Placing Donation within End-of-Life Care in Intensive Care in Europe

Prof Chris Rudge CBE FRCS

Madrid June 28th 2013
Agenda

1. Introduction
   1. The wide variation in Organ Donation across Europe
   2. What influences/causes this?
2. DOPKI
3. ACCORD
4. A new Donation Paradigm
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Deceased Donors 2011
per million population

Spain, Croatia, Belgium, Malta, Portugal, France, Austria, Italy, Ireland, Latvia, Luxembourg, Czech R, Finland, UK, Estonia, Slovenia, Sweden, Germany, Poland, Hungary, Netherlands, Denmark, Slovakia, Lithuania, Greece, Cyprus, Romania, Bulgaria
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What limits the number of donors?

Two very distinct answers:

1. A limited number of Possible donors
2. Not all Possible donors become Actual donors
A common nomenclature of the process of donation after brain death

Utilised Donor: At least one organ transplanted

Actual Donor: At least one organ recovered for transplantation purposes

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Potential Donor: Possible donor in whom the brain death diagnosis has been initiated or completed

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www.dopki.eu
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www.dopki.eu
A limited number of Possible donors

- Age
A limited number of Possible donors

- Age
- Die in hospital
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- Age
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- Free of cancer and transmissible infections
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- Age
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- Satisfactory individual organ function at the time of death
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- Die in hospital
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- Satisfactory individual organ function at the time of death
- For Donation after Brain Death, after the determination of death using neurological criteria
Important Questions...

• How many possible donors are there?

• How many possible donors become actual donors?
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Improving the Knowledge and Practices in Organ Donation

The DOPKI project
DOPKI: a great consortium

Improving the Knowledge & Practices in Organ Donation

13 Organizations / 16 EU countries

80% EU population
80% EU activity of donation and transplantation
DOPKI: a great consortium

www.dopki.eu
To develop an **applicable methodology** to estimate the **potential of deceased organ donation**

- and evaluate **performance in the deceased donation process**,

- and to increase the knowledge on the **safety limits in organ transplantation**
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DOPKI: Objective

To develop an applicable methodology to estimate the potential of deceased organ donation
and evaluate performance in the deceased donation process,
and increase knowledge on the safety limits in organ transplantation

Current situation of donation and transplantation activities in the EU

| Basis for international comparisons | What is possible? |
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[www.dopki.eu](http://www.dopki.eu)
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**Cost-benefit model**

[Link with the WHO](www.dopki.eu)
## Methodologies to estimate the potential of donation

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| **CLINICAL CHART REVIEW** | - Accurate / Gold standard  
- Sensitive to local variations in factors that affect the potential of donation  
- Allows evaluation of the person's suitability  
- Allows the identification of areas for improvement | - International comparisons hindered by the lack of a harmonized methodology  
- Mostly based on self-reporting  
- Time consuming  
- Costly  
- Mainly focused on critical care units |
A common structure of the process of donation after brain death

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www.dopki.eu
Potential of Deceased Donation in DOPKI countries (estimated with data from quality assurance programmes). Year 2006

- Germany (North Eastern Region): 20.8 Actual Donors, 39 Potential Donors
- Italy: 21.7 Actual Donors, 33.3 Potential Donors
- Spain: 33.8 Actual Donors, 48.3 Potential Donors
- UK: 12.9 Actual Donors, 24.8 Potential Donors

www.dopki.eu
A Common Methodology for:

- **Self-review of clinical charts** of patients dying in the Intensive Care Unit, and
- **Mortality data** analysis to:

1. Estimate the **potential** of deceased donation
2. Identify **areas for improvement**
3. Evaluate **performance**
4. Analyze the relevant **hospital factors and demographic characteristics**
Guide of recommendations for Quality Assurance Programmes in the Deceased Donation Process

Developed by:
Dopki project
Funded by the European Commission
DOPKI NEWSLETTER 2007
A quick view on DOPKI project and shots of information on the state of the art in donation and transplantation in European countries
www.dopki.eu
DOPKI NEWSLETTER 2009

Participants and Organisation of the Work
DOPKI’s consortium is composed by 13 organisations on behalf of 16 European countries. **p.4**

The DOPKI Project
During the DOPKI project several meetings were organized; hundreds of e-mails circulated among the partners, and more than 800 hundred documents were produced available in [www.dopki.eu](http://www.dopki.eu). **p.5**

Measuring the Potential Supply of Organs for Transplantation
Organ transplantation is the best and frequently the unique therapeutic alternative for patients with end stage organ failure and many other life-limiting conditions. Excellent results achieved with this therapy have made transplantation become a victim of its own success with supply of organs for transplantation not being able to fulfill the demands. **p.5** Francis L. Delmonto, Luc Noel and Rafael Mateosz.

Mortality Rates in Countries
Standardised death rates (SDRs) across the countries ranged from 519.96 to 1090.83 per 100,000. Investigations of differences in country wide mortality showed no significant relationship between SDRs and donation rates. **p.8**

Effect of Social, Economic and Structural Health Care Factors on Donation and Transplantation Rates
A multiple regression analysis was performed, for each of the three outcome measures as pmp rates: number of heartbeating donors, deceased kidney transplants and the number of patients on the kidney transplant waiting list at 31 December 2004. **p.12**

Performance in the Deceased Donation Process: Results of a Pilot Action
There are two different methods of estimating the potential of donation: the use of mortality data and the registry of potential deceased organ donors on the bases of a retrospective clinical chart review or ideally on a prospective fashion. This last also provides the unique opportunity of identifying areas in the process where improvement is possible. **p.16**

Dopki Registry for Expanded Criteria Donors
DOPKI aims to define the limits in the use of organs for transplantation from donors with specific and infrequent conditions that might benefit from an international cooperation. **p.18**

Cost-Effectiveness Study
Successful organ donation programmes require a substantial initial financial investment. We have constructed a Markov model capable of estimating the net present value cost savings and additional quality-adjusted life years in renal transplantation that occur as the result of improved organ donation activities. **p.17**

Dissemination of DOPKI Project
Because the characteristics of DOPKI project, it is extremely important that all the knowledge acquired through this project is spread in general terms and, in particular, to those figures direct or indirectly involved in the donation process. Dissemination should be a tool itself to increase donation activity not only in Europe, but also in other regions in the world. In the end of this project, DOPKI consortium will publish a guide providing a set of general recommendations to build up these programmes in European countries, as well as organise one last event in 24th March 2009, in Auditorio Fundación Mutua Madrileña, Madrid. **p.18**
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Not all Possible donors become Actual donors
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www.dopki.eu
Not all *Possible* donors become *Actual* donors

- Consent
Not all **Possible** donors become **Actual** donors

- Consent
- Clinical decision making
Important Questions...

• Why do possible donors not become actual donors?

• Can anything be changed?
Who is the most important person in organ donation?
Who is the most important person in organ donation?

• The clinician providing end-of-life care to the patient who has the possibility to be an organ donor
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ACCORD

Achieving Comprehensive Coordination in Organ Donation

• Registry of Living Donors
ACCORD
Achieving Comprehensive Coordination in Organ Donation

• Registry of Living Donors

• Twinning
ACCORD

Achieving Comprehensive Coordination in Organ Donation

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• Fostering the collaboration between intensive care and donor transplant coordinators
ACCORD: Fostering the collaboration between intensive care and donor transplant coordinators
ACCORD Member States

Deceased Donors 2011
per million population
Many factors influence the donor rate

- Mortality rates
  - Events (Traffic accidents, Intra-cerebral bleeding)
  - Interventions (Neurosurgery, neuro-radiology)
- Intensive care bed availability
- Possible donor identification
- The Donor Coordination infrastructure
- Consent
- The Legal framework
- Clinical Decision Making
The Hypothesis

• That variations in Clinical Decision Making may have a significant impact on the size of the potential Deceased Donor pool.
Variations in Clinical Decision Making

• Most possible donors die as a result of a catastrophic brain injury
• Patients are managed by clinicians in Emergency Medicine and Intensive Care.
• There are stages during the management of such patients at which treatment decisions about the clinical management will either
  – Preserve the possibility of eventual DBD donation
  
  or

  – Remove the possibility of eventual DBD donation
In order to be a DBD donor the patient...

- Must be intubated
- Must be ventilated
- Must be haemodynamically stable (within reason)
- Must be recognised as possibly brain dead
- Must be tested for brain death
- Must be certified dead according to neurological criteria
- Must be referred to a donor coordinator network or transplant team
**Key Decision-making points**

- Is the patient resuscitated on arrival at hospital, or after a critical event whilst in hospital?
- Is the patient admitted to hospital for ongoing critical care?
- Is the patient intubated and connected to a ventilator?
- Is Brain Death considered?
- Are tests for Brain Death performed?
- Is death confirmed by neurological criteria?
INTENSIVE CARE AND DONOR TRANSPLANT COORDINATION COLLABORATION

1. Develop a Questionnaire
2. Collect and Analyse Data
3. Rapid improvement methodology development/training and Implementation
4. Review of Outcomes
Rapid Improvement Methodology

- Improvement and Toolkit Methodology designed to achieve simple systemic improvements in clinical decision making that maintain the option of donation wherever possible.
- The PDSA cycle will be implemented in each Member State to address a relevant area of practice.
- An assessment will be made of the effectiveness of the process.
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A New Donation Paradigm:
“Put the interests of the donor first”
A New Donation Paradigm: “Put the interests of the donor first”

As part of end-of-life care, the wishes of the patient about donation should be established.
A New Donation Paradigm: “Put the interests of the donor first”

As part of end-of-life care, the wishes of the patient about donation should be established.

If the person wished to donate, that *in itself* is a reason for doing everything possible (that is ethically and legally justified) to enable donation to occur.
A New Donation Paradigm: “Put the interests of the donor first”

As part of end-of-life care, the wishes of the patient about donation should be established.

If the person wished to donate, it is in that person’s best interests to donate, and therefore that in itself is a reason for doing everything possible (that is ethically and legally justified) to enable donation to occur.

Any benefits to recipients are a consequence of, not a primary reason for, facilitating donation.
Deceased donors in the UK

Historical  ODTF  Post-ODTF

Historical

ODTF

Post-ODTF

Deceased donors in the UK

Historical  ODTF  Post-ODTF

Deceased donors in the UK

Historical  ODTF  Post-ODTF
Deceased donors in the UK

Historical  ODTF  Post-ODTF


[Bar chart showing the number of deceased donors in the UK from 2000/1 to 2012/13, with bars representing historical, ODTF, and post-ODTF periods.]
Deceased donors in the UK

Historical  ODTF  Post-ODTF

- 2000/1
- 2001/2
- 2002/3
- 2003/4
- 2004/5
- 2005/6
- 2006/7
- 2007/8
- 2008/9
- 2009/10
- 2010/11
- 2011/12
- 2012/13
Conclusions

• Organ Donation rates differ between European Member States
• It is essential to understand the true donation potential – DOPKI
• Donation relies on excellent relationships between doctors providing end-of-life care and the donor system
• It is essential to identify, and improve, every step of the process – ACCORD
• Donor rates can be improved based on these concepts - UK
Thank You

Transplants save lives
• State of the art of the process of donation after brain death in different EU countries based on the data shared by participating countries on what defined as possible, potential, consented, actual and utilized donor (bear in mind that this classification in DOPKI inspired the critical pathway that was released by WHO afterwards). In such state of the art it is made already evident the important differences in the potential of donation after brain death and in the conversion rates of potential into actual donors between EU countries, i.e. UK and Spain.

• Hospital based study: we made an evaluation of the process of donation after brain death between voluntary hospitals in Europe which reported data retrospectively collected (not ‘prospectively’ as being done in ACCORD and with a view of modifying practices).

• Guidelines for a quality assurance programme in the donation process released for competent authorities as a way of evaluating performance.

• Non standard risk donors: we built a data base for the follow-up of recipients transplanted from donors with different conditions (positive serologies, neoplasias, etc).
Conclusions

- **Donors pmp**: Practical and realistic for international comparisons
  - Standardization not needed in the EU setting
  - Additional metrics able to be constructed.

- **Mortality data**: Attractive methodology but not readily available

- **Clinical chart review**: Gold standard
  - QAP do not use an international standardized methodology
  - QAP should be put in place at every hospital
  - **Combined indicators** (mortality data) are essential for evaluating the critical step of identification
  - **Interpreting indicators based on factors** (demographic and hospital factors) with an impact on their value