July 2006. This report summarises the main findings of the PDA over the 36-month period.

UK Transplant were still receiving completed PDA forms for the period from January to March 2006 at the time of analysis and so the results summarised in this report are subject to change.

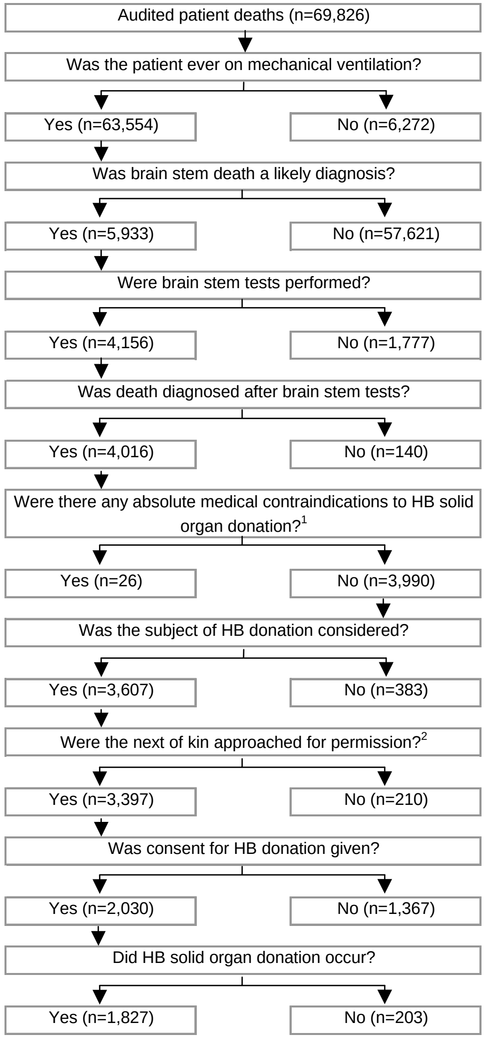
Definitions

The majority of this report refers to potential heartbeating (HB) donors, defined as patients for whom death was diagnosed following brainstem tests and who had no absolute medical contraindications to HB solid organ donation.

Appendix 9 refers to potential non-heartbeating (NHB) donors, defined as patients for whom NHB donation was possible and active treatment was withdrawn.

Breakdown of Audited Deaths In ICUs

In the 36-month period from 1 April 2003 to 31 March 2006 there were a total of 69,826 audited patient deaths in UK ICUs. A detailed breakdown from the number of audited patient deaths to the number of HB solid organ donors is given in Figure 1 and Table 1 summarises the key percentages by financial year.



[1] Either known or suspected CJD or known HIV

[2] Includes cases where the next of kin made the approach

Figure 1 A breakdown from audited patient deaths to HB donors

Table 1 **Summary of key percentages from ventilated patients to HB donors**

	2003/2004 N	2004/2005 N	2005/2006 N	TOTAL N
Patients on mechanical ventilation at some point during their stay in ICU	20,888	21,989	20,677	63,554
Brain stem death possible	2,166	2,016	1,751	5,933
Brain stem death tested (percentage of brain stem death possible patients)	1,447 (67%)	1,418 (70%)	1,291 (74%)	4,156 (70%)
Potential HB donors	1,392	1,356	1,242	3,990
No record of discussion/approach regarding HB solid organ donation (percentage of potential donor families)	201 (14%)	223 (16%)	169 (14%)	593 (15%)
Consent given for HB solid organ donation (percentage of families who were approached)	695 (58%)	685 (60%)	650 (61%)	2,030 (60%)
Consent not given for HB solid organ donation (percentage of families who were approached)	496 (42%)	448 (40%)	423 (39%)	1,367 (40%)
Actual HB solid organ donors, based on data provided through the PDA (percentage of patients with family consent)	625 (90%)	620 (91%)	582 (90%)	1,827 (90%)

Overall HB Refusal Rate

Refusal rate is based on potential donors, for whom HB solid organ donation was considered and the next of kin were approached for permission (or made the approach). The refusal rate is the proportion of these families who did not consent to HB solid organ donation.

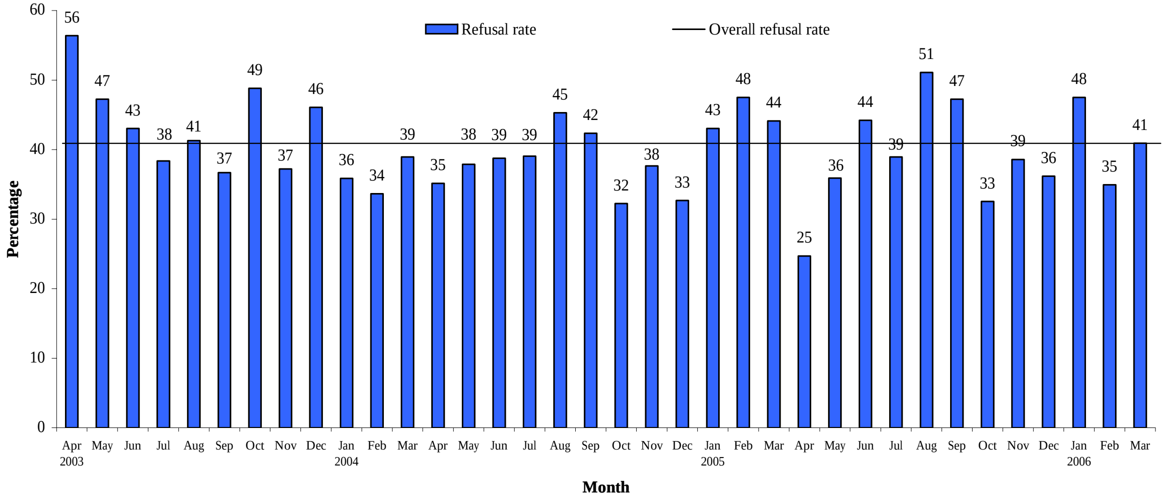
During the 36-month period, the overall refusal rate was 40% and the 95% confidence limits for this percentage range from 38% to 42%.

The number of refusals (n=1,367, 40% of 3,397) includes families who did not give their consent to solid organ donation because their loved one had stated in the past that he/she did not wish to be a donor. By excluding the 206 patients who had told their families in the past that they did not wish to be a donor, and this was given as a reason for non-consent, the overall *relative* refusal rate was 36%. The remainder of this report includes these 206 patients in the calculation of the refusal rate.

Monthly Variation In The HB Refusal Rate

Monthly refusal rates are shown in Figure 2. From this figure it is apparent that over the 36-month period there is no clear monthly pattern. This figure also shows that the refusal rate was highest in April 2003 (56%) and lowest in April 2005 (25%). The differences in the monthly refusal rates from 1 April 2003 to 31 March 2006 are statistically significant (p=0.03) and remain so (p=0.02) after taking account of differences in the refusal rate due to monthly variation in all the considered demographic variables (i.e. age, sex and ethnicity of potential donors).

Figure 2 **Month-to-month variation in HB refusal rate**

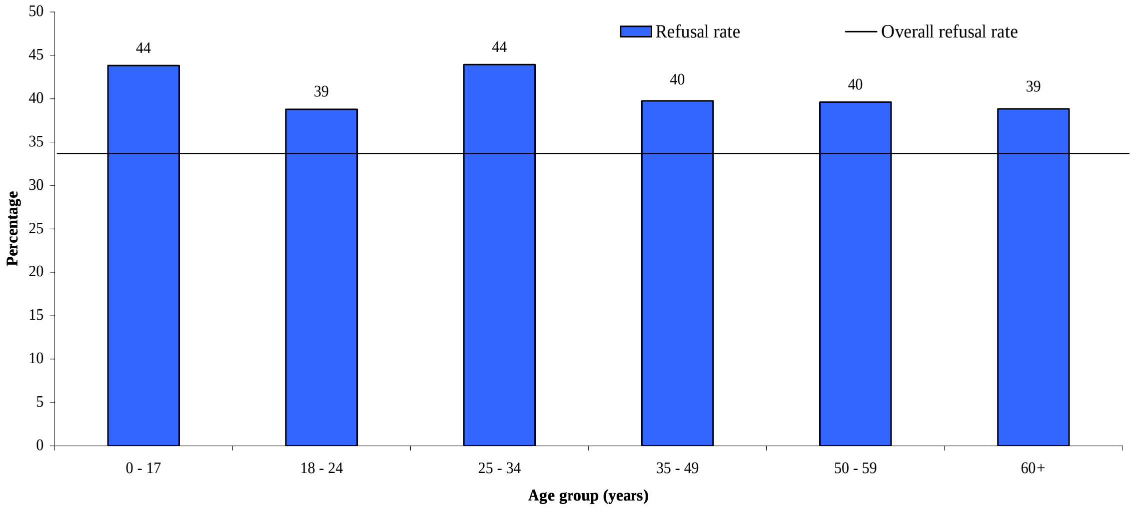


Effect Of Demographic Variables On The HB Refusal Rate

The refusal rates for males and females (for the 3,392 potential donors out of 3,397 for whom sex was recorded) were both 40%.

Age is represented by a categorical variable with intervals 0 – 17, 18 – 24, 25 – 34, 35 – 49, 50 – 59 and 60+ years. The refusal rates for the six age groups (for the 3,395 potential donors out of 3,397 for whom age was recorded) are illustrated in Figure 3. The highest refusal rate occurred in the 0 – 17 and 25 – 34 year-old age groups (44%). The lowest refusal rate occurred for potential donors between 18 and 24 years of age and for potential donors aged 60 plus years (39%). The differences between the six refusal rates are not statistically significant (p=0.5).

Figure 3 **Age variation in HB refusal rate**



To conduct a meaningful analysis, ethnicity has been split into white and known non-white groups. The refusal rates (for the 3,201 potential donors out of 3,397 for whom ethnicity was recorded) were 35% for white potential donors and 70% for known non-white potential donors. The 95% confidence limits for these two refusal rates range from 33% to 37% for white potential donors and 64% to 76% for known non-white potential donors.

There is very strong statistical evidence ($p<0.001$) of a difference between the refusal rates for white and known non-white potential donors and the ethnicity effect remains highly significant after allowing for age, sex and temporal effects.

Overall HB Relative Approach Rate

Relative approach rate is based on potential donors for whom HB solid organ donation was considered. The approach rate is the proportion of this group of potential donors whose relatives were approached for permission for donation, or whose relatives made the approach.

During the 36-month period from 1 April 2003 to 31 March 2006, the overall approach rate was 94% and the 95% confidence limits for this percentage range from 93% to 95%.

Donor Transplant Co-ordinator Team

Table 2 shows the number of potential HB donors, the referral and the conversion rate by donor transplant co-ordinator (DTxC) team. The referral rate is the percentage of potential donors referred to a co-ordinator, and the conversion rate is the percentage of potential donors who became actual HB donors. The referral rates range from 44% in Liverpool to 72% in East of Scotland and the conversion rates range from 37% in North Thames to 63% in Portsmouth. There is a significant difference in both the referral and conversion rates between the DTxC teams, p<0.001 and p<0.001, respectively. After risk adjusting the referral and conversion rates for patient age, sex and ethnicity and temporal effects there are no significant differences between the teams.

Table 2 Number of potential HB donors and the referral and conversion rates

Donor transplant coordinator team	Number of potential HB donors	Number of referrals (referral rate)		Number of conversions (conversion rate)	
Belfast	176	92	(52%)	76	(43%)
Bristol	99	62	(63%)	56	(57%)
Cambridge	128	75	(59%)	65	(51%)
Cardiff	198	99	(50%)	102	(52%)
East of Scotland	87	63	(72%)	49	(56%)
Leeds	214	143	(67%)	102	(48%)
Leicester	75	48	(64%)	34	(45%)
Liverpool	278	122	(44%)	118	(42%)
Manchester	327	174	(53%)	143	(44%)
Newcastle	266	151	(57%)	115	(43%)
North of Scotland	43	24	(56%)	21	(49%)
North Thames	575	330	(57%)	214	(37%)
Nottingham	96	55	(57%)	45	(47%)
Oxford	171	104	(61%)	89	(52%)
Plymouth	90	47	(52%)	47	(52%)
Portsmouth	102	61	(60%)	64	(63%)
Sheffield	122	78	(64%)	56	(46%)
South Thames	456	273	(60%)	196	(43%)
West Midlands	351	221	(63%)	165	(47%)
West of Scotland	136	65	(48%)	70	(51%)

Donor transplant coordinator team	Number of potential HB donors	Number of referrals (referral rate)	Number of conversions (conversion rate)

Table 3 **Number of families approached and the refusal rate**

Donor transplant coordinator team	Number of potential HB donors	Number of families approached	Number of refusals (refusal rate)	Risk adjusted refusal rate
Belfast	176	149	67 (45%)	42%
Bristol	99	88	28 (32%)	39%
Cambridge	128	117	46 (39%)	37%
Cardiff	198	169	56 (33%)	29%
East of Scotland	87	76	24 (32%)	40%
Leeds	214	185	76 (41%)	41%
Leicester	75	60	23 (38%)	37%
Liverpool	278	227	90 (40%)	41%
Manchester	327	277	104 (38%)	40%
Newcastle	266	225	97 (43%)	41%
North of Scotland	43	39	14 (36%)	41%
North Thames	575	480	243 (51%)	41%
Nottingham	96	81	33 (41%)	41%
Oxford	171	151	57 (38%)	39%
Plymouth	90	83	27 (33%)	40%
Portsmouth	102	86	16 (19%)	29%
Sheffield	122	109	48 (44%)	43%
South Thames	456	369	145 (39%)	40%
West Midlands	351	317	138 (44%)	41%
West of Scotland	136	109	35 (32%)	40%

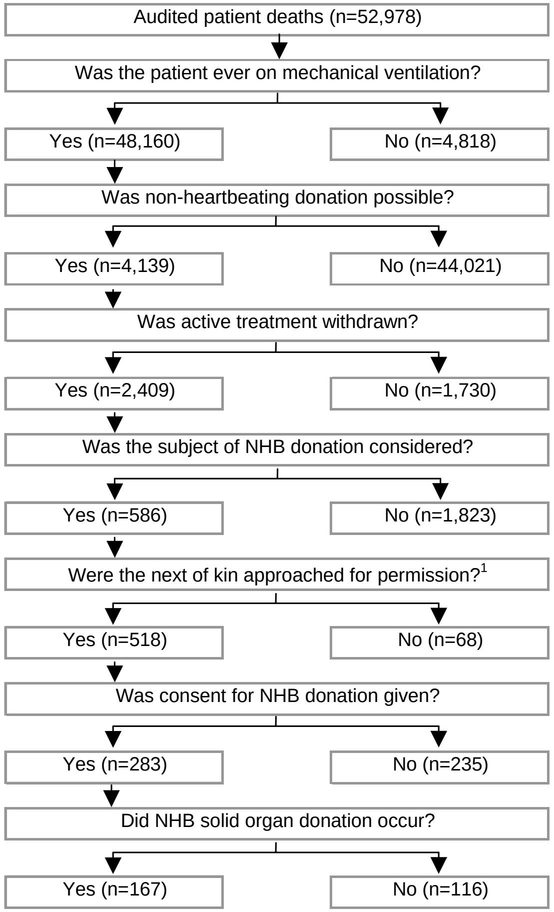
The number of potential donors whose family were approached for consent to donation and the number who refused consent are shown in Table 3, by DTxC team. The unadjusted refusal rates range from 19% in Portsmouth to 51% in North Thames and there is a significant difference across the teams, p<0.001. Risk adjusting the refusal rate for patient age, sex and ethnicity and temporal effects takes account of most of the variation, but there are still some differences between the teams, mainly due to two teams having a lower refusal rate than nationally.

Potential For Non-Heartbeating Donation

The potential for non-heartbeating donation could be obtained from the PDA forms from January 2004 onwards. The following results comprise data for all audited patient deaths in UK ICUs over the period 1 January 2004 to 31 March 2006. Some of the subgroup analyses are based on relatively small numbers of individuals and as a consequence some of the percentages quoted suffer from a lack of precision and should be regarded with some caution.

In this 27-month period there were a total of 52,978 audited patient deaths in UK ICUs. A detailed breakdown of the 52,978 audited patient deaths is given in Figure 4, and Table 4 summarises the key percentages by financial year.

Figure 4 **A breakdown from audited patient deaths to NHB donors**



[1] Includes cases where the next of kin made the approach

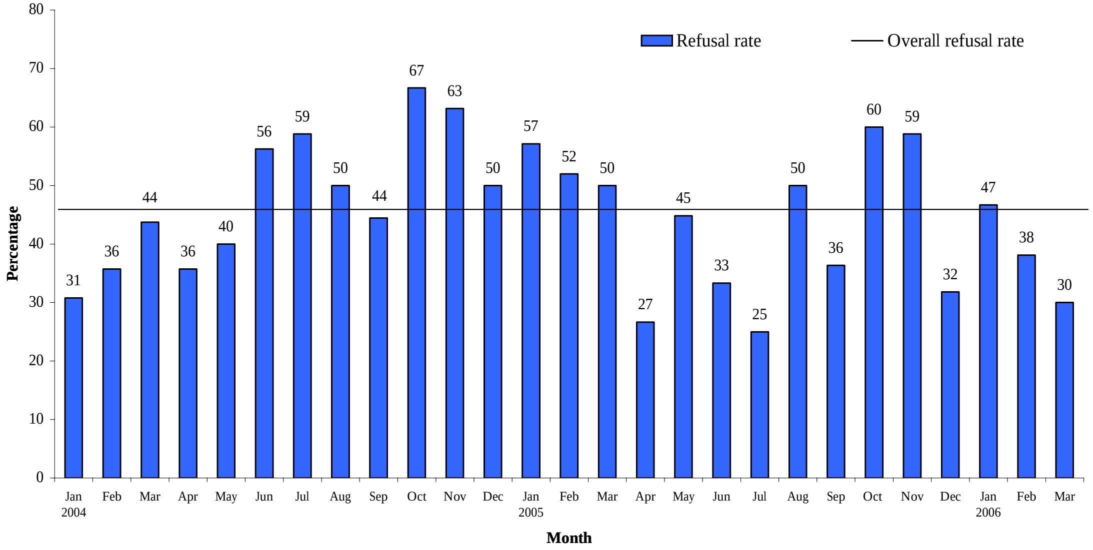
Table 4 Summary of key percentages from ventilated patients to NHB donors

	Jan-Mar 2004 N	2004/2005 N	2005/2006 N	TOTAL N
Patients on mechanical ventilation at some point during their stay in ICU	5,494	21,989	20,677	48,160
NHB donation possible	455	2,076	1,608	4,139
Potential NHB donors - active treatment withdrawn (percentage of NHB donation possible)	307 (67%)	1,251 (70%)	851 (53%)	2,409 (58%)
No record of discussion/approach regarding NHB solid organ donation (percentage of potential donor families)	264 (86%)	1,030 (82%)	597 (70%)	1,891 (78%)
Consent given for NHB solid organ donation (percentage of families who were approached)	27 (63%)	105 (48%)	151 (59%)	283 (55%)
Consent not given for NHB solid organ donation (percentage of families who were approached)	16 (37%)	116 (52%)	103 (41%)	235 (45%)
Actual NHB solid organ donors, based on data provided through the PDA (percentage of patients with family consent)	19 (70%)	60 (57%)	88 (58%)	167 (59%)

The overall refusal rate for 518 potential NHB donors whose families were approached or made the approach during the 27-month period was 45% and the 95% confidence limits for this percentage range from 41% to 49%. Note that these limits are wider than those for the refusal rate for HB donors.

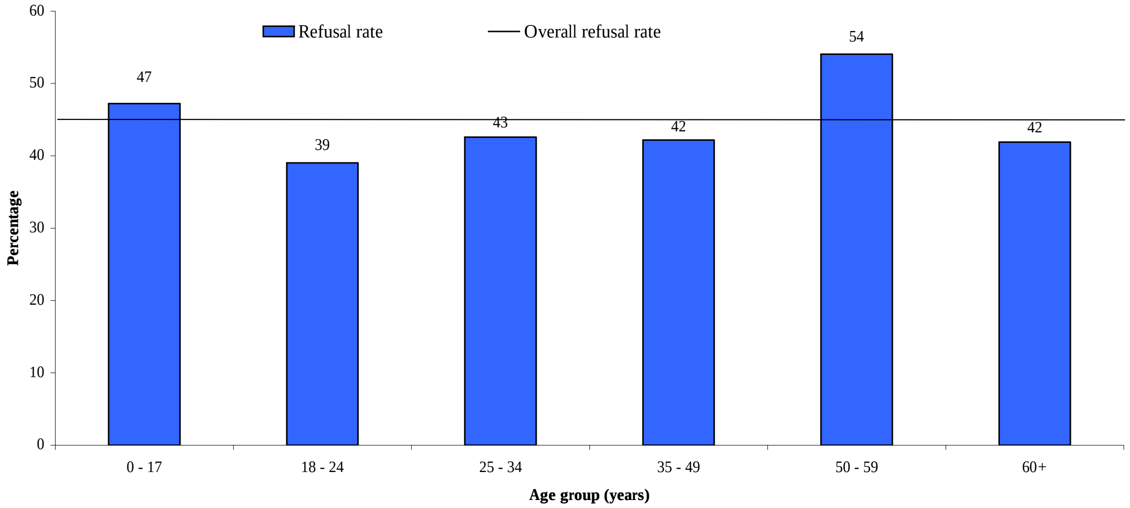
When looking at the month-to-month variation, the refusal rate was highest in October 2004 (67%) and lowest in July 2005 (25%). This can be seen in Figure 5. The differences in the monthly NHB refusal rates over the 27-month period were not statistically significant (p=0.4).

Figure 5 Month-to-month variation in NHB refusal rate



The refusal rates for males and females were 43% and 49%, respectively, with no statistically significant difference between them (p=0.2). There was also no significant difference in the refusal rate between the six age groups 0 - 17, 18 - 24, 25 - 34, 35 - 49, 50 - 59 and 60+ (p=0.3). The refusal rates for these age groups are shown in Figure 6.

Figure 6 **Age variation in NHB refusal rate**



Ethnicity information was available for 456 (88%) of the 518 potential NHB donors whose families were approached for consent. Of these potential donors, with known ethnicity, 24 were non-white and in 19 (79%) of these cases consent for donation was not given. The refusal rate for white patients was 39%, with a 95% confidence interval of 34% to 44%. There is evidence to suggest differences in the refusal rate between white and non-white patients, but the number of non-white patients analysed is very small.

Summary

In the 36-month period, 1 April 2003 to 31 March 2006, there were 3,990 potential HB donors. The overall HB refusal rate, for the 3,397 patients whose relatives were approached or made the approach for consent to donation, was 40%, although there is evidence of variation in this rate over the time period analysed. There is also a clear difference in the refusal rates for white and non-white potential HB donors, but no differences related to sex or age group. The overall HB approach rate was 94%.

There are significant differences in the referral, conversion and refusal rates for HB donation across the donor transplant co-ordinator teams. Risk adjusting the refusal rate for patient age, sex and ethnicity and temporal effects takes account of most of the variation, but there are still some differences across the teams, mainly due to two teams having a lower refusal rate than nationally.

In the 27-month period, 1 January 2004 to 31 March 2006, there were 2,409 potential NHB donors. The overall NHB refusal rate, for the 518 patients whose relatives were approached or made the approach for consent to donation, was 45%. There was no statistical evidence of variation in this rate over the time period analysed. There was also no significant difference in the refusal rate between males and females or across the age groups. There was evidence of differences in the refusal rate between white and non-white patients, although the numbers used in the analysis were small.

Miss Claire Hamilton, Mrs Joanne Blackwell and Dr Dave Collett, UK Transplant, September 2006

Appendix 6: Support & Encouragement for Trust CEOs to Increase Organ Donation

Objective: *To understand senior manager's attitudes and knowledge of organ donation.*

Key Messages:

- There was support for amongst CEOs/COOs and others for organ donation.
- Most CEOs/COOs reported that organ donation did not feature strongly, if at all, in their priorities.
- Those interviewed from Strategic Health Authorities were uncertain as to what their role was in promoting organ donation.
- Most of those interviewed had seen little performance information in general or relating to their area of work.
- In terms if incentives, a "carrot" rather than "stick" approach" would yield more results.
- Those in intensive care reported concerns over non heart beating donation (see previous sections on legal and ethical issues).

Contents:

- Investigating the role of NHS Trust Chief Executives/Divisional Chief Operating Officers in the future of transplantation in the UK

Appendix Commissioned by: UKT

Investigating the role of NHS Trust Chief Executives in the future of transplantation in the UK

Prepared by Dr Jennie Jewitt-Harris

Visits completed between March and May 2007

Background

The current strategic plans for UK Transplant include good relationship development with key customers, an increase in both living and deceased donation, incorporating a decrease in refusal by relatives, and enhanced support from centres with the greatest potential for organ donation.

All of the above require the Chief Executives and other key senior managers of NHS Trusts to support organ donation in their centres, including those key centres where transplantation is not undertaken but which have a significant number of potential donors e.g. major neurosurgical centres.

The main objective of this project was to work with key Trust Chief Executives,/Chief Operating officers and Medical Directors, to:

- Gain an understanding of their perspective on organ donation and transplantation
- Identify any barriers to organ donation within their trust, either as a transplant centre or as a potential provider donor organs
- Establish their needs in relation to organ donation, and
- Make recommendations to UK Transplant based on the information gathered.

Outcome of this Project

To provide UK transplant with an insight into the thinking of NHS Trust Chief Executives/Chief Operating Officers and Medical Directors regarding organ donation – and how their future support can be gained to improve the success of the organ transplant programme.

Objectives

To establish a relationship with key Trust Chief Executives/Chief Operating Officers and Medical Directors/Clinical Directors

To understand their perceptions of organ donation, their motivation to help it to succeed and the barriers to achieving this

To provide a summary of feed-back to UK Transplant and recommendations based on the findings

Process

The following steps were undertaken:

- Identification of 5 key NHS Trusts including
  - Trusts with transplantation units (particularly those with more than one organ transplantation unit)
  - Trusts with no transplant unit but greatest potential for organ donation
  - A trust in Wales and Division in Scotland
- Establish in greater depth with UKT the detail of the questions that need to be asked (meeting with David Shute and Sue Falvey)
- Identify the Chief Executives and Clinical Directors
- Chris Rudge wrote to Chief Executives outlining the purpose of the meetings
- Dr Jennie Jewitt-Harris held one to one meetings with Chief Executives/Operating Officers and other Directors
- One Strategic Health Authority was contacted to gain a regional perspective on the issues discussed
- Dr Jennie Jewitt-Harris recorded the detail of all the interviews
- Presentation and recommendations to UK Transplant

Centres identified and visited

Newcastle Upon Tyne Hospitals NHS Trust	• Chief Executive • Medical Director • Clinical Director • ITU Director
North West Wales NHS Trust	• Chief Executive

Sandwell and West Birmingham Hospitals NHS Trust	• Chief Executive • Medical Director
NHS Forth Valley Acute Division	• Chief Operating Officer • Medical Director
Oxford Radcliffe Hospitals NHS Trust	• Chief Executive • Medical Director • ITU Director
NHS London – Strategic Health Authority	• Director of Public Health

Summary of findings:

Overall, all Chief Executives and Medical Directors of trusts were willing to meet and discuss organ donation. The two SHAs contacted did not see organ donation as part of their remit. The meeting held with Sheila Adam from the London SHA was informative in terms of her personal enthusiasm for transplantation, but not in terms of any role that the SHA intends to play in the future.

Summary of feed-back from Chief Executives:

For most of the Chief Executives /Chief Operating Officers, organ donation had not been on their agenda at all. They had not seen anything in terms of documentation pass their desks, and had not given it any thought until the meeting – unless there had been specific issues raised. The Chief Executives that were most engaged with it were those with transplant units within their trust.

Most however had never seen any data relating to the performance of their trust in providing organs for donation. Most didn’t seek it before the meeting, but two did.

They were all highly supportive of organ donation, and were keen to know the performance of their trust. There was a high level of interest in understanding the issues, and addressing them where possible. They had not previously seen it as part of their remit to take an active interest in organ donation, but all were aware of the benefits of transplantation, both medical and financial, and were willing to play the appropriate role to support it in the future.

Perceptions of barriers to organ donation:

Chief Executives/Operating Officers generally suspected a high level of refusal by relatives to consent/authorisation , and were concerned that donation was affected by the pressures that ITUs are under for beds. Two centres identified the motivation and leadership of ITU Directors as critical motivators or barriers (depending on the commitment of the ITU Director). There was some concern that poor relationships with retrieval teams had created barriers.

One Chief Executive identified lack of clarity about the point of contact with UKT as a barrier to making progress.

The main barrier that was universal was a lack of data and information on which to base any discussion and look for routes to make progress.

Perceptions of motivators to organ donation:

All Chief Executives/Operating Officers would be motivated (as they also felt would their colleagues involved) by data showing their performance with regard to conversion, in comparison with previous years and with other trusts/Divisions/centres.

All Chief Executives/Operating Officers talked about “natural competitiveness” and raising performance above national averages. Comparative data vs other trusts/Divisions, even when not related to any performance targets, would have an impact on them – and make them want to address any apparent poor performance. This would be particularly evident if compared with other local trusts.

Some Chief Executives/Operrating Officers referred to financial incentives and targets, but this was not universal. Those that did found it hard to see how either could work, and still seemed motivated by the prospect of benchmarking and local data. One Chief Executive explored in great detail how it might be possible to turn organ donation into a target – but still concluded that he would act as much upon local data vs regional and national.

They would welcome the opportunity to praise high performing teams within their trust if the data showed them to be doing well. They suggested that UKT encourages them to do this where appropriate.

All Chief Executives/Operating Officers fully supported transplantation in general, and were keen to know how many patients in their trust/division had benefited, and would also like to see regular data on this point. It would help them to make the “connection” between the value they were getting from transplantation, and the organs that their trust was supplying.

They would all like to receive succinct data, with local, regional and national comparisons. If it is clearly laid out and quick to read they would all take action as requested – i.e. to address an issue, pass on thanks, investigate further etc. This may mean delegation which, in most cases, would be to the Medical Director. They stressed the need for UKT to provide them with the tools to make the changes, and to clearly communicate the action that would be required – in a collaborative way.

Summary of feed-back from Medical Directors:

As with the Chief Executives/Operating Officers, there was a higher level of previous exposure to organ donation issues in trusts with a transplant centre. Otherwise the level of engagement had been very low, and most had not given any thought to organ donation before this meeting.

From all Medical Directors there was a high level of interest and engagement with the issues. Some regarded it as “their remit” to ensure that the trust was performing to the highest level. Those that didn’t currently were receptive to doing so.

All would appreciate regular reliable data and clearer guidance from UKT and all would act upon it. They asked for clear data on the performance of their trust, over time and compared with national data.

They suggested using already existing peer group meetings such as the Medical Directors Group in Scotland as a route for UKT to communicate with and “make passionate presentations to” to engage the Medical Directors community in organ donation.

Perceptions of barriers to organ donation

Most Medical Directors saw other pressures (at all levels) as being the main barrier to donation. These ranged from pressures on staff in ITUs to pressures of the Chief Executives/Chief Operating Officers with regards to finance and targets.

Most discussed the barriers to consent as being a key issue. Some were also concerned about variable levels of training of ITU staff, and the fact that it is not adequately addressed on the Medical School curriculum. Some felt that if staff came from a transplant centre to work on an ITU that there would be much more enthusiasm as they had a greater understanding of the impact and issues.

Perceptions of incentives to organ donation

As with the Chief Executives/Operating Officers, data were key to informing them about best clinical practice – and appealing to their professionalism.

Local transplant centre interest and enthusiasm could really help to motivate ITUs and more could be done to utilise this.

More knowledge about the number of patients in the trust that are benefiting would also help to motivate ITU staff and Chief Executives/Operatimng Officers as well as the Medical Directors themselves.

Most Medical Directors felt that the Chief Executive/Operating Officer would only engage with the issue if it was related to finance and targets – and that UKT would therefore need to point out the financial benefits to increasing organ donation nationally.

Medical Directors would like to see “more carrot and less stick” from UKT, and leadership on how to address issues in donation. This, coupled with good well-collected reliable trust/divisional data would provide a real incentive to making changes.

Most would also be motivated by a better understanding of the work that UKT is doing to change public perceptions about transplantation, and to decrease refusals – so that they could echo these messages in their own trusts.

Summary of feedback from ITU Directors

There was a high level of motivation to support organ donation – but clearly a lot of stress related to it. Issues relating to NHBD in one centre were causing significant problems which could be spilling over into the relationships needed to sustain heart beating donation. They felt a lot of pressure from UKT but not a lot of support or encouragement and recognition.

Their motivation related to good clinical practice, good medicine and leadership – particularly around transplant centres. They would all be keen to see appropriate benchmarking data and would appreciate "being left to get on with it". They only referred to Medical Directors if there were issues, and did not see a place for involving the Chief Executive/operating officers unless there was a financial or wider issue.

Summary of Findings

- There was a high level of motivation to improve organ donation where there was scope for this to be achieved.
- There is a need for more data and communication on trust performance
- Appealing to natural competitiveness and a desire to improve services will lead to action to address organ donation issues
- Information sent to Chief Executives/Operating Officers, if clear and succinct, is likely to result in action
- These visits in themselves created some action. For example, the Chief Operating Officer in Forth Valley was motivated by it to encourage a local "clinical champion" to investigate the performance of the Division.

Recommendations

Review the option of providing annual organ donation data by trust to all Chief Executives/Operating Officers, Medical Directors and ITU Directors. Some have offered to "pilot" this by giving feedback on the data presentation etc.

The report would ideally contain:

- Individual ITU data on conversion and other key statistics
- National data
- Regional data
- An A4 summary with clearly visible summaries of performance
- Access to more data for further analysis/comparison
- A reminder of national issues and measures being taken to address them

- Clarity on what action is expected

Further visits to Chief Executives/Operating Officers and Medical Directors with particular issues:

- Acknowledgement of the role of ITUs and measures to develop a collaborative relationship with them. This may include engagement with existing regional ITU groups.
- Review of ways in which trust communications departments can be involved in national campaigns to support organ donation, including dissemination of messages internally i.e. within the trust /division
- Review of Medical School and Nursing training in transplantation and organ donation
- Seek points of contact with Medical Directors e.g. Scottish Association of Medical Directors
- Follow up on the Falkirk initiative to nominate a “clinical champion” for the Division.
- Review opportunities to write to Medical Directors (and possibly ITU Directors) to keep them informed of national issues and campaigns and to maintain their engagement with organ donation during the interim period between annual reports

Appendix 7: Option Appraisal – Donor Transplant Co-ordinators

Objective: *To present the various options for providing a Donor Transplant Co-ordination service in the UK*

Key Messages:

- Current employment arrangements, whereby DTCs are employed by various Trusts/Divisions, is unsustainable.
- From an analysis of the various options direct employment by a central organisation was seen as the only viable option to provide consistent and high performing DTCs.

Contents:

- Option Appraisal – Donor Transplant Co-ordinator

Appendix Prepared by: UKT Support Group

Options Appraisal for donor co-ordination services within the UK

Strategic Position

Since 2001 UKT Transplant (UKT), now an operating division of NHS Blood and Transplant, has had responsibility for the provision of central support and leadership to donor co-ordination services within the UK. This responsibility has been discharged through the establishment of a Director of Donor Care and Co-ordination supported by a senior management structure providing professional leadership at a regional level.

Significant progress has been made within the donor transplant co-ordination (DTC) service with improvements in working practices being supported by the implementation of national standards, protocols and policies.

Whilst the adoption of these improvements has brought quality gains in donor management and the donor family experience, the supply of donor organs has only marginally improved and remains a significant limiting factor in the number of transplants able to be performed in the UK.

DTC services at a local level have developed from an historic synergy with renal services, and whilst logical in its day, such close links are now impacting upon the efficiency of the NHS to provide a DTC service that operates within a national framework. One of the major consequences of this historic link was the development of the duel role co-ordinator whereby an individual would have clinical responsibilities not only for donor facilitation, but also for care of recipients. Due to the unpredictable nature of donor co-ordination this often meant that there was a compromise within both aspects of the role. A situation that was less problematic whilst programmes were in their infancy. Although now largely separate, this duel role does remain in some units despite a body of evidence to support the separating of the donor and recipient role.

Problems associated with delivering a national model for DTC services whilst not directly managing those individuals responsible for the service at a local level has also led to a degree of sub optimality. Competing agendas between an employing organisation and UKT has placed local DTC services in conflict and often led to frustration and confusion within the service.

The establishment of a Ministerial Review and the DH Organ Donation Taskforce provides an opportunity to examine the existing organ donation and transplantation service and propose an alternative. This opportunity challenges recent trends in health service reconfiguration by proposing a national solution whilst maintaining health delivery at a local level. This will remove barriers that currently reduce the efficient and effective delivery of the service and will result in a significant increase in donor numbers.

This paper sets out three options for the future provision of DTC services within the UK.

Scoring

A number of criteria were identified as being the most valuable to improving DTC services. A weighting was applied to each criteria where 5 was most important and 1 was least important. Each criterion was then ranked with a score of 1 to 5 based on the likely success of the criteria in relation to the individual option. These two figures were then multiplied together and totalled to give an overall value for each option

Option 1 - Do Nothing

Introduction

This option explores the strengths and weaknesses of maintaining the status quo within DTC services. This 'Do Nothing' option has the major disadvantage is that any catalyst for change and service improvement will be lost.

The potential weakness to such a change and service improvement programme is that it is accompanied by a degree of uncertainly. This makes the Do Nothing option seem attractive to those within the service for whom change process is undesirable.

Strengths

- No additional costs for the provision of DTC services
- No disruption to the current DTC service
- No addition costs to UKT division to support new DTC model
- No new estate or building rental costs
- No additional training for DTCs as model is unchanged
- No increase in NHSBT costs for provision of expanded HR services
- No increase in NHSBT costs for provision of expanded IT costs
- No increase in clinical governance responsibility
- No increase in Health and Safety responsibility
- Maintains a degree of goodwill to those currently providing DTC services who would be resistant to change

Weaknesses

- Local employment of DTCs reduces the workforce flexibility to provide a national framework model where vacancies occur. The inability to cross cover vacancies within DTC services impacts upon the robustness of a local service which may result in missed donation
- Maintains sub optimal line management support for DTC services. DTCs are line managed by managers without experience or an in-depth understanding of the specialism
- Maintains, in some areas, conflicting role between donor and recipient services.
- Perpetuates local versus national priorities in DTC services. DTC services may operate around local preferences at the detriment to the national organ allocation model
- Current DTC service is not outcome focused
- Increased risk of non delivery of local DTC services due to their small size and inability to respond to recruitment problems
- Location of local DTC services are based on historic renal service sites and not where donor potential has been identified. Sometimes making the service inefficient in terms of travel etc
- Increased clinical governance risk for NHS Trusts/Divisions who are responsible for DTC services without fully understanding their responsibilities
- Split between the professional and the managerial lines of support
- Potential for short term vacancies within DTC services as those who would support a new model become disillusioned and leave the service
- Maintains parochial mindset
- Management by influence remains with all the incumbent problems for UKT
- Competing healthcare agenda at a local level between provider and primary care commissioner seen as risk to service
- Maintains professional differentials within DTC bandings since adoption of the Agenda for Change programme
- Difficulty in developing, implementing and enforcing national standards and policies and procedures

Scoring

The following table shows the outcome of this Option 1 when measured against the critical success factors

Criteria	Weighting	Value	Outcome
Costs	3	5	15
Increase donor numbers by reducing relative refusal rates,	5	1	5

better identification and conversion of donors and achieving more suitable organs per donor			
Improve and maintain the standards of the Donor Co-ordination Service throughout the UK	5	2	10
Ensure that Donor Co-ordination Services can adapt to future changes	3	1	3
Ensure that Donor Co-ordination Services are responsive to performance management methods	4	2	8
Ensure complete separation of donor and recipient co-ordinator role	4	3	12
Ensure Donor Co-ordination Services can respond flexibly to variations in donation demands	3	1	3
Removal of the parochial mindset around nation or local organ donation	3	1	3
			59

Option Two - Commissioning Model (a)

Introduction

This option is based on NHSBT through the UKT operating division contracting through a hybrid commissioning arrangement with NHS Trusts /Divisionsfor the provision of DTC services. It assumes there is NO change to existing DTC service location, but looks to bring about service change and improvement by the implementation of a robust contractual and financial framework

Unlike the standard commissioning models for the NHS the ability for UKT to move co-ordination services to more competitive and or efficient providers is constrained. Factors that limit ability to move DTC services include the geography and travel time for DTCs to access potential donors, the high costs of entrance to the market for providers and the recognition by those providers that their service model is free from market forces.

In reality this means that this commissioning model does little other than detailing UKT service specifications within a contract that more fully recognises providers' operational costs.

Strengths

- Full costs of the providing the DTC service are recognised and passed to the service provider within a service level agreement framework
- Improved accountability for UKT detailed within service level agreement framework
- Increased ability to improve and change DTC services through development of service specifications contained within service level agreement framework
- Improved synergy of professional and managerial accountability through development of service specifications contained within service level agreement framework

Weaknesses

- Any commissioning model would need local modification to suit differing requirements within Devolved Administrations
- Increased donor / transplant activity would increase primary care lifecycle costs, which may not be supported
- Increased level of complexity required to implement and manage commissioning model
- Increased costs within UKT division to implement and manage commissioning model
- Perpetuates UKT division remoteness from donor operational issues
- Inexperience of commissioning model requiring increased costs for local training, development and implementation
- Fails to reduce the risk of under performing service provision despite Service Level Agreement
- Commission model flawed as UKT unable to relocate service to new provider
- Disruption to current DTC service
- Resolution and agreement of true costs for the provision of DTC services may not be achieved
- DTC services still exposed to competing resources and agendas within provider setting despite Service Level Agreement
- Maintains parochial mindset
- Maintains professional differentials within DTC bandings since adoption of the Agenda for Change programme
- Potential for short term vacancies within DTC services as those who do not support a new model become disillusioned and leave the service
- Difficulty in identifying current funding within system and or extracting this funding from current allocations

Scoring

The following table shows the outcome of this Option 2a when measured against the critical success factors

Criteria	Weighting	Value	Outcome
Costs	3	3	9
Increase donor numbers by reducing relative refusal rates, better identification and conversion of donors and achieving more suitable organs per donor	5	3	15
Improve and maintain the standards of the Donor Co-ordination Service throughout the UK	5	3	15
Ensure that Donor Co-ordination Services can adapt to future changes	3	2	6
Ensure that Donor Co-ordination Services are responsive to performance management methods	4	2	8
Ensure complete separation of donor and recipient co-ordinator role	4	4	16
Ensure Donor Co-ordination Services can respond flexibly to variations in donation demands	3	1	3
Removal of the parochial mindset around nation or local organ donation	3	2	6
			78

Option Two - Commissioning Model (B)

Introduction

This option is based on NHSBT through the UKT operating division contracting through a hybrid commissioning arrangement with a reduced number of NHS Trusts for the provision of DTC services.

These would be based and located in centres more appropriate for the provision of organ retrieval and retrieval teams and would equate to around nine in number. It assumes changes to existing DTC service location, and would seek to use this opportunity as the catalyst to bring about service change and improvement.

Whilst many of the strengths and weakness for this option are similar to that of Commissioning Model (A), there are some explicit differences.
It is still true that unlike the standard commissioning models for the NHS the ability for UKT to move DTC services to more competitive and or efficient providers is constrained. Factors that limit ability to move DTC services include the geography and travel time for DTCs to access potential donors, the high costs of entrance to the market for providers and the recognition by those providers that their service model is free from market forces
However in this model theses assumptions .are more open to challenge. Fewer but larger providers may be able to respond more competitively to opportunities and will control the market place, thus potentially, providing UKT with an opportunity to move services easier

Strengths

- Full costs of providing the DTC service are recognised and passed to the service provider within a service level agreement framework
- Improved accountability for UKT detailed within service level agreement framework
- Increased ability to improve and change DTC services through development of service specifications contained within service level agreement framework
- Improved synergy of professional and managerial accountability through development of service specifications contained within service level agreement framework
- Reduced risk of DTC vacancies as new model seen as attractive to current disillusioned staff group

Weaknesses

- Any commissioning model would need local modification to suit differing requirements within Devolved Administrations
- Increased donor / transplant activity would increase primary care lifecycle costs, which may not be supported
- Increased level of complexity required to implement and manage commissioning model
- Increased costs within UKT division to implement and manage commissioning model
- Perpetuates UKT division remoteness from donor operational issues - although less than Do Nothing option
- Inexperience of commissioning model requiring increased costs for local training, development and implementation
- Fails to reduce the risk of under performing service provision despite Service Level Agreement
- Disruption to current DTC service
- Resolution and agreement of true costs for the provision of DTC services may not be achieved

- DTC services still exposed to competing resources and agenda within provider setting despite Service Level Agreement
- Maintains parochial mindset - although less
- Difficulty in identifying current funding within system and or extracting this funding from current allocations
- Potential for short term DTC vacancies as new model in new locations does not suit individuals
- Increased operational costs as size of teams increase
- Increased short term relocation / transient costs
- Loss of goodwill to those currently providing DTC services who would be resistant to change

Scoring

The following table shows the outcome of this Option 2b when measured against the critical success factors

Criteria	Weighting	Value	Outcome
Costs	3	2	6
Increase donor numbers by reducing relative refusal rates, better identification and conversion of donors and achieving more suitable organs per donor	5	3	15
Improve and maintain the standards of the Donor Co-ordination Service throughout the UK	5	3	15
Ensure that Donor Co-ordination Services can adapt to future changes	3	3	9
Ensure that Donor Co-ordination Services are responsive to performance management methods	4	3	12
Ensure complete separation of donor and recipient co-ordinator role	4	4	16
Ensure Donor Co-ordination Services can respond flexibly to variations in donation demands	3	1	3
Removal of the parochial mindset around nation or local organ donation	3	3	9
			85

Option Three - single national employer

Introduction

This option is the only option that fully addresses, and as a result negates, the current problems of trying to provide a national service through a local framework. Direct employment provides an improved DTC service by ensuring the development, implementation and enforcement of professional standards is achieved, whist at the same time offering the DTC professional a secure and robust framework from within which to operate. It is also the only option that provides a real opportunity to ensure that DTC services can deliver the predicted increases in donor activity and changes to organ retrieval models discussed elsewhere.

Strengths

- Improved flexibility with DTC workforce
- Improved delivery of new DTC model
- Improved synergy with new organ retrieval team model
- Ability to standardise terms and conditions of employment through UK
- Removes dichotomy between professional and managerial lines of support
- Increased ability to develop, implement and enforce national standards and policies and procedures
- Improved quality of service to NHS users
- Improved family donor experience
- Improved donor outcomes
- Follows international models for DTC services
- Improves international benchmarking opportunities
- Local modification to suit requirements within Devolved Administrations possible
- Removes the risk of under performing service provision
- DTC services not exposed to competing resources and agenda within provider setting
- DTC services not exposed to competing resources and agenda within provider primary care interface
- Removes parochial mindset
- Removes professional differentials within DTC bandings since adoption of the Agenda for Change programme
- Improved career opportunities within new DTC model
- Improved clinical governance
- Removes current conflicting role between donor and recipient services.
- Removes local versus national priorities in DTC services

- Increased size of DTC services increases the ability to respond to recruitment problems
- Location of local DTC services matched to where donor potential exists
- Improved retention within DTC profession
- Ability to develop, implement and enforce national standards and policies and procedures
- Clearer clinical governance arrangements

Weaknesses

- Increase in NHSBT staffing levels against principles of Arm's Length Body review
- Increase in NHSBT costs for provision of expanded HR services
- Increase in NHSBT costs for provision of expanded IT services
- Increase in Health and Safety responsibility
- Increase in clinical governance responsibility
- Significant increase in operational costs
- Disruption to DTC service
- Development and implementation of new UKT structures to support model
- Change in UKT workforce profile to 50% remote working
- Expansion of facilities (remote) to locate additional workforce - increased rental costs
- New DTC model identifies shortfall in skill set of current DTC staff
- Redundancy costs due to relocation of DTC services.
- Poor fit with Devolved Administration model
- Loss of goodwill to those currently providing DTC services who would be resistant to change

Scoring

The following table shows the outcome of this Option 3 when measured against the critical success factors

Criteria	Weighting	Value	Outcome
Costs	3	1	3
Increase donor numbers by reducing relative refusal rates, better identification and conversion of donors	5	5	25

and achieving more suitable organs per donor			
Improve and maintain the standards of the Donor Co-ordination Service throughout the UK	5	5	25
Ensure that Donor Co-ordination Services can adapt to future changes	3	5	15
Ensure that Donor Co-ordination Services are responsive to performance management methods	4	5	20
Ensure complete separation of donor and recipient co-ordinator role	4	5	20
Ensure Donor Co-ordination Services can respond flexibly to variations in donation demands	3	4	12
Removal of the parochial mindset around nation or local organ donation	3	5	15
			135

Recommendation

The 'Do Nothing' option perpetuates the problems of UKT having to deliver a national service through influence. It fails to address the known problems within the DTC service that occur at a local level and that impact upon national outcomes. It misses the opportunity to implement a new service model and maintains the current position where service funding is inadequate and subject to local pressures.

Option Two A and B, whilst providing UKT with a more robust framework within which to work, where a fully costed service is commissioned, it still fails to pass management responsibility for a national programme to a national provider. There is a significant risk that delivery will suffer from local variance as DTC teams remain within the control of local provider organisations.

Option Three is the preferred option. It is the only option that provides a national model of DTC services managed and fully funded by a national organisation. It puts accountability for delivery solely within a single organisation and by doing so it allows that organisation to develop new service models mirroring that of other first world countries that have shown increases in donation activity and donor quality by adoption of similar frameworks. By having national ownership the organisation is best placed to develop new service models that will be responsive to changes within the organ retrieval team structure and more importantly the fluidity and flexibility within this national model makes it the only option that is able to influence and respond to the required increase in donation rates

Scoring

The following summary table shows the outcome of all options when measured against the critical success factors

Criteria	Option 1 Do Nothing	Option 2a Commissioning Model A	Option 2b Commissioning Model B	Option 3 Single National Employer
Costs	15	9	6	3
Increase donor numbers by reducing relative refusal rates, better identification and conversion of donors and achieving more suitable organs per donor	5	15	15	25
Improve and maintain the standards of the Donor Co-ordination Service throughout the UK	10	15	15	25
Ensure that Donor Co-ordination Services can adapt to future changes	3	6	9	15
Ensure that Donor Co-ordination Services are responsive to performance management methods	8	8	12	20
Ensure complete separation of donor and recipient co-ordinator role	12	16	16	20
Ensure Donor Co-ordination Services can respond flexibly to variations in donation demands	3	3	3	12
Removal of the parochial mindset around nation or local organ donation	3	6	9	15
	59	**78**	**85**	**135**

Appendix 8: The Role of Coroners

Objective of this Appendix: *To identify the impact of Coroners on organ donation*

Key Messages:

- Although the biggest reason why brainstem dead patients did not go onto become organ donors was family refusal there were other circumstances where the opportunity for organ donation was lost.
- Legal obstacles appear to have a significant impact, particularly:
  - Why the family was not approached (24%)
  - Where the family consented/authorised, but donation could not proceed (11%)

Contents:

Appendix Prepared by: Dr Paul Murphy, Consultant in Neuroanaesthesia and Neurocritical Care, The General Infirmary at Leeds

Why do brainstem dead patients not go on to donate their organs? An analysis of data from the UK Potential Donor Audit.

An audit of the organ donation potential of all patients dying on intensive care units (ICUs) in the United Kingdom (UK) began in April 2003, and demonstrated that family refusal is the biggest single reason why patients who are brainstem dead (BSD) do not go on to donate their organs[45]. However, it also suggested that there were three other groups of BSD patients whose potential to donate was unexpectedly lost, *viz.* those in whom donation appeared not to have been considered at all, those in whom donation was considered but the family not approached, and finally those in whom consent was obtained only for donation not to occur. This paper explores the real donor potential of these three groups, using supplementary data collected by potential donor audit (PDA) between April 2003 and December 2006.

The PDA incorporates all the key stages in the pathway from possible brainstem death to organ donation, and includes the three stages referred to above. The auditors are required to identify why such patients' donation potential might have been lost, with subsequent review allowing the reported explanations to be summarised under the major headings listed in the table below:

Reason for losing donor potential	donation not considered	family not approached	consented, donation did not take place
number of patients / year	140	75	70
	% total	% total	% total
cardiovascular instability	1.4	1.1	8.1
known family objection	14.7	28.5	10.2
legal obstacles	5.3	24.3	11.5
medical contra-indications	41.4	36.6	48.1
organ retrieval / allocation	not applicable	not applicable	5.1
unknown	37.2	9.5	17.0

Although medical unsuitability was the commonest reason for donation not to be considered, it was not always clear whether such decisions were made independently or after discussion with the local retrieval team. Prior knowledge that a family would reject a request to consider donation understandably appeared to influence whether a formal approach was made, and suggests that the actual family refusal rate in the UK is somewhat higher than the quoted figure of 40%[46], particularly when the effect of families who subsequently withdraw their initial consent is taken into account. Objections from the Coronial service or investigating police officers have also emerged as barriers to donation, as do problems with the availability of retrieval services or suitable recipients. It is concluded that efforts to improve the donation potential of these patients should focus on family consent/authorisation rates, conflict with legal enquiries and, possibly, improved liaison with local donor co-ordinators to improve the identification of “marginal donors”.

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[46] Barber K, Falvey S, Hamilton C, Collette D, Rudge C. *BMJ* 2006; **332:** 1124-1127

Appendix 9: International Approaches to Organ Donation

Objective of this Appendix: *To identify different approaches to increasing organ donation in other countries and to reflect how these lessons may be applicable to the UK.*

Key Messages:

- There are different approaches that can be taken to increase organ donation, there is no one that can deliver rapid and sustained increase in organs.
- The more successful countries tend to be those that have greater control and direct employment of, staff along the donation pathway and pay particular attention to performance.
- Spain has the highest rate of organ donation with 35 per million population. Although Spain is the only country in this study with “opt out” legislation15% of potential donors still did not proceed to donation due to consent.
- From a visit to the US the following issues were found to be critical in ensuring that all the key aspects of the donation pathway were meeting their full potential:
  - There was strong political leadership. This ranges from clear commitment to practical day-to-day issues.
  - The involvement of hospitals in organ donation was mandatory and there were substantial financial implications if this didn’t happen.
  - Hospital Donation Committees were useful forums to develop hospital commitment and to identify and deal with local blockages that prevent donation.
  - The role of the DTC was split into various key tasks.
  - It was recognised that improving organ donation was multi-factorial.

Contents:

- Table Showing International Approaches to Organ Donation
- Approach to Organ Donation within the US: Finding from a Visit to US Organ Procurement Organisations

Appendix Prepared by: UKT Support Group

Table Showing International Approaches to Organ Donation

The Aim of this Appendix is to give the reader an indication of alternative international approaches to organ donation. Each country has its own characteristics, both social and political and many more, which means one approach is not directly applicable elsewhere. The following table gives a very brief overview as to a few of these different approaches and the context in which they sit. At the end of each section there are measures. These give an indication as to where one country is compared to another. There are two caveats: firstly these measures are not intended to imply that there is a direct correlation between the approaches taken and the effect; secondly, there will be different approaches to how this information is obtained and processed.

Political, legal and societal context				
	England/Wales/NI	Spain	USA	Germany
Pre-consent: is there an “opt-in” or “opt-out” scheme	Opt-in (Informed consent)	Opt-out (Presumed consent)	Opt-in (Informed consent)	Opt-in (Informed consent)
Non Heart Beating Donation (NHBD)	Uncontrolled and controlled NHBD permitted	Only uncontrolled NHBDs; controlled NHBDs not permitted.	Uncontrolled and controlled NHBD permitted	Not permitted as declaration of death by brainstem testing mandatory for donation.
Measures: Donors Per Million Population - 2005	12.8	35.1	25.5	14.8

Registries that indicate a persons wish in life				
	UK	Spain	USA	Germany
Is there a registry scheme that allows a person to express their wish in life that their organs are to be donated after death?	Yes	No	In some States	No
Measures: % of population on a registry	24%	N/A	N/A	N/A

Donation pathway				
	UK	*Spain*	*USA*	*Germany*
Donor Transplant Co-ordination *1. Employment of medical staff* *2. Central employment*	No No	Yes Yes	No Yes - Employed by Organ Procurement Organisation (OPO)	No No
Organ Retrieval: dedicated or non-dedicated surgical staff	No		Some dedicated in OPOs some hospital based as in the UK	No
Organ allocation: central allocation scheme	Yes	No	Yes	No
Measures: Consent/authorisation	59%	85%	75%	Not known

rates (2005)				

Approach to Organ Donation within the US: Finding from a Visit to US Organ Procurement Organisations

A fact finding visit to the US to visit three Organ Procurement Organisations (OPOs) was arranged in order to see how organ donation services were structured and delivered in comparison with the UK.

OPOs are not-for-profit organisations responsible for the identification and care of organ donors, organ retrieval, organ preservation, transportation and data follow up regarding deceased organ donors. There are 58 OPOs in the US each covering an average population of 4.5 million with the smallest covering 1 million and the largest, California, covering 18 million. The Department of Health and Human Service (DHHS) certify the OPOs and they are regulated by the CMS (Centres for Medicare and Medicaid Services). The DHHS specify which counties the OPOs will serve in each State.

U.S. Congress established the Organ Procurement and Transplantation Network (OPTN) when it enacted the National Organ Transplant Act (NOTA) of 1984. The act called for a unified transplant network to be operated by a private, non-profit organisation under federal contract, this was awarded to the United Network for Organ Sharing (UNOS) who has administered the OPTN under contract since then.

There is a requirement for all OPOs to belong to the OPTN and under federal law all OPOs must be members to receive any funds through Medicare/Medicaid. All the OPOs have to meet set performance standards in order to remain designated.

The role of the Government in organ donation in the US is significant. This includes legislating that certain steps, particularly referral and request, take place and that OPOs meet a minimum donation rate benchmark for certification. Since 1998 hospitals have been mandated to have a relationship with their local OPO and are required to notify the OPO of all potential donors, failure to do so can result in the hospital being removed as a Medicare/Medicaid designated hospital which has financial implications for that hospital. In practice all deaths, or in the case of potential organ donors, all impending deaths, are notified to the OPO. In addition the mandate also stated that hospital staff should not consent families for donation unless they have received appropriate training.

In 2003, in order to improve transplant rates further the DHSS joined with key national leaders and practitioners to launch the Organ Donation Breakthrough Collaborative. The Collaborative was intended to dramatically increase access to transplantable organs and was committed to achieving donation rates of 75% or higher in the largest hospitals. At that time in the US 50% of eligible organ donors came from 200 hospitals. Fourteen of the largest hospitals in the US already achieved organ donation rates of 75% or greater. Many other large hospitals also had donation rates significantly higher than the national average of 46%. The aim of the Collaborative was to share practice and help other OPOs and hospitals achieve higher donation rates.

The Collaborative was seen to have been successful in achieving its aim.

Most hospitals have Donation Committees to support their donation programmes. Membership would normally include an ICU clinician and nurse/manager, an ER representative, a senior administrator, a representative from risk management and other ‘champions’ within the hospital as well as the OPO representative usually the hospital development manager.

The 3 OPOs visited were LifeGift, Houston, Gift of Life, Michigan and the New England Organ Bank, Boston. Operationally the OPOs were very similar although there were some differences.

All 3 OPOs had a 24 hour communications centre whose staff were responsible for triaging all the routine notifications of deaths or impending deaths. A significant number were deferred immediately due to unsuitability for donation; all ventilated patients were referred to the donor co-ordination team. Patients thought suitable for tissue donation were handled by the communications centre staff who were trained in telephone consenting and patient assessment.

All 3 OPOs had separate teams to deliver public education and raise awareness and a donor family liaison team for long-term family follow-up and support.

The donor co-ordination service broadly consisted of 4 distinct roles, a designated requestor for seeking consent, in most cases this person was also responsible for hospital development and was the in-house co-ordinator; a clinical donor co-ordinator responsible for donor management, donor assessment and organ allocation and an operating theatre co-ordinator. One of the OPOs had a completely separate team who were solely responsible for hospital development. By having distinct roles for delivering the donor co-ordination service resulted in 2 appropriately skilled staff attending when a potential donor was referred and a third for theatre if donation went ahead.

All the OPOs had developed a core concept that identified the core donating hospitals where an in-house co-ordinator, employed by the OPO, would be based. Some in-house co-ordinators were responsible for more than one site if the hospitals were geographically close. The in-house co-ordinator would be responsible for hospital development and would work closely with the key personnel who were regarded as the Chief Executive, the Chief Nurse and increasingly the ‘Quality Manager’.

All 3 OPOs saw the development of such a donor co-ordination service, ensuring that the appropriately trained staff were in these key posts, as fundamental to the success of the donation programme.

Performance management of all involved in the donation programme was deemed very important and robust arrangements were in place. Measures for both hospitals and OPOs and their staff included 100% identification and referral of all potential donors, 75% minimum target for the conversion of potential donors to actual donors and 3.75 organs retrieved per donor as supported by the Organ Donation Breakthrough Collaborative.

All the OPO staff were very outcome driven. Debriefs following potential donor referrals and actual donations were considered a high priority to review what had gone well and what could have been improved.

The commitment shown to deceased donation in the US, from the Government down, is undoubtedly key to the US achieving a donor per million population rate almost double that of the UK. The reasons for this success is, clearly multi-faceted however the fact that hospitals are mandated to refer all potential donors to their local OPO is considered a key component with hospitals required to be accountable for their donation activity.

Sue Falvey
Director of Donor Care and Co-ordination,
UK Transplant an Operating Division of NHSBT **April 2007**

Appendix 10: Glossary of Terms Used

Active transplant list
The list of patients who are waiting for a transplant and who are in a suitable condition to have a transplant if a donated organ becomes available. At any one time some patients who need a transplant are temporarily “suspended” from the active list for short periods as a result of other medical events.

Acute irreversible heart failure
Sudden and unexpected failure of the heart, often the result of viral infection, which may lead to the death of the patient within days or weeks without a heart transplant.

Acute Trusts
The NHS bodies responsible for the management of hospitals that provide acute services to patients in England /Wales and NI.

Acute Operating Division
The NHS bodies responsible for the management of hospitals that provide acute services to patients in Scotland

Agenda for Change
The system that grades most staff working within the NHS and establishes the pay-bands and terms and conditions applicable to each individual.

Brain death / brainstem death (BSD)
Death diagnosed and confirmed following neurological tests of the brainstem. The diagnosis of death can be made whilst the body of the person is attached to an artificial ventilator, and thus whilst the heart is still beating.

Brainstem
The critical part of the brain that is responsible for consciousness, breathing and other functions that is essential for life.

Brainstem tests
A series of clearly defined tests that establish that the brainstem no longer has any function.

British Medical Association
The professional association for doctors

British Transplantation Society (BTS)
The professional society for clinicians, scientists, co-ordinators and others involved in transplantation.

Cardiac death
Death certified by a doctor after the heart has irreversibly ceased to beat.

Cardio-respiratory
Relating to the heart beat and breathing.

Cardiothoracic
Relating to the heart and lungs.

Chief Operating Officer
Scottish equivalent of a Chief Executive

Coroner
An independent legal officer whose responsibilities include, in certain circumstances, establishing how patients came to their death.

Donation Advisory Group (DAG)
An Advisory Group of UK Transplant with wide representation from critical care clinicians, nurses, and co-ordinators that provides professional advice to UK Transplant.

Donation after brain death (DBD)
The donation of organs after death has been certified following tests of the brainstem.

Donation after cardiac death (DCD)
The donation of organs after death has been certified following permanent cessation of the heartbeat.

Donor identification & referral
The recognition that someone who has died or is expected to die in hospital could possibly donate their organs, and the notification to the donor co-ordinator service.

Donor co-ordination
Donor transplant co-ordinators are the crucial link between staff caring for a potential donor and the transplant teams and organisations.

Donor hospital
Any hospital where a potential or actual organ donor is cared for.

Donor management
The process that ensures that the organs of a potential donor function as well as possible after death has been certified by brainstem tests until organ removal takes place.

DonorNet
The on-line system of donor registration introduced in the USA in 2006.

Donor Transplant Co-ordinators (DTCs)
Specially trained clinical staff, usually from a nursing background, who play a crucial role in providing a link between critical care staff and the transplant organisations and units.

DTC
Donor Transplant Co-ordinator.

Epidemiological
The study of diseases in the population, and the impact of changes within the population on the incidence of diseases.

Eurotransplant
An independent Foundation that is responsible for organ allocation in seven European countries – Netherlands, Belgium, Luxembourg, Germany, Austria, Slovenia, and Croatia.

General Medical Council
The regulatory and disciplinary body responsible for ensuring that doctors work within the law and within accepted standards of clinical practice.

Healthcare Commission
The independent regulator and inspector of the provision of healthcare by the NHS. Foundation Trusts are not within its remit, being the responsibility of another organisation, Monitor.

Heartbeating donor
A donor whose organs are removed after death has been confirmed following neurological tests of the brainstem.

Histocompatibility and Immunogenetics
The study of the HLA system and its role in organ transplantation, also known as “tissue-typing”. A necessary service to match organs and patients for many, but not all, organ transplants.

HLA antigens
The proteins on cell surfaces that make up a person’s “tissue-type”. They allow the body to recognise as “foreign” an organ from another individual and this may lead to the process of rejection of a transplanted organ unless drugs to modify the immune system are used.

Human Tissue Acts
The Human Tissue Act 2004 applies in England, Wales and Northern Ireland and the Human Tissue (Scotland) Act 2006 applies in Scotland. Both Acts were introduced in September 2006. The Acts are very similar but not identical, and cover (amongst other issues) the removal, storage and use of organs from dead people for transplants.

Human Tissue Authority (HTA)
The regulatory Authority established under the Human Tissue Acts that, amongst many functions, defines the consent process required for deceased organ donation in England, Wales and Northern Ireland.

In-house co-ordinators
Fully trained donor co-ordinators who are based in single critical care teams with a role to promote organ donation.

Intensive Care Society
The professional body for critical care staff.

Intensive Care Unit (ICUs)
Special units within hospitals where the most complex care and life-support for severely ill patients is provided.

Kidney dialysis
The use of artificial kidney machines or techniques to keep alive a patient whose kidneys have failed.

Living donation
Donation of an organ or part of an organ by a healthy volunteer for a transplant – usually for someone with whom the donor has a close family or emotional relationship.

Mental Capacity Act
The Act that describes, amongst many other things, what can and cannot be done to a person or patient who lacks the capacity to give consent themselves.

National Blood Service
An operating division of NHSBT responsible for ensuring that there is a safe and secure supply of blood and most blood products for England and North Wales. It also has responsibility for some, but not all, tissue donation, banking and supply.

Neurological
Relating to the nervous system – specifically in this report to the functions of the brainstem.

NHS Blood & Transplant (NHSBT)
See NHSBT below

NHSBT
NHS Blood and Transplant. A Special Health Authority within the NHS, established in 2005, that incorporates both UK Transplant and the National Blood Service, together with Bio Products Laboratories (BPL).

Non-heartbeating donor
A donor whose organs are removed after death has been certified following cessation of breathing and the heartbeat (cardiac death).

Organ donation
The process of allowing organs (including kidneys, liver, heart, lungs and pancreas and occasionally other organs) to be removed after death and used for transplants.

Organ Donation Breakthrough Collaboratives
The initiatives introduced in the USA since 2003 that bring together all parts of the healthcare system to promote organ donation

Organ Donor Register (ODR)
The NHS computer register that has the names of those who have recorded their wish to donate their organs and/or tissue after death.

Organ retrieval
The surgical removal after death, in an operating theatre, of organs for transplants.

Physiological
The normal way in which organs such as the heart, liver and kidneys function.

Potential Donor Audit (PDA)
A UK-wide audit of patients that die in Intensive Care Units that was established in 2003 and provides information about the number of possible organ donors and whether they became actual donors or not.

Renal failure
The failure of kidney function that leads to death unless the patient receives dialysis or a kidney transplant.

Royal College of Anaesthetists
The professional college responsible for training and standards within anaesthesia.

Severe acute liver failure
Sudden and unexpected liver failure, often the result of viral infections or drug toxicity, which may lead to the death of the patient within hours or days without a liver transplant.

Strategic Health Authority (SHA)
The 10 NHS authorities in England responsible for the overall healthcare provision for the population they serve.

Transplant
Replacement of the function of a failed organ(s) with an organ from a human donor.

Type 2 diabetes
A form of diabetes that is more common in older patients than Type 1 (“insulin – dependant”) diabetes, and which can cause kidney failure. It may be associated with obesity and diet.

UK Transplant
An operating division of NHSBT with responsibility to manage the transplant waiting lists allocate organs for transplants, collect all necessary information about donors and transplants and to promote organ donation.

Appendix 11: Taskforce Membership

Members

Elisabeth Buggins (Chair), Non-Executive Director of NHSBT & Chair of West Midlands Strategic Health Authority

Helen Bevan, Executive Director of Service Transformation, NHS Institute for Innovation & Improvement I don't recall her being a member

Robert Bonser, Director of Thoracic Transplantation, Queen Elizabeth Hospital, Birmingham

Simon Bramhall, Consultant Surgeon, Liver and Hepatobiliary Unit, Queen Elizabeth Hospital, Birmingham

Mark Britnell, Director General for Commissioning and System Management in the NHS, Department of Health

Bob Dunn, National Kidney Federation

Christine Elding, Donor Nurse Specialist, Brighton & Sussex Hospital Trust

Bobbie Farsides, Professor of Clinical & Biomedical Ethics, University of Sussex

Michael and Kathryn Lewis, Donor Family

Julie Moore, Chief Executive, University Hospital Birmingham NHS Foundation Trust

Karen Morgan, Donor Transplant Co-ordinator Regional Manager (South West)

Paul Murphy, Consultant in Neuroanaesthesia and Neurocritical Care, The General Infirmary at Leeds

Vivienne Parry, Writer and Broadcaster

Gurch Randhawa, Professor of Diversity in Public Health, University of Bedfordshire

Martin Smith, Consultant in Neurointensive Care, The National Hospital for Neurology & Neurosurgery, University College London Hospitals

Chris Watson, Consultant Liver, Kidney & Pancreas Transplant Surgeon, Addenbrooke's Hospital, Cambridge

In Attendance:

NHS Blood and Transplant

Kathy Cardwell (Secretary), UK Transplant

Sue Falvey, UK Transplant

Martin Gorham, NHSBT

Terry Male, NHSBT

Chris Rudge , UK Transplant

Rob Warwick, NHSBT

Department of Health

Edmund Jessop (NCG)

Gareth Jones

Neil Moors

Triona Norman

Hugh Whittall

Dan Wood (ESOR)

Representatives from devolved administrations of Scotland, Wales & NI

Will Scott/Jennifer Armstrong (Scotland)

Caroline Lewis (Wales)

Siobhan McKelvey (NI)

Appendix 12: Terms of Reference

To identify barriers to organ donation and transplantation and recommend solutions within existing operational[47]*and legal frameworks.*

To identify barriers to any part of the transplant process and recommend ways to overcome them to support and improve transplant rates.

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[47] Within existing NHS structural arrangements.