

UK DONATION ETHICS
COMMITTEE

ANNUAL REPORT 2010

UKDEC

UK Donation Ethics Committee

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Designed and Typeset by
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INTRODUCTION

The UK Donation Ethics Committee was established in January 2010, with the aim of providing an independent, UK-wide source of advice on the difficult ethical dilemmas that can arise in relation to organ donation. Its establishment is one part of a much wider programme of work initiated following the Organ Donation Taskforce's report 'Organs for Transplants', published in 2008.

The implementation programme has seen a significant increase in the numbers of staff dedicated to organ donation, through appointing Clinical Leads for Organ Donation (CLODs) and establishing Donation Committees within acute trusts.

The number of Specialist Nurses for Organ Donation (SN-ODs, previously known as Donor Transplant Co-ordinators) has more than doubled. The Professional Development Programme for CLODs has run throughout 2010, bringing together these local champions and creating opportunities to debate the legal and ethical issues that surround organ donation, as well as the more practical aspects of managing a successful organ donation programme.

In other recent developments the Department of Health, NHSBT, Intensive Care Society and British Transplantation Society have worked together with key experts and stakeholders to explore the remaining barriers to donation after circulatory death (DCD) and how to overcome them. The British Transplantation Society and Intensive Care Society have published a joint consensus document regarding DCD.

Against this backdrop the first year of the UKDEC has seen the committee established, forging links with other organisations in the field. A rapid consultation in January demonstrated the pressing need for advice on the ethical aspects of donation after circulatory death. Recommendations for consultation formed the first major publication from UKDEC in January 2011.

This first annual report from UKDEC summarises all our work in what has been a busy year. We look forward to building on this momentum through to next year and beyond.

HIGHLIGHTS

Establishment of the Committee

As an independent Committee the chair and nine members were appointed following an open competition, which was managed by the Appointments Commission. Sir Peter Simpson accepted the role of chair, with a 3 year term of office to January 2013. Members were appointed for 2 years in the first instance. After reviewing the expertise available at the first meetings, three further members were co-opted to strengthen the legal, ethical and communications expertise.

Observers were invited from key organisations, including NHS Blood and Transplant, the Human Tissue Authority, and the UK Health Departments. The Committee had a short initial teleconference in January, followed by four full meetings in February, April, July and October.

Communications

The UKDEC is hosted by the Academy of Medical Royal Colleges, and has a dedicated webpage on the AoMRC website (www.aomrc.org.uk). This includes details of members, with a register of members' interests, and brief details of the work programme. The work of the UKDEC is subject to the Freedom of Information Act, and the website includes a publication scheme in accordance with the relevant legal requirements.

Early Priorities

The Chairman undertook a series of meetings with key organisations and individuals to introduce the Committee and take soundings about where it should focus its efforts. An open invitation was sent out to healthcare professionals and others with an interest in organ donation to get additional views about areas for action. About 20 responses were received, including both formal responses from organisations and brief communications from individuals.

The issues raised were both general and specific and fell into a number of themes. Donation after circulatory death (also known as donation after cardiac death), featured strongly, as did conflicts of interest, families and consent, and research. UKDEC considered all the responses, together with their terms of reference, and developed an initial workplan that balanced topics with an immediate, practical importance donation after circulatory death and research in transplantation), with longer term issues in faith and organ donation.

WORKSTREAM 1: DONATION AFTER CIRCULATORY DEATH

Donation after circulatory death (DCD) has been the subject of considerable debate in the organ donation and transplantation community. As rates of donation after brain stem death have fallen in recent years, so rates of donation after circulatory death have risen. DCD brings with it ethical and logistical challenges. Ethical questions referred to the UKDEC include:

- Is there a conflict of interest if a clinician who is also the Trust Clinical Lead for Organ Donation treats a potential donor?
- Once it has been agreed that withdrawal of life-sustaining treatment is in the patient's best interests, what, if any, interventions aimed at maintaining the organs in the best state for transplantation are ethical?
- Is it acceptable to vary from the normal practice of withdrawal of life-sustaining treatment?

UKDEC considered these and other issues relating to DCD in some depth over the course of their first year, and a consultation document containing some 35 recommendations was published on 10 January 2011.

The consultation was launched at the National Review event for Clinical Leads for Organ Donation on 18 January. Following the consultation period, a final guidance document will be published.

WORKSTREAM 2: RESEARCH

Transplantation research has a number of unique features. These include:

- Research on the deceased (organ donors)
- Unpredictability – organ donors may be in any hospital so all have to give R&D approval, although only a few will ultimately take part. Similarly it cannot be predicted accurately which potential recipients will be offered which organs.
- Time constraints – once a donor is available there is very little time to make decisions about participating in research, as the organs have to be retrieved and transplanted in a matter of hours.

Respondents had reported multiple problems in getting research studies approved, including lack of understanding by Research Ethics Committees, contradictory requirements being set by different parts of the system (RECs, Human Tissue Authority, insurers), and problems associated with licensing requirements under the Human Tissue Act.

In some cases projects had taken more than three years to be fully approved, and in one case researchers had to withdraw from a planned international study as legal obstacles could not be overcome. UKDEC established a small sub-group under the chairmanship of Anthony Warrens to consider ethical issues in transplantation research.

A joint UKDEC/NRES workshop was held on November 10 to bring together researchers, members of research ethics committees, clinicians involved in organ donation and transplantation and representatives from regulatory and governance organisations. The aims were:

- To identify the barriers to transplantation research, both ethical and technical; and
- To make recommendations to address the issues raised.

65 people attended the workshop, and the day began with introductory talks from researchers sharing their experiences of the challenges of transplantation research, followed by legal, regulatory, and donor and recipient perspectives. Participants moved on to consider a number of specific scenarios, considering how the issues could best be addressed.

A workshop report summarising the findings and agreed by the workshop participants was presented to the UKDEC, with recommendations for action. UKDEC will take this work forward in 2011. The editors of the journal 'Transplantation' have invited UKDEC to submit the findings of the workshop for publication as a 'Forum' article.

The UKDEC research sub-group also submitted evidence to the Academy of Medical Sciences review of regulation and governance of medical research. The Academy was asked by the Department of Health in March 2010 to conduct the review, and during summer 2010 the new Government made an additional request to the Academy to consider their proposal for a single research regulator.

The UKDEC research sub-group provided a submission that highlighted the difficulties researchers in transplantation face, expressing the view that a single research regulator could be a significant improvement, although other issues also need to be addressed.

WORKSTREAM 3: FAITH AND ORGAN DONATION

The Organ Donation Taskforce noted that there was a higher need for transplants, but a significant lack of donors from black and minority ethnic backgrounds and recommended that more work was needed to address this health inequality.

As part of the Organ Donation Taskforce's subsequent work related to examining the impact of opting-in and opting-out systems, it engaged with national faith leaders, via Professor Gurch Randhawa. Following this positive engagement with faith communities, the Department of Health have continued to support this constructive dialogue, via the Organ Donor Campaign (Komal Adris) and Professor Randhawa to progress discussions with Faith Leaders at a local and national level respectively. The final reports from these two projects provided a very valuable basis for developing further work in this area.

Professor Randhawa's work with faith leaders highlighted the importance of the definition of death to some faith groups, in particular the Catholic and Jewish faiths. Their concerns were linked to the term 'brain stem death', which they felt from their respective faith points of view did not constitute death as they would describe it.

Komal Adris's report 'Faith and Organ Donation: Engaging with UK faith communities' reporting findings from focus group work, and described how many groups perceive a lack of trust and transparency in hospital, healthcare professionals and the process of organ donation. Previous work to engage with faith communities is thought to have been tokenistic with little evidence of change as a result. These concerns about tokenism were also reflected in the Randhawa report.

Both reports contain a number of recommendations about how to raise awareness and improve understanding about organ donation within faith communities.

The UKDEC, with its brief to consider the ethical issues that arise in organ donation, is well placed to continue the dialogue with faith communities. During the year the Chairman and Professor Randhawa (as a member of UKDEC), held introductory meetings with representatives from the Catholic Bishops Conference, and with the Board of Deputies of British Jews. Both of these meetings were very positive, with the opportunity for further dialogue and discussion welcomed, particularly in areas relating to the definition of death.

Following this a programme of 6 events is planned for early 2011, whereby we can enable faith leaders to discuss definition and diagnosis of death within their own faith communities. We will focus the work to begin with the Black Christian Church; Roman Catholics; Sikhs, Jews, Hindus, and Muslims – as they have previously expressed concerns around definition and diagnosis of death. The aim is for each of the faiths to reach a position statement on definition and diagnosis of death.

ADDITIONAL WORK: RESPONSES TO CONSULTATIONS

UKDEC responded to three consultations during the year.

The Nuffield Council on Bioethics established a Working Party to examine the ethical issues that arise in connection with a person's decision to 'donate' some part of their body (including whole organs, eggs and sperm, blood, and other bodily material such as bone, skin, heart valves and corneas) or to 'volunteer their body' through participation in 'first in human' clinical trials of new medicines.

The Working Party issued a consultation paper 'Give and Take? Human bodies in medicine and research' in support of this work in April 2010. UKDEC responded, with comments limited to organ donation and transplantation, in line with the remit of UKDEC. NICE began development of a clinical practice guideline on organ donation, for use in the NHS in England, Wales and Northern Ireland. UKDEC registered as a stakeholder for this guideline and provided comments on the draft scope in July 2010.

The Academy of Medical Sciences was asked by the then Secretary of State for Health in March 2010 to conduct an independent review of the regulation and governance of UK medical research. In August 2010, following publication of the Department of Health's report on Arm's Length Bodies, the Academy of Medical Sciences issued a call for evidence focusing on the Coalition Government's proposal for a 'single research regulator'.

This proposal is of considerable interest to the transplantation research community, as if implemented effectively it could lead to simplification of the approval processes for transplantation research, which would be very welcome. The UKDEC Research Sub-Group submitted a response on behalf of the UKDEC.

MEASURING SUCCESS

The success of UKDEC cannot be measured in simple statistics; our role is not to increase organ donation per se – it is to provide the ethical frameworks and advice that will enable clinicians to have the confidence to make appropriate, timely decisions.

We are using more direct feedback channels with the community to provide us with snapshots of whether we are addressing the issues of most concern in a way that meets their needs.

In this first year UKDEC has received 3 invitations to speak at symposia or other meetings, and 6 additional requests to participate in invitation-only events. We expect these numbers to increase significantly in the coming months. More specifically, the transplantation research workshop we held on 10 November attracted 65 participants, of whom 40 completed a feedback form.

All agreed with the statement ‘Overall, I found this workshop useful’ (37 strongly agree; 3 agree), and all would recommend the workshop to a colleague (35 strongly agree, 5 agree). General comments stressed how valuable the opportunity for discussion and debate in a multidisciplinary forum had been, and there were a lot of suggestions for future workshop topics on other aspects of organ donation and transplantation.

The responses to the consultation on donation after circulatory death will be the key indicator as to whether our work is meeting the needs of the community.

Longer term we will need to assess whether major recommendations we make are implemented. With no legal standing, we can only succeed by working with the community to build the momentum for change, presenting clear recommendations backed by cogent arguments. This is a more difficult, but ultimately far more sustainable approach to improving organ donation and transplantation.

The Academy has a contract with the Department of Health to provide the UK Donation Ethics Committee. The Devolved Administrations are not signatories to the contract, but have agreed to provide funding in support of the UKDEC, with the funding split between the Administrations in accordance with Barnett principles. The contract runs from April 2010 – March 2012, with a break clause at the end of year 1 (March 2011) and year 2 funding being subject to the outcome of the 2010 Spending Review.

Income and expenditure for UKDEC is set out below. Table 1 shows figures from its establishment in January 2010 to 31 March 2010. Table 2 shows 01 April 2010 to December 2010. The Department of Health provided funding for the year 2009-10, as it was originally anticipated the committee would begin work in autumn 2009. In the event the committee could not begin work until January 2010, so most of these funds have been carried over. (Devolved administrations did not provide any funds in 2009-10).

The Secretariat staff are seconded from the Department of Health, and to minimise bureaucracy the DH retains these costs and pays the staff directly.

Table 1

| DATE RANGE: UNTIL MARCH 31, 2010 | |
|--|------------------------------|
| ACCOUNT: DONATION ETHICS COMMITTEE | |
| Report as at 20 December 2010 | |
| DONATION ETHICS COMMITTEE | TOTAL |
| Turnover | |
| 4027 — Donation Ethics Committee | 94,295.00¹ |
| Gross Profit or Loss | 94,295.00 |
| Operating Expenses | |
| 5841 — Professional Fee | 1,675.00 |
| 5842 — Travel Expenses | 1,681.30 |
| 5843 — Project Expenses | 582.38 |
| | 3,938.68 |
| Operating Income | 90,356.32 |
| Other Expenses | |
| 9000 — Allocation of Costs to Restricted Funds | 7,500.00 ² |
| | 7,500.00 |
| Profit or Loss | 82,856.32 |

Notes:

1. Contribution from DH only. Includes £20K additional funding for faith and organ donation project.
2. £7,500 payment for AoMRC overhead costs.

Table 2

| DATE RANGE: APRIL 1, 2010 - DECEMBER 31, 2010 | |
|--|-------------------|
| DONATION ETHICS COMMITTEE, CLOSING POSTINGS: NOT INCLUDED | |
| Report as at 20 December 2010 | |
| DONATION ETHICS COMMITTEE | TOTAL |
| Turnover | |
| Carried over | 82,856.32 |
| 4027 - Donation Ethics Committee | 40,241.001 |
| Gross Profit or Loss | 123,097.32 |
| Operating Expenses | |
| 5841 — Professional Fee | 8,475.00 |
| 5842 — Travel Expenses | 4,175.27 |
| 5843 — Project Expenses | 22,966.29 |
| | 35,616.56 |
| Operating Income | 87,480.76 |
| Other Expenses | |
| 9000 — Allocation of Costs to Restricted Funds | 11,250.002 |
| | 11,250.00 |
| Profit (to be carried forward) | 76,230.76 |

Table 2 Notes

1. Contributions from Devolved Administrations from Q1 and Q2. Further contributions for Q3 and Q4 will bring the total income for the financial year April 2010 to Mar 2011 to £73,858.
2. Contribution to AoMRC overheads.

FORWARD LOOK

January 2011 will see publication of the UKDEC's first consultation document, on donation after circulatory death (previously known as donation after cardiac death). This will be a major milestone for UKDEC, and feedback from the consultation will be used to help shape the work programme for the future, as well as shaping the final recommendations for publication in the spring.

Transplantation research will continue to be an active workstream as we take forward the recommendations made by the workshop held on 10 November 2010.

Other areas that would benefit from further discussion and debate that have emerged during the course of the first year include:

- The variation in practice for withdrawal of life-sustaining treatment in potential DCD donors;
- Whether it is ethically appropriate to administer some treatments or interventions before death aimed solely at improving the quality of donated organs;
- The potential for the Organ Donor Register to hold more detailed information about people's wishes regarding organ donation.

Continuing the work of UKDEC is contingent on the Health Departments agreeing to continue to provide funds. A business plan has been submitted and the outcome is awaited.

CONCLUSION

This first year has been one of establishing the committee - getting the right balance of expertise; finding the best ways of working; taking soundings to determine what the clinical community is looking to UKDEC to provide. As we reach the end of this year with our first major publication open to scrutiny, we are confident we have put in place a firm foundation on which to build in future years.

UKDEC MEMBERSHIP 2010-2012

Sir Peter Simpson (Chair)

Past President, Royal College of Anaesthetists

Paula Aubrey

Regional Manager,
NHS Blood and Transplant

Keshwar Baboolal

Consultant Physician and Nephrologist,
University Hospital of Wales, Cardiff

Joe Brierley

Consultant Paediatrician, Paediatric and Neonatal Intensive Care Unit,
Great Ormond St Hospital, London

Graham Brushett

Lay member, heart and kidney transplant recipient

Stephen Cole

Consultant in Anaesthesia and Intensive Care Medicine,
Ninewells Hospital, Dundee

Heather Draper

Professor of Biomedical Ethics and Director of the Centre for Biomedical
Ethics, Department of Primary Care Clinical Sciences,
University of Birmingham

Bobbie Farsides

Professor of Clinical and Biomedical Ethics,
Brighton and Sussex Medical School

Leslie Hamilton

Consultant Cardiac Surgeon,
Freeman Hospital, Newcastle Upon Tyne

Penney Lewis

Professor of Law, School of Law and Centre of Medical Law and Ethics,
King's College London

Gurch Randhawa

Professor of Diversity in Public Health and Director, Institute for Health
Research, University of Bedfordshire

Anthony Warrens

Honorary Consultant Physician and Dean for Education,
Barts and The London School of Medicine & Dentistry

Eleanor Updale

Writer

Helen Lovell

Secretary to UKDEC

Observers from the Department of Health and Devolved Administrations,
the Academy of Medical Royal Colleges, NHS Blood and Transplant
and the Human Tissue Authority may also be in attendance.

TERMS OF REFERENCE

The UKDEC will:

- consider ethical issues, both general and specific, relating to the field of organ donation and transplantation and provide independent advice to clinicians, policy leads and others as appropriate and/ or relevant issues referred to the group by local donation committees.
- develop and maintain links with relevant professional and ethical associations/ societies.
- ensure that advice given is independent and not unduly influenced by the views of any other organisation or individual.
- produce, maintain and promulgate guidelines relating to ethical issues on organ donation and transplantation.
- support Local Clinical and Research Ethics Committees, and Donation Committees in their provision of out of hours advice at a local level, based on DEC frameworks.
- assist in the development of training content for those involved in organ donation and transplantation.
- receive and collate any advice given locally, based on DEC frameworks, to harmonise advice where appropriate, determine whether any issues have any regional/ national implications and take action as appropriate.
- be accountable to the Academy of Medical Royal Colleges:
 - a. Setting out an annual work programme
 - b. Providing an annual report summarising work undertaken and accounting for the use of funds
 - c. Liaising with the Academy before publications are put in the public domain.

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