

Patient choice or doctor's persuasion: Donor choices, consent and communicating risk



Outline

- What is consent
- The legal environment
 - Montgomery vs Lanarkshire
- Understanding risk
 - Risk vs probability
 - Perceptions of risk
 - Risk in transplantation
 - Absolute vs relative risk
- Risks in transplantation
 - Recipient
 - Donor
 - Immunosuppression
- Communicating risk
 - Timing: when to do it
 - Presenting information
 - Numeracy and literacy



What is consent?



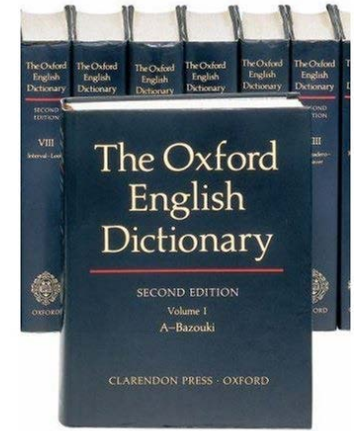
Oxford English Dictionary

- Consent:

“Voluntary agreement to or acquiescence in what another proposes or desires; compliance, concurrence, permission”

- Informed consent:

- *Law*: permission granted in the knowledge of the possible consequences;
- *Medicine*: consent to a medical or surgical procedure given after all relevant information (esp. regarding potential risks and benefits) has been disclosed to the patient or the patient's guardian



Permission granted in the knowledge of
the possible consequences

What risks should be disclosed?

Bolam vs Friem Hospital Management Committee 1957: the Bolam Test

- John Hector Bolam underwent electroconvulsive therapy without muscle relaxant and without restraint

- He sustained many injuries including a pelvic fracture
- He sued the hospital



- In summing up the case, justice McNair said:
“There is no breach of standard of care if a responsible body of similar professionals support the practice that caused the injury, even if the practice was not the standard of care.”

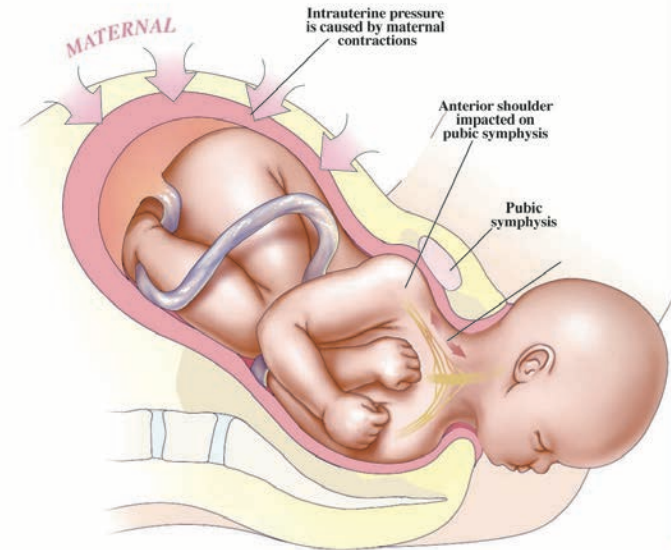
Sidaway v Board of Governors of the Bethlem Royal Hospital 1985

- Amy Doris Sidaway underwent cervical cord decompression
 - Neurosurgeon did not mention risk of paraplegia, which was <1%
- Lord Diplock stated "we are concerned here with volunteering unsought information about risks of the proposed treatment failing to achieve the result sought or making the patient's physical or mental condition worse rather than better. The only effect that mention of risks can have on the patient's mind, if it has any at all, can be in the direction of deterring the patient from undergoing the treatment which in the expert opinion of the doctor it is in the patient's interest to undergo. To decide what risks the existence of which a patient should be voluntarily warned and the terms in which such warning, if any, should be given, having regard to the effect that the warning may have, is as much an exercise of professional skill and judgment as any other part of the doctor's comprehensive duty of care to the individual patient, and expert medical evidence on this matter should be treated in just the same way. **The Bolam test should be applied"**

Montgomery vs Lanarkshire Health Board 2015

Supreme Court, Lord Neuberger presiding

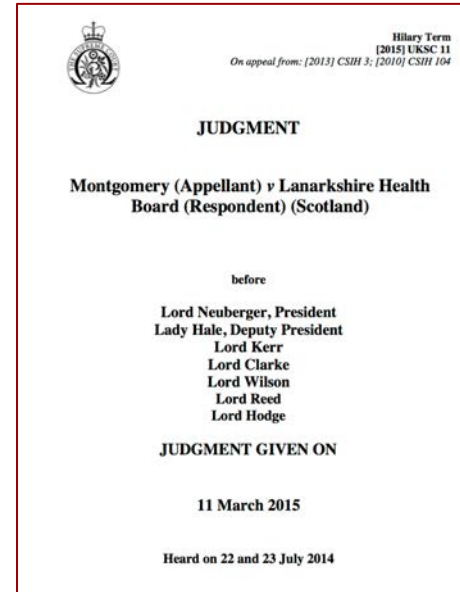
- Plaintiff: Nadine Montgomery
 - Molecular biologist; mother & sister were doctors
- 5 feet tall & diabetic
 - Diabetics have tendency to big babies with wide shoulders
- Not warned of 9-10% risk of shoulder dystocia
 - And that Caesarian would avoid this risk
- Baby born with cerebral palsy



Montgomery vs Lanarkshire Health Board 2015

Supreme Court, Lord Neuberger presiding

- 'The doctor is ... under a duty to **take reasonable care** to ensure that the patient is aware of **any material risks** involved in any recommended treatment, and of **any reasonable alternative** or variant treatments.'
- 'The test of materiality is whether, in the circumstances of the particular case, **a reasonable person in the patient's position would be likely to attach significance to the risk**, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'



Understanding Risk

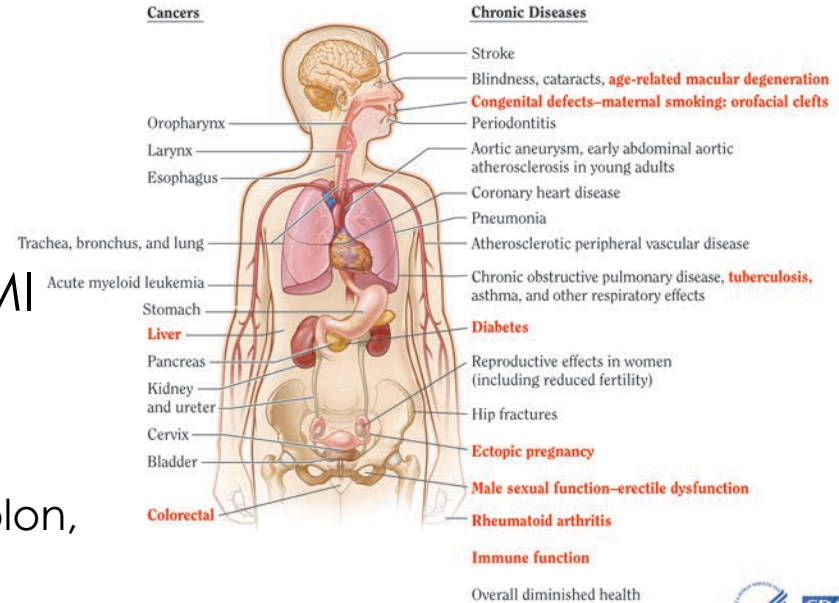


Risks from Smoking

Smoking can damage nearly every part of your body

Who smokes?

- Reduces life expectancy by 7 years
- 25x more likely to get Lung Cancer
- 2-4x more likely to have a CVA or MI
- Many cancers more common
 - Kidney, ureter, bladder, cervix, larynx, oesophagus, stomach, pancreas, liver, colon, rectum...
- Other problems more common in smokers
 - Impotence
 - Progression of diabetic complications





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Wigan transplant patient given lungs of 30-year smoker

The father of a woman who died after a double lung transplant said she would have been "horrified" to discover the organs were from a smoker of 30 years.

Cystic fibrosis sufferer Lynsey Scott, of Wigan, died months after surgery at Wythenshawe Hospital last year.

Allan Scott said she was not told that the donor smoked and is calling for patients to be given more information.

The University Hospital of South Manchester (UHSM) NHS Trust said it had followed national guidelines.

Ms Scott, 28, who was born with cystic fibrosis, underwent the surgery in February 2009 to prolong her life after her condition deteriorated.

She died a few months later in July. Tests later concluded the primary cause of death was pneumonia.



Lynsey Scott died a few months after her lung transplant

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- Woman dies after lung transplant
13 January 10 | Kent
- Organ transplants' hidden risk
24 November 09 | Health

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Smoking and donation: facts

- 50% of deceased donors are smokers
 - That's why they die young
- Smoker's lungs do less well than non-smokers lungs
 - 48% survival at 5 years c.f. 58% at 5 years
 - The more cigarettes the worse the outcome
- Recipients who accept lungs from donors who smoke live longer
 - 25% waiting list mortality for a lung transplant

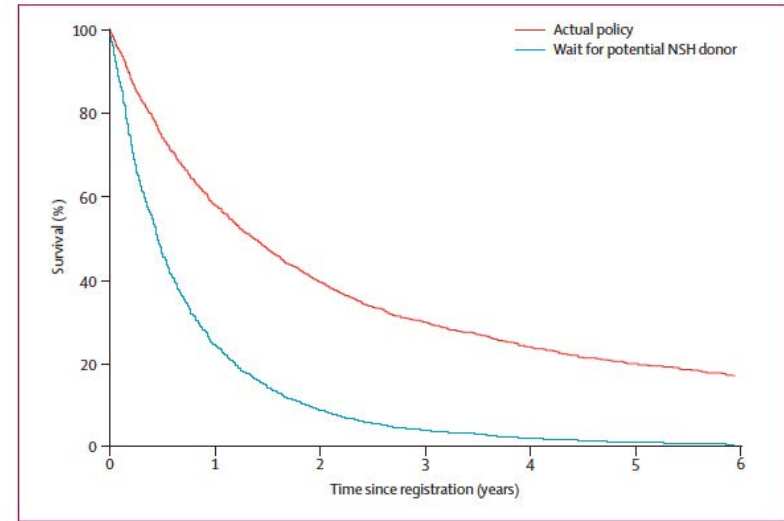
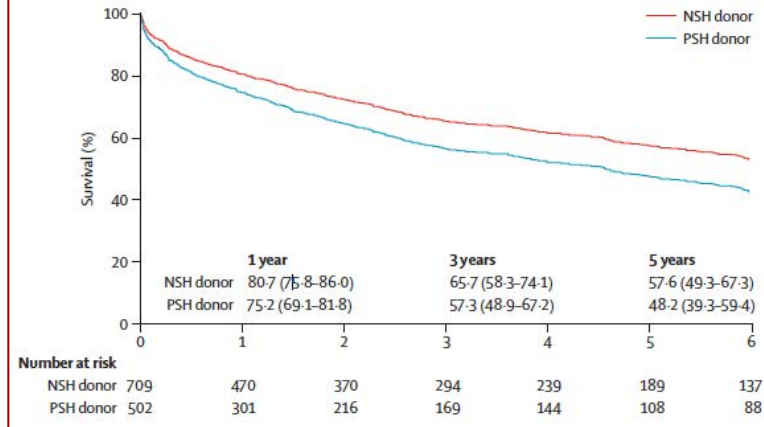


Figure 4: Actual survival from waiting-list registration for patients with a diagnosis of pulmonary fibrosis listed between 1999 and 2003, and an estimated survival if lungs from donors with positive smoking histories were excluded from the donor pool and patients chose to wait for lungs from donors with negative smoking histories

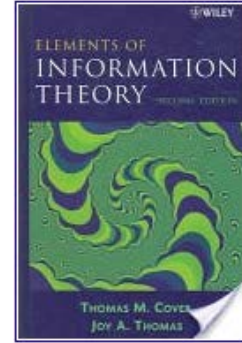
NSH=negative smoking history.

Informed consent and risk

- Information

- A reduction in uncertainty
- Knowledge of a possible event and its likelihood

- How likely is an event?



Probability and Risk

- Probability

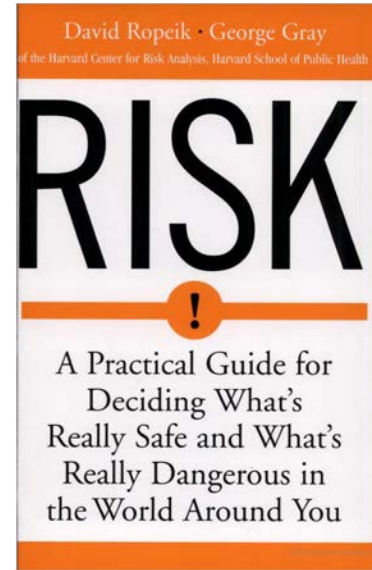
- the chance of an event occurring

- Risk

- Implies not only the chance of an event occurring, but also that the event has a consequence

- In medicine, risk implies harm,


Risk = probability x harmful consequence



What is an important risk?

- One that is common
 - high probability
- One that has a seriously harmful consequence,
 - e.g. death
- One that matters to the patient
 - Even if a small probability

Risk = probability x harmful consequence



		Impact →				
		Negligible	Minor	Moderate	Significant	Severe
Likelihood ↑	Very Likely	Low Med	Medium	Med Hi	High	High
	Likely	Low	Low Med	Medium	Med Hi	High
	Possible	Low	Low Med	Medium	Med Hi	Med Hi
	Unlikely	Low	Low Med	Low Med	Medium	Med Hi
	Very Unlikely	Low	Low	Low Med	Medium	Medium

Perception of risk



- Two sorts of risk
 - Actual risk – objective likelihood of event occurrence
 - Perceived (or emotional) risk
 - Based on belief of event occurrence,
 - Affected by emotion not fact
 - Illustrated well by gambling, where chance of winning over estimated
- Lottery risk
 - Chance of winning jackpot (6 numbers): 1 in 14 million
 - Chance of winning £10 (3 numbers, £10): 1 in 57
 - *“the lottery is a tax on people who are bad at maths”*



Perception of risk 2

- Prior experience
 - Risks of events that are perceived as well understood (familiar) or as less severe are readily dismissed
 - E.g. an anaesthetic for a non emergency operation*
 - events perceived as not understood (unfamiliar) are viewed as more consequential, more severe
 - e.g. a parachute jump*
- Numbers close to zero, e.g. $\leq 1\%$
 - Perceived as no risk.



* Both have a 1 in 100 000 risk of death.



TAKING RISK

There's a fine line between taking a calculated risk and doing something dumb.

Risk taking requires a knowledge of the risk



- There are known knowns.
 - These are things we know that we know.
- There are known unknowns.
 - That is to say, there are things that we know we don't know.
- But there are also unknown unknowns.
 - There are things we don't know we don't know.

Donald Henry Rumsfeld, b 9/7/32.
Secretary of Defence under Ford and Bush Jnr.

Factors affecting outcome in transplantation

- The donor
 - Donor organ recovery
 - Warm and cold ischaemic time
 - Logistical issues, e.g. patient & organ transport; theatre access; cross match
- The transplant surgery
- The recipient
- Post transplant care
- Immunology



Outcome measures in transplant: Survival

■ Graft survival

- How long did the transplant last?
- e.g. kidney transplantation

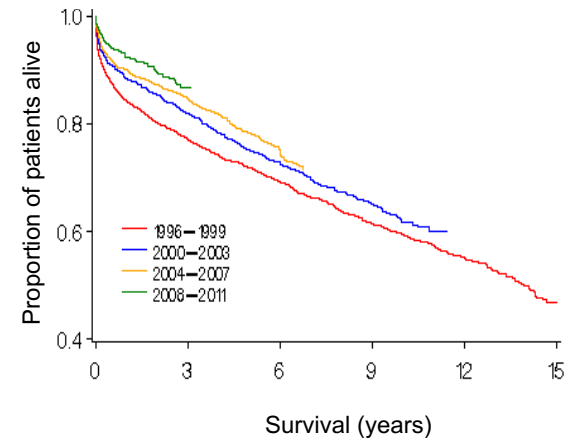
■ Patient survival

- How long did the patient survive
- Equates to graft survival for heart and lung transplantation

■ Time points

- 1 or 3 months: surgical factors
- 12 months: marker of “long term” outcome
- **Years:** what the patient wants to know is how long will I survive once I am listed

First adult elective liver only transplants,
1996-2011 followed to end 2011

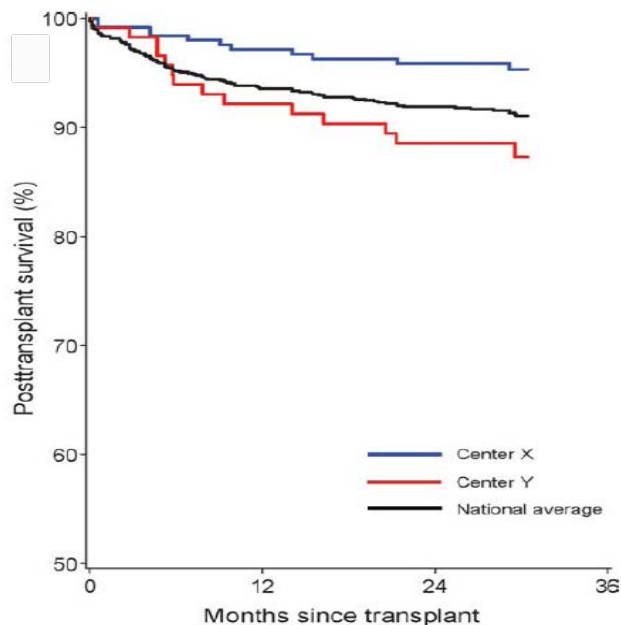


Risk taking and liver transplant survival

Centre X: Risk averse.

Centre Y: Risk taking

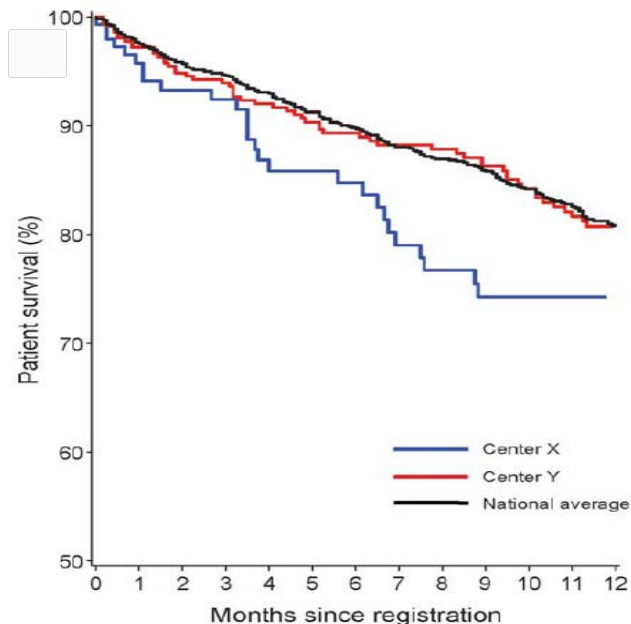
X has better survival post Tx



Centre X: Longer wait for better liver

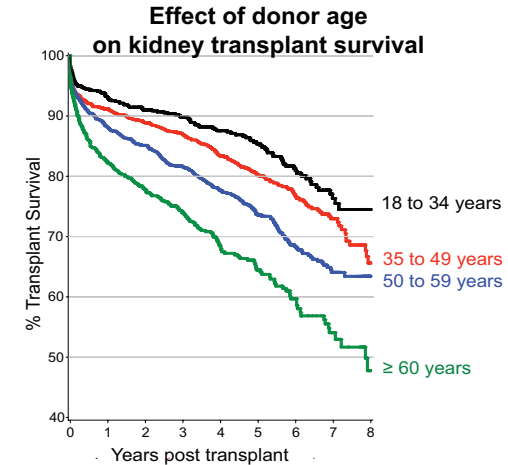
Centre Y: Shorter wait for worse liver

X has poorer survival from listing



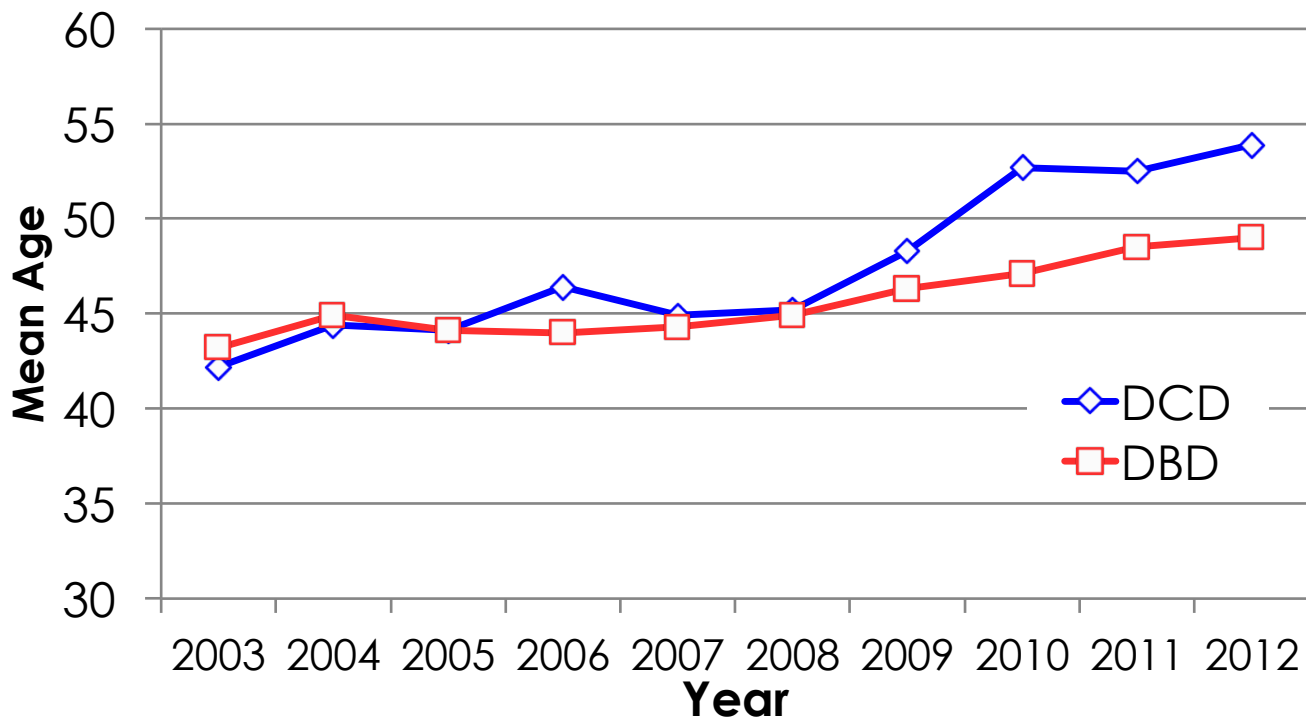
Known knowns: Donor factors affecting outcome

- Factors common to all organs
 - Donor age
 - Cause of death – trauma vs CVA
 - Ischaemic time



Donors are getting older

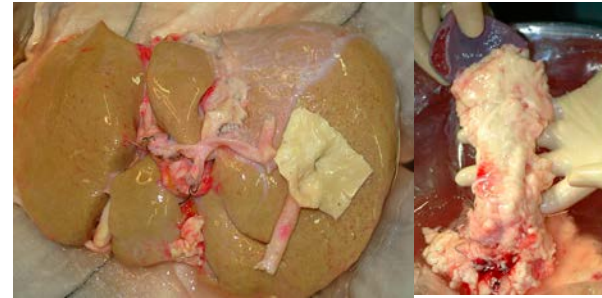
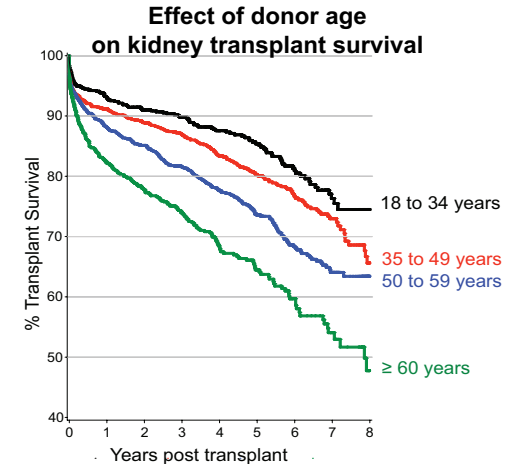
Mean age of deceased donors, 2003-2012.



Courtesy Rachel Johnson, NHSBT

Known knowns: Donor factors affecting outcome

- Factors common to all organs
 - Donor age
 - Cause of death – trauma vs CVA
 - Ischaemic time
- Organ specific factors
 - HLA mismatch – heart, lung and kidney
 - Smoking – lung
 - Hypertension – kidney
 - Obesity – Liver, pancreas
 - ...



Risk indices to predict donor organ outcome

- Multiple variable analysis of donor factors affecting outcome
 - Analysis of thousands of donors
- Index to aid:
 - Acceptance of donor organ
 - Allocation of donor organ
 - Audit of outcomes

American Journal of Transplantation 2006; 6: 763-790
Blackwell Munksgaard

Journal compilation © 2006 The Authors
Transplantation and the American Society of Transplant Surgeons
doi: 10.1111/j.1800-6143.2006.01242.x

Characteristics Associated with Liver Graft Failure: The Concept of a Donor Risk Index

American Journal of Transplantation 2010; 10: 837-845
Wiley Periodicals Inc.

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doi: 10.1111/j.1800-6143.2009.02996.x

Systematic Evaluation of Pancreas Allograft Quality, Outcomes and Geographic Variation in Utilization

CLINICAL AND TRANSPLANTATION RESEARCH

A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index

CLINICAL AND TRANSPLANTATION RESEARCH

A Simplified Donor Risk Index for Predicting Outcome After Deceased Donor Kidney Transplantation

Christopher J. E. Watson,¹ Rachel J. Johnson,² Rhiannon Birch,² Dave Collen,² and J. Andrew Bradley¹

Background. We sought to determine the deceased donor factors associated with outcome after kidney transplantation and to develop a clinically applicable Kidney Donor Risk Index.

Methods. Data from the UK Transplant Registry on 7620 adult recipients of adult deceased donor kidney transplants between 2000 and 2007 inclusive were analyzed. Donor factors potentially influencing transplant outcome were investigated using Cox regression, adjusting for significant recipient and transplant factors. A United Kingdom Kidney Donor Risk Index was derived from the model and validated.

Results. Donor age was the most significant factor predicting poor transplant outcome (hazard ratio for 18–39 and 60+ years relative to 40–59 years was 0.78 and 1.49, respectively, $P < 0.001$). A history of donor hypertension was also associated with increased risk (hazard ratio 1.30, $P = 0.001$), and increased donor body weight, longer hospital stay before death, and use of adrenaline were also significantly associated with poorer outcomes up to 3 years posttransplant. Other donor factors including donation after circulatory death, history of cardiovascular disease, diabetes history, and terminal creatinine were not significant. A donor risk index based on the five significant donor factors was derived and confirmed to be prognostic of outcome in a validation cohort (concordance statistic 0.62). An index developed in the United States by Rao et al., *Transplantation* 2009; 88: 231–236, included 15 factors and gave a concordance statistic of 0.63 in the UK context, suggesting that our much simpler model has equivalent predictive ability.

Conclusions. A Kidney Donor Risk Index based on five donor variables provides a clinically useful tool that may help with organ allocation and informed consent.

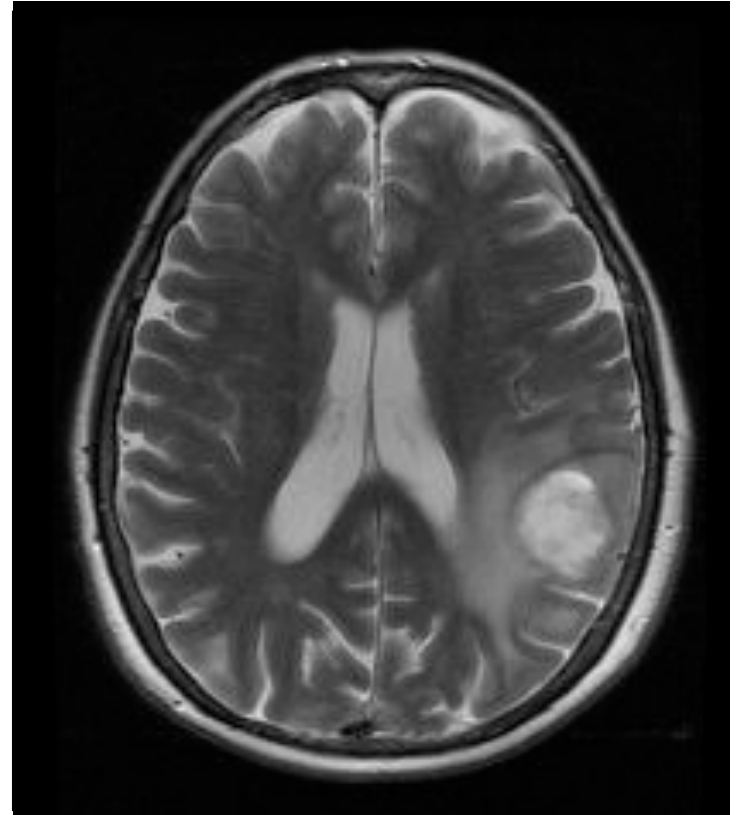
Keywords: Kidney transplantation, Deceased donation, Graft survival.

(*Transplantation* 2012;93: 314–318)

The severe shortage of deceased donor (DD) organs available for transplantation has led to increased use of about organ allocation and allows appropriate counseling of potential recipients.

Known unknowns: Donor associated risks

- Mode of death
 - Carbon monoxide poisoning
 - Hanging / Drowning
- Transmission of Infection
 - Definite risk
 - Hepatitis B or C pos
 - HIV positive
 - High risk behaviour
 - Sex workers; Prisoners; iv drug use
 - "seronegative infectious window"
- Transmission of cancer
 - Primary brain tumour
 - Rarely transmitted (2% for GBM)
 - History of previous cancer
 - Rarely transmit if "cured" 5 years ago



Selection of donors in an era of organ shortage

Figure 2.1 Number of deceased donors and transplants in the UK, 1 April 2009 - 31 March 2019, and patients on the active transplant list at 31 March

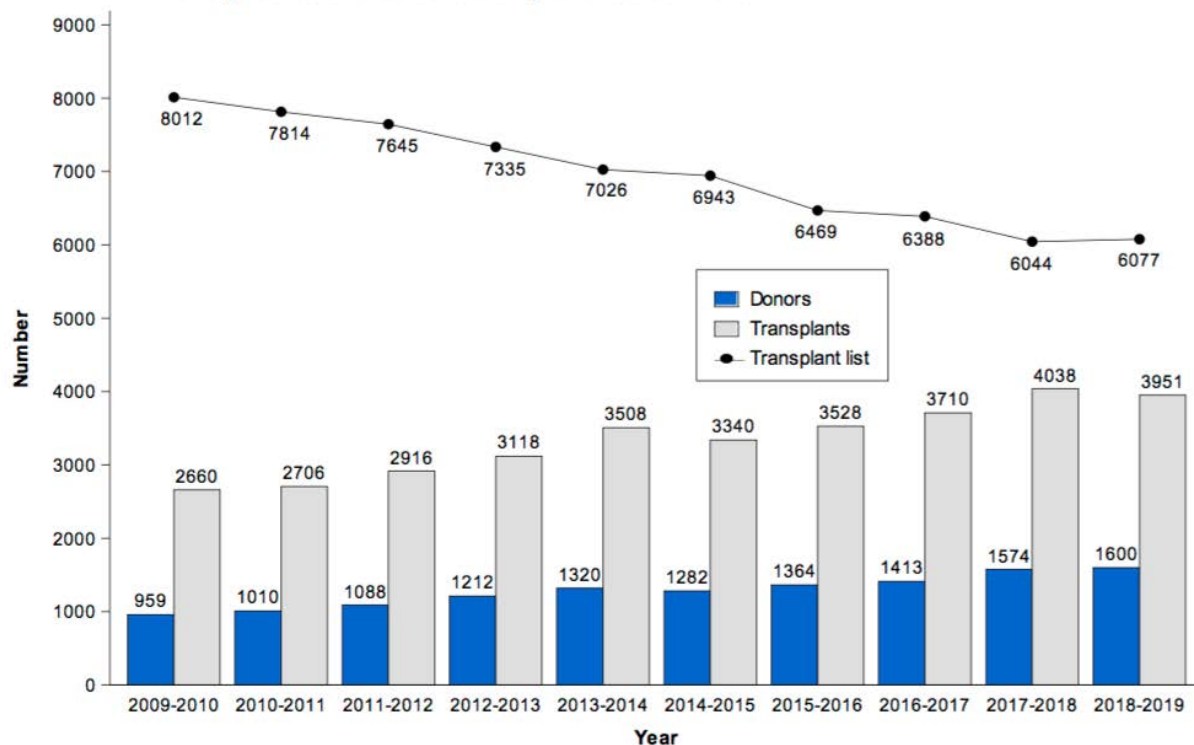


Figure 7.5 Post-registration outcome for 269 first lung only registrations made in the UK, 1 April 2015 - 31 March 2016

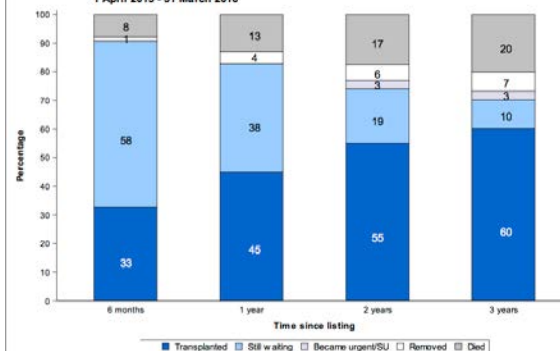
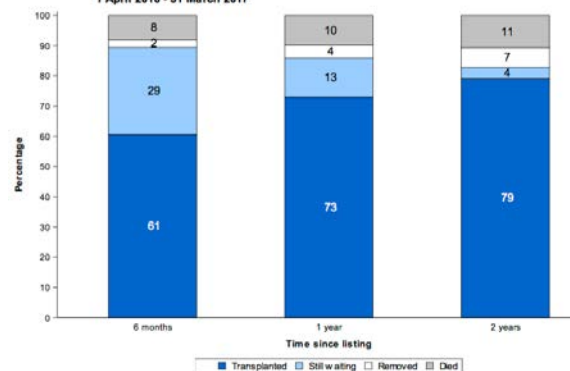


Figure 8.2 Post-registration outcome for 1021 new elective liver only registrations made in the UK, 1 April 2016 - 31 March 2017



Risks in transplantation

- Transplantation
 - Peri-operative death
 - Surgical
 - Anaesthetic
- Immunosuppression related adverse events
 - Cancer
 - Infection
 - Drug side effects e.g. diabetes
- Transmission from donor
 - Infection: CMV, EBV
 - HIV, HCV; HBV; rabies; West Nile fever;
 - Cancer:
 - Donors with known history:
 - Donors with no history: 1 in 2000
 - Disease, e.g. ITP
- Poor donor organ function
 - Primary non function
 - Donor quality
 - Organ quality indices: DRI, DLR

Risk is relative

- Risk in normal life
 - Tends to be avoided
 - Most of us are risk averse
- But
 - Transplantation involves risk
 - Delaying transplantation involves risk



Absolute vs Relative Risk

- Absolute risk
 - Risk of death with this transplant: 10 in 100
 - Risk of death on waiting list: 15 in 100
- Relative risk
 - Comparing risk on waiting list versus risk of accepting donor, e.g. 1.5 times more likely to die if wait than if have this lung/liver/etc.

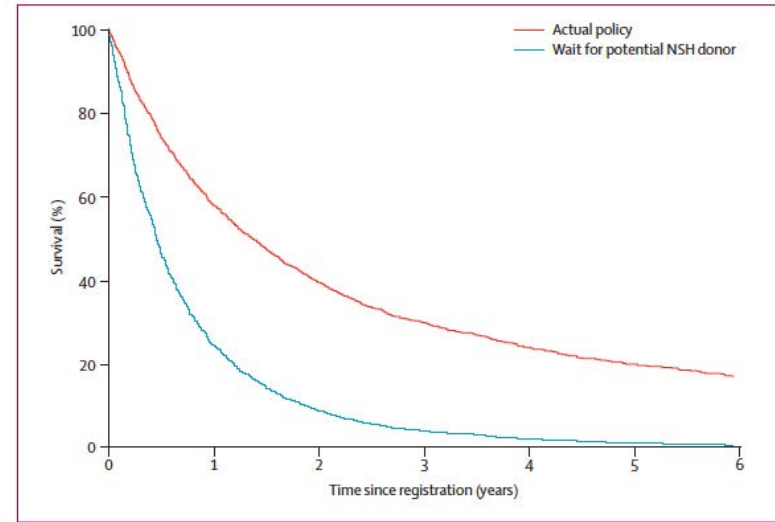
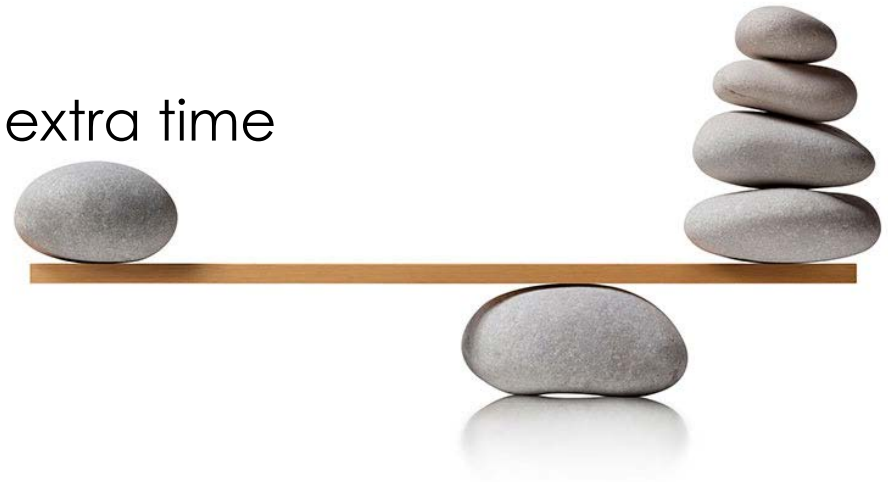


Figure 4: Actual survival from waiting-list registration for patients with a diagnosis of pulmonary fibrosis listed between 1999 and 2003, and an estimated survival if lungs from donors with positive smoking histories were excluded from the donor pool and patients chose to wait for lungs from donors with negative smoking histories
NSH=negative smoking history.

What the patient must know, & understand: Absolute vs Relative Risk

- The risks for that individual associated with waiting
- Any additional risks that the donor poses
- Chance of another transplant offer (and when) if decline the initial offer
- Risk of death while waiting the extra time



Annual Risk of Death

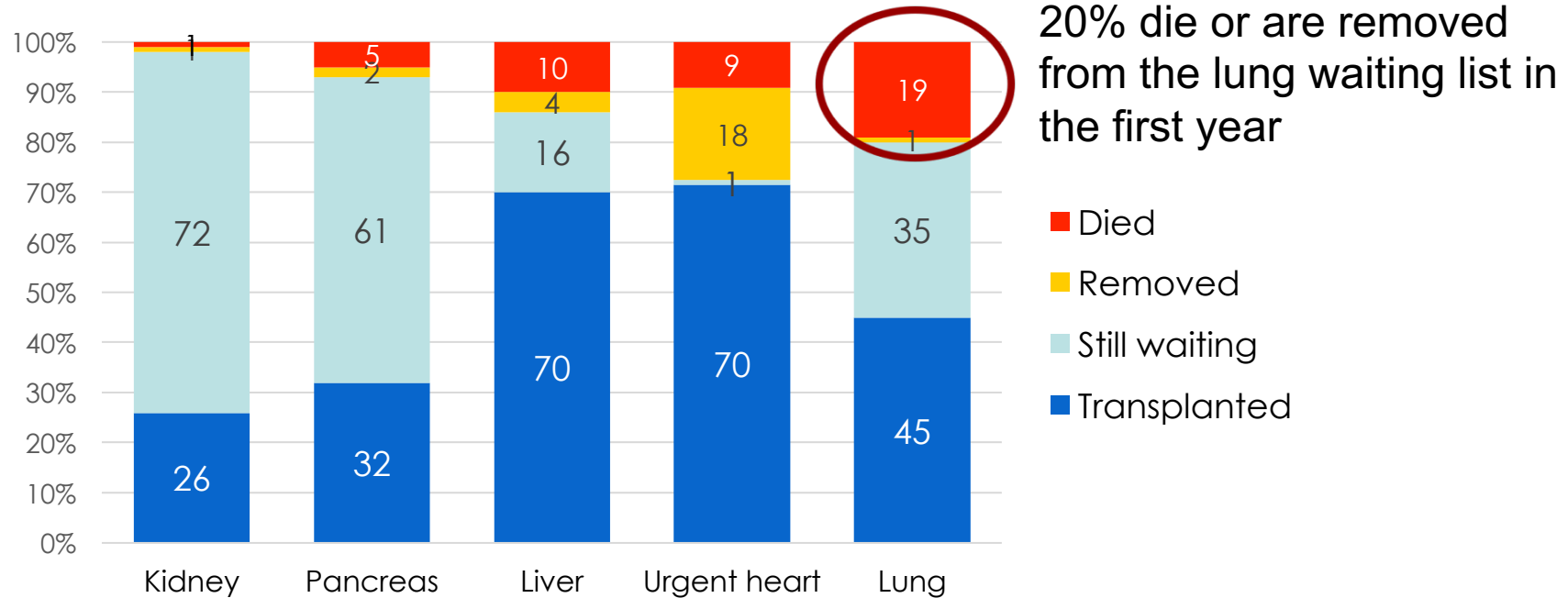


- Lung transplant waiting list: 250 per 1000
- Annual mortality rate in England & Wales:*
- Age 25-34: 0.8 per 1000
- Age 35-44: 1.5 per 1000
- Age 45-54: 3.6 per 1000
- Serving in Afghanistan: 171 per 1000 per year**

*Data for men. ONS data for 2005. <http://www.ons.gov.uk/>

** Blastland & Spiegelhalter: The Norm Chronicles

Patient outcomes one year after joining the transplant waiting list



Formula 1 motor racing is safer than waiting for a lung



Mark Webber, Valencia, 2010
"Red Bull gives you wings"

Everyday risk: My risk of death in coming to give this talk

- Cambridge to Bristol: 340 miles return trip
- By motorbike: 49 in 1,000,000
 - 1 micromort per 7 miles
- By car: 1 in 1,000,000
 - 1 micromort per 333 miles
- By train or commercial plane: 0.045 in 1,000,000
 - 1 micromort per 7500 miles
 - By light aircraft: 23 in 1,000,000



Sir David Spiegelhalter: 1 micromort is a 1 in a million chance of death.

Someone waiting for a lung transplant

- 25 in 100 chance of dying
 - 250 000 micromorts
- Flying a mission for Bomber Command in WW2
 - 25 000 micromorts
- i.e. being on the lung list is like flying 10 bombing missions



How to present the concept of risk



Communicating risk

- Nothing is safe
 - There is a risk of death on waiting list
- Organs are not new
 - They are all second hand
“from someone who died”
- Avoid emotive terms
 - “suboptimal”
 - “marginal”
 - “high risk”

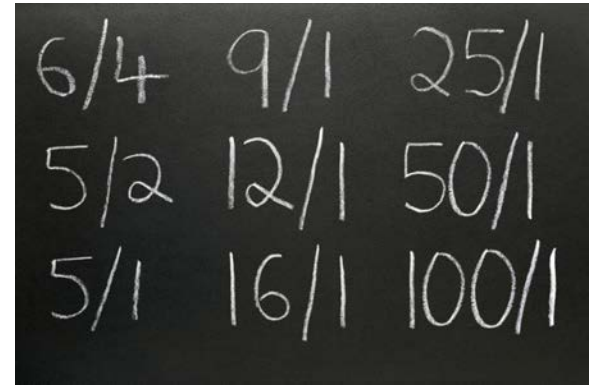


“You’re what we call ‘high risk.’”

Numeric description of risk

Possible numeric formats

- Percentages, e.g. 10%
- Frequencies, e.g. 10 in 100
- Odds, e.g. 10 to 1
- Classical probabilities 0.0 to 1.0



IMPLIED PROBABILITY	FRACTIONAL ODDS
99.01%	1/100
80.00%	1/4
75.00%	1/3
66.67%	1/2
55.56%	4/5
50.00%	1/1
45.45%	6/5
40.00%	3/2
33.33%	2/1
13.33%	13/2
5.00%	19/1

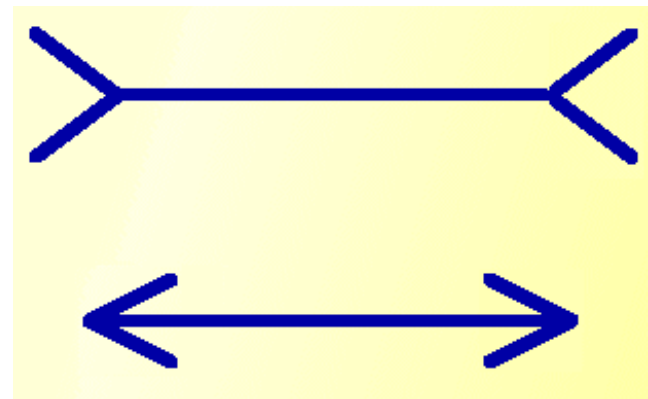
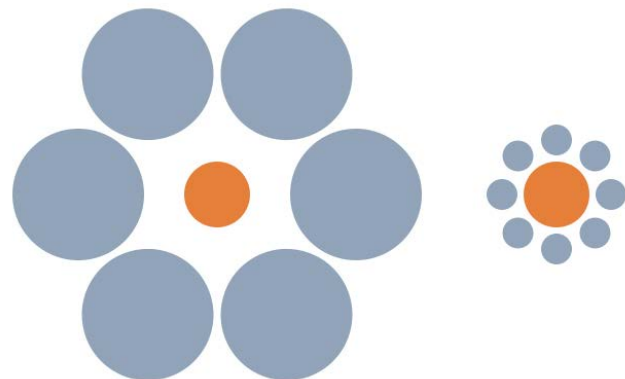
Which is bigger?

A

- 1 1 in 1000
- 2 74 in 100
- 3 20 in 50
- 4 9 to 1 against
- 5 12% patients die

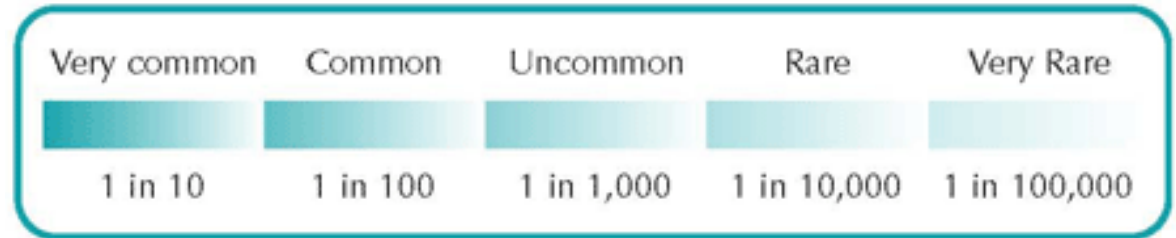
B

- 10 in 10000
- 3 in 4
- 40%
- 1 in 10
- 7 out of 8 patients survive



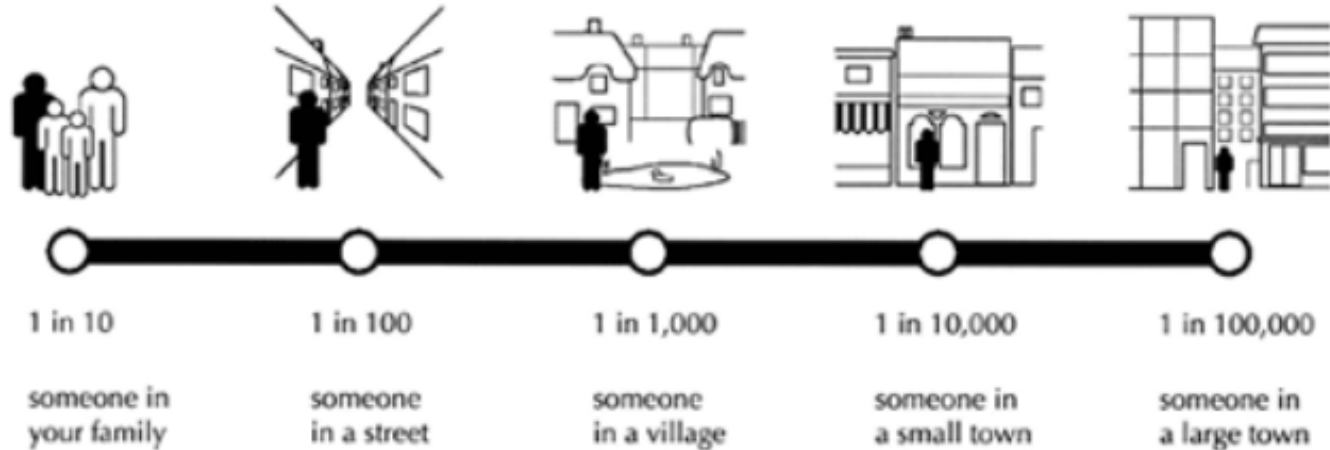
Descriptive terms

- Avoid descriptive terms such as:
 - “common”, “rare”, “possible”, “unlikely”
 - Different perceptions between healthcare professional and patient
- Standardise terminology
 - As in figure below*



How common: Making frequencies meaningful

The following diagram may help you decide how you feel about a risk:



In 2018: Cambridge 129,000; Oxford 154,600; Bristol 459,300

Making frequencies meaningful: 2



- 8 in 100:
 - Chance of drawing an Ace from a deck of cards
 - Chance of dying in the first year after a liver transplant
 - Chance of a deceased donor kidney failing in the first year
- 2 in 100
 - Chance of getting £10 on the lottery
 - Chance of dying following a kidney transplant if you're under 60 and not diabetic

Recommendations for numeric estimates



- Actual frequencies
- Consistent denominator
 - 5 in 100 vs. 11 in 100 rather than 1 in 20 vs. 1 in 9
- Whole numbers, not decimals
- Numerator
 - Some perceive risk by size of numerator, so 10 in 100 is greater than 1 in 10.
Influences choice of denominator
- Avoid logarithmic scales
 - No one understands them

Numerator
Denominator

WHICH HEALTH MESSAGES WORK?

EXPERTS PREFER NEGATIVE ONES BUT
THE PUBLIC FOLLOWS POSITIVE MESSAGES.

Framing

- Positive and negative framing
 - Doctors tend to concentrate on negative risk
 - 5 in 100 chance of death
 - Patients want to know success
 - 95 in 100 chance of survival
- Positive framing
 - Evidence suggests more effective in persuading patients to take “risky” treatment



Numeracy

= numerical literacy

- Patient numeracy very poor
 - 60% of patients innumerate in US transplant study*
 - 22% of school leavers in UK in 2010.
- Healthcare professionals
 - may not be good either

*Elisa Gordon, Northwestern. ATC presentation.

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Fifth of school leavers 'illiterate and innumerate'

One in five teenagers is practically unemployable after leaving school lacking the English and maths skills needed for everyday life, research suggests.

By Graeme Paton, Education Editor
Published: 3:24PM BST 07 May 2010

The number of 16- to 19-year-olds rendered functionally illiterate or innumerate has failed to improve over the last two decades, the study said, despite billions spent attempting to raise standards in the three-Rs.

Teenagers' reading ability has barely changed since 1960, it was claimed, leaving thousands of young people struggling to "partake fully in employment [and] family life".

The conclusions – in research from Sheffield University – come amid continuing fears over levels of basic skills.

Last month, a cross-party committee of MPs said that the number of school leavers without a job or college place had failed to improve "despite one policy strategy after another".

It will also raise doubts over Labour claims that school standards have risen dramatically in the last 13 years.

On Friday, the National Union of Teachers warned that more action was needed to tackle the "long tail of underachievement" in schools.

In the latest study, academics assessed evidence relating to levels of basics skills among young people between 1948 and 2009.

It said the latest data suggested 22 per cent of 16- to 19-year-olds were now functionally innumerate, while 17 per cent were illiterate.

Related Articles

- 900,000 young classed as 'Neets'
- School homework is 'polluting family life'
- Private and state school gap 'widening under Labour'
- Labour has failed to reduce 'Neets', say MPs
- Neets figures 'to top one million for first time'
- OECD: UK has more 'Neets'

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We can only show you averages. It is impossible to predict whether your results will be positive or negative.



The Palling Palette© of 1000 Women. Copyright 2001 John Palling & Co.

Odds for a 39 year old woman of producing a child with Downs Syndrome or other chromosome abnormality 12 out of 1000

Odds of a woman having a miscarriage as a result of amniocentesis 4 out of 1,000

Data from Hook EB, Cross PK and Schreinemachers DM. Chromosome abnormality rates at amniocentesis and in live born infants. JAMA 249(15):2034-8

Which way is best?

- 68 yr man, 6.5cm AAA
- Options: Operate or observe
- Patient choices
 - Numerical: 100% chose surgery
 - Bars: 92% chose surgery
 - Icons: 67% chose surgery
- Confidence in decision
 - Less confident with decision when information in icons

Timmermans et al. Pat Edu Council 2004; 54: 255
(a Dutch study; elderly subjects (age 72))

Treatment options

Mortality risk of operation:

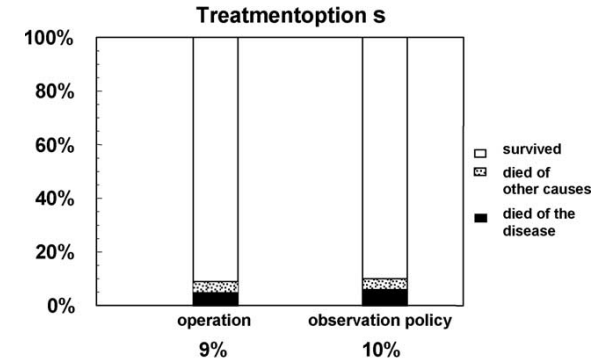
9% of the patients die:

5% of the disease, 4% of other causes

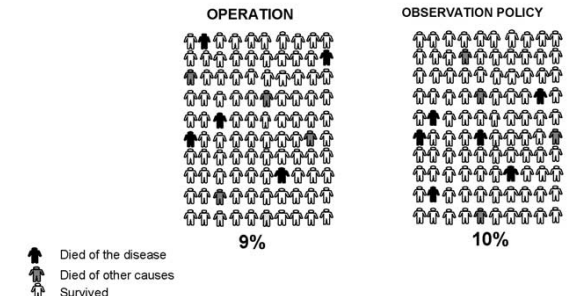
Mortality risk of observation policy:

10% of the patients die:

6% of the disease, 4% of other causes



Treatment options



Which is the best way to convey risk?

- Evidence mixed
- Many studies favour graphical representation
- Some suggests people are less risk averse with numbers rather than bar graphs or icons
- Depends on
 - Cognitive ability of patient
 - Age
 - Level of education

* Stone et al. J Exp Psych:Appl 1997; 3: 243. Timmermans et al. Pat Edu Coun 2004;54:255

** Lipkus et al. J Natl Cancer Inst Monogr 1999;25: 149

Challenges in communicating risk

- Personalise risk
 - Statistics are for populations
 - How typical of the population is the patient?
 - 2% of patients die after a kidney; 5% if they are diabetic
 - How closely does the patient associate himself with the risk
 - Eg if 5 in 100 may get a donor cancer, emphasise that the patient may be one of the 5 or one of the 95
- Communicating interactions
 - How do multiple risks interact
- Communicating small probabilities
 - Less than 1% tends to be ignored



Giving the information?

■ Who?

- Nurse
- Doctor
- Peers – fellow patients

■ How?

- A process, not an event
- With information to take away
 - Booklets
 - Videos
 - Websites
 - NB: Literacy



Summary

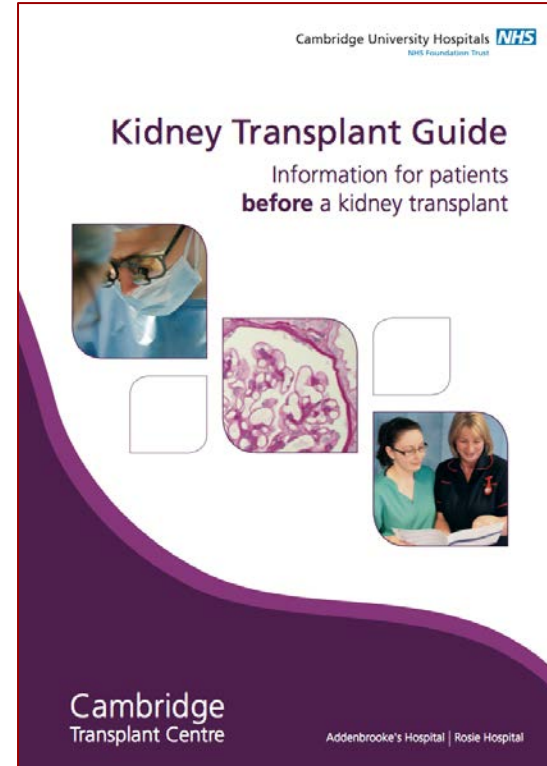
- Informed consent
 - relies on a dialogue between an informed patient and healthcare professional
 - demands communication of the risks and benefits of the choice available
- Good communication of risk is essential
 - Treatment options and associated risks
 - Organ quality
 - Donor disease
 - Transplant complications
- Multiple modalities of risk information are probably best
 - Information at time of listing
 - Reiterated during waiting period
 - Confirmed at time of transplant



How do I do it?

3 stages

- Written information
 - Patient booklet
 - An information sheet
 - The consent form
- The clinic appointment
- The repeat appointment
 - Completion of assessment
 - Reviews on the waiting list



The information sheet

20 pages

Patient Information

Cambridge University Hospitals **NHS**
NHS Foundation Trust

Patient information and consent to kidney transplantation

Key messages for patients

- **When you are called to come in for a transplant follow the instructions given by the transplant coordinator; they will usually ask you not to eat or drink anything following the call.**
- **Please read this information carefully,** you and your health professional will sign it to document your consent.
- **Please bring with you any medications you use and its packaging (including patches, creams, inhalers, insulin, herbal remedies and CPAP machines)** and any information that you have been given relevant to your care in hospital, such as x rays or test results. If you are on peritoneal dialysis please bring a bag of PD fluid with you so you can do this on the ward if you have to wait before the transplant.
- When a suitable kidney is available, you will be contacted by phone. This may be **at any time of the day or night; please keep your mobile phones charged and with you.** You will be asked to report to **Ward G5** without delay. This is because the new kidney cannot survive outside the human body for more than a few hours.
- **Transplantation is not without risk.** Some of these risks are outlined in this document. By putting you on the transplant waiting list your doctors have decided that the risks to your life from having a transplant are less than the risks of long-term dialysis. Nevertheless if there are some risks that you would rather avoid you can indicate them when you sign the consent form.
- Please call the **kidney transplant co-ordinators** via the hospital switchboard on **01223 245151** if you have any questions or concerns.

Please read this information carefully. You and your health professional will sign it to document your consent. **After signing this consent form please give or send it to your kidney transplant coordinator.** This form must be signed before you are put on the kidney transplant waiting list. After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent up to the time the operation begins. If you do change your mind and no longer wish to have a transplant, it is important that you inform your transplant co-ordinator immediately, so that you can be removed from the transplant waiting list.

A kidney transplant operation requires a general anaesthetic. You will have the opportunity to discuss this with the anaesthetist.

Kidney transplantation, CF171, Version 5, July 2014

Patient Information

Cambridge University Hospitals **NHS**
NHS Foundation Trust

Cambridge Transplant Unit

Pancreas transplantation

What is the pancreas and why is it transplanted?

The pancreas is an organ situated inside the abdomen, behind the stomach. It makes digestive juices which enter the gut and helps digest the food we eat. It also makes hormones, which it releases into the blood. One of these hormones is insulin. Insulin is made by small clusters of cells within the pancreas called islets. When these cells are damaged, they don't make insulin, and it is this lack of insulin that causes diabetes. By transplanting a new pancreas into a diabetic patient we also transplant the islets. These islets provide a new source of insulin, which means patients no longer need to inject insulin.

Why transplant a whole pancreas and not just the islet insulin producing cells?

Although research has been conducted for many years into islet transplantation, it is still experimental. Only about 2% of the pancreas is made up of islet cells and is a difficult procedure to extract those cells to transplant them on their own. A few patients have received islet transplants, with some success. However having a whole pancreas transplant usually gives better results and lasts for longer, although it does require a bigger operation.

Is a pancreas transplant suitable for all diabetics?

No. A pancreas transplant is only suitable for type 1 diabetic patients, those who become diabetic when they are young and do not make any insulin. Patients with type 2 diabetes do still make insulin, but develop a resistance to it. In most cases a pancreas transplant would not help someone with type 2 diabetes. In addition pancreas transplantation is normally restricted to patients who also need a kidney transplant.

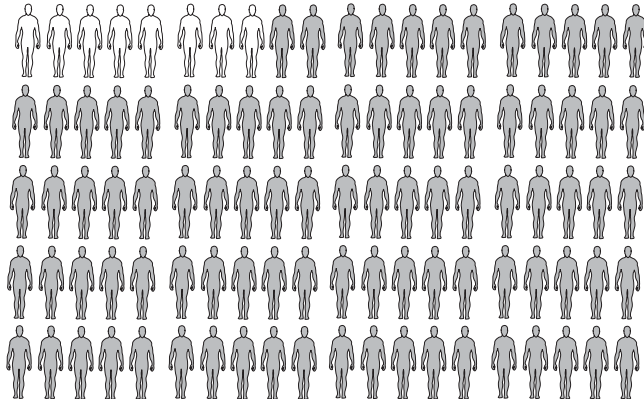
Is it a simple procedure?

A pancreas is usually transplanted at the same time as a kidney. It is a more complicated procedure than a kidney transplant and takes much longer to perform. The operation involves connecting the blood supply of the pancreas to the blood vessels that take blood to and from the leg, usually the right leg. The leg normally gets much more blood than it needs and does not suffer from the operation. In addition to connecting up the blood vessels, another join has to be made into a piece of bowel to drain away the digestive juices that the new pancreas produces. This is carried out through a long cut made in your abdomen. The blood supply to the new kidney is usually connected to the vessels going to and from the left leg.

How does the consent form convey risk?

Significant, unavoidable or frequently occurring risks of this procedure

At the end of the first year after a kidney transplant around 92 out of 100 (92%) kidney transplants will still be working. To help you understand what these mean visually we have printed below a drawing showing 100 people. 92 of the 100 are shaded black, representing the proportion of patients with a functioning kidney a year after the operation, and the remaining eight figures are the proportion of patients whose kidneys will fail. To put it another way, your chance of losing your kidney in the first year is the same as your chance of drawing an ace from a deck of cards.



A kidney transplant is a complex procedure. **There is a small risk (2 in 100) of death in the first year;** this proportion is illustrated by the two white figures in the cartoon above. To put this in perspective, there is also a significant risk of dying whilst on dialysis. The risk of dying on dialysis is higher in patients with diabetes and in older patients. For example, there is a 2 in 100 chance of dying each year on dialysis in patients aged 18 to 34, increasing to 15 in 100 in patients aged 65 to 74. Patients who face higher risks from the transplant operation will be asked to sign a separate consent form.

Donor choices

5 Donor specific choices	
We assume that you are willing to accept livers from any donor that we consider appropriate for you considering your health at the time unless you indicate donor types below that you do not wish to consider. A full explanation is given in the information sheet. If you indicate you do not wish a particular type of donor you should remember that you reduce your chance of receiving a liver.	Initial the box if you do not wish to have a liver from the type of donor described.
a). I do not wish to receive a liver from a donor after circulatory death and understand that there is a slightly higher chance (3 in 100 instead of 2 in 100) that it may not function immediately and there is a higher chance (1 in 15) of bile duct problems afterwards; I understand that 25 in 100 liver donors are circulatory death donors.	<input type="checkbox"/>
b). I do not wish to receive a liver from a donor who has died from a brain cancer, although I realise that there is only a small (less than 2 in 100) chance of the cancer being transmitted to me. I understand that 2 in 100 donors die from a brain cancer.	<input type="checkbox"/>
c). I do not wish to receive a liver lobe. I understand that 7% of donor livers are liver lobes, and that there is a higher chance (6 in 100) of bleeding and bile leaking from the cut surface of the liver.	<input type="checkbox"/>
d). I do not wish to receive an otherwise healthy liver from a donor known to have hepatitis B (HBcAb pos) or hepatitis C. I understand that if I had such a liver I would need to take anti-viral drugs as a consequence, and that 2 in 100 donors have hepatitis B or C.	<input type="checkbox"/>
e). I do not wish to receive a liver from a donor known to use intravenous drugs or whose behaviour puts them at risk of viral infections even though their viral tests suggests you would have less than 2 in 100 chance of becoming infected and needing to take antiviral drugs as a result.	<input type="checkbox"/>
f). I do not wish to receive a liver from a donor who has a history of cancer, although I understand that there is only a very small (less than 1 in 100) chance of that cancer being transmitted to me.	<input type="checkbox"/>

5 Donor specific choices		Initial the box if you do not wish to have a kidney from the type of donor described
We assume that you are willing to accept a kidney from any donor that we consider appropriate for you considering your health at the time unless you indicate donor types below that you do not wish to consider. A full explanation is given in the information sheet. If you indicate you do not wish a particular type of donor you should remember that you reduce your chance of receiving a kidney. In deciding what to accept you need to be mindful that dialysis isn't perfect, and that for most patients it has a higher risk of death than a transplant.		
a). I do not wish to receive organs from a donor after circulatory death and understand that nearly half of all donors are circulatory death donors. Kidneys from such donors have equal long term outcomes, but are slower to start to work immediately after transplantation. By deciding not to have a kidney from this type of donor I realise I may spend longer on the waiting list.	<input type="checkbox"/>	
b). I do not wish to receive a kidney from a donor who has died from a brain cancer, although I realise that there is only a small (less than 2 in 100) chance of the cancer being transmitted to me. 2 in 100 kidney donors have died from a brain cancer.	<input type="checkbox"/>	
c). I do not wish to receive organs from a donor who has a history of cancer, although I realise that there is only a small (less than 1 in 100) chance of that cancer being transmitted to me.	<input type="checkbox"/>	
d). I do not wish to receive organs from a donor known to use intravenous drugs or whose behaviour puts them at risk of viral infections even though their viral tests suggests I would have less than 2 in 100 chance of becoming infected and needing to take antiviral drugs as a result. Around 2 in 100 donors exhibited such high risk behaviour.	<input type="checkbox"/>	
e). I do not wish to receive a kidney from a donor over 60, because the function of the kidney is often poorer. I realise that 34 in 100 kidneys are from donors over 60 and I will therefore have to wait longer for a transplant.	<input type="checkbox"/>	
f). I do not wish to receive a pair of kidneys as a "dual" kidney transplant. I understand that this is done because the transplant team believe one kidney alone will not be enough, but two would be sufficient for me. Between 5 and 10 in 100 transplants in Cambridge are dual transplants.	<input type="checkbox"/>	

need to know?

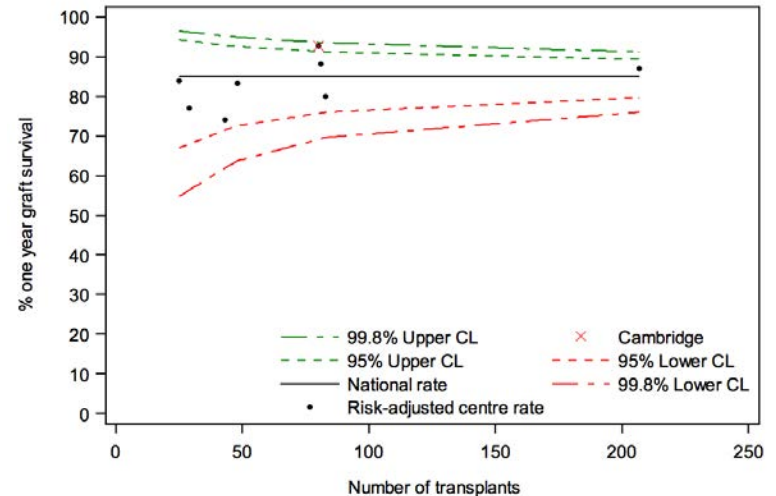
- How much information?
 - Do I need to give?
 - Can the patient and family take in?
 - Blog feedback
- Role of paternalism?
 - What do you think Doc?
- Protection from litigation
 - Of me and of the hospital
 - A fear more than a reality in the UK?



My tendency: Play down benefits, emphasise risks

- Its not an insignificant procedure
- Email enquiry from the US: Why are your results so bad?

Figure 3 Risk-adjusted one year graft (death censored) survival rates for deceased donor SPK transplants, between 1 April 2008 and 31 March 2012



A patient's view of the information sheet



- "I read it and cried"
- I had considered "putting the blinkers on" and not reading it properly, but I knew that I shouldn't
- After I had cried and had time to think about it properly it dawned on me that I should focus on the long term benefits
- I feel better about it now.
- Its your everyday job, you're an experienced team and I'm in good hands. I have to put my trust/faith in that
- *My pancreas coordinator said she was impressed by that, because she hasn't yet managed to achieve that level of trust with the doctors looking after her daughter*

*Carol, after reading the pancreas information sheet

Are they listening?



Hearing, not listening

- East Anglian Renal Meeting
- Talk about pancreas transpantation, risks and benefits
- Deborah: “If you had told me that before the transplant I would never have had it”
 - She had had all the information we give
- 10 years after transplant
 - Qualified as a nurse
 - Married
 - 1 child



Risk taking, the surgeon, the patient, and the waiting list

- Risk taking benefits waiting list as a whole
 - But may not benefit the individual patient
- Surgeon – takes risk for his patients
- Patient – risk averse for himself
- Consent – informed?

SOUNDING BOARD

Informing Candidates for Solid-Organ Transplantation about Donor Risk Factors

Scott D. Halpern, M.D., Ph.D., Abraham Shaked, M.D., Ph.D., Richard D. Hasz, M.F.S.,
and Arthur L. Caplan, Ph.D.

For the first time in 15 years, there has been documented transmission of the human immunodeficiency virus (HIV) through solid-organ transplantation.¹ Although transmission of infectious agents through transplantation is rare,² such cases raise important questions about how informed consent for transplantation should be obtained and about the type of resource that transplantable organs represent.

Among the questions raised are the following: Should potential recipients be informed about the general risks associated with transplantation or those specifically associated with an identified organ? Should the risks engendered by the behavior of donors be treated differently from those associated with the medical profiles of donors? Finally, is the supply of transplantable organs a singular public good to be distributed to maximize public health or is it a market of intermittently available goods from which eligible recipients might select in order to maximize their own well-being?

THE CHICAGO CASE

A 38-year-old man died after a motor vehicle accident in January 2007. His liver, heart, and both kidneys were subsequently transplanted into four recipients. At the time of the donor's death, all routine tests for transmissible diseases³ were negative. However, the local organ-procurement organization and the transplantation surgeons to whom the organs were sent knew that this donor had a behavioral risk factor that increased the possibility that the antibody-based assays for HIV and other viruses might show false negative results.^{1,4}

All four organ recipients have since tested positive for both HIV and the hepatitis C virus (HCV). At least one of the recipients is considering a suit against the transplantation center and the local organ-procurement organization, charging that

she was harmed by not being notified of the donor's above-average risk of HIV and, therefore, was denied the opportunity to decline the donation. Her attorney has declared, "it's up to the patient . . . to make the decision whether to incur the risk."⁵

BEHAVIORAL RISKS AMONG DONORS

A well-known limitation of the safety of organ transplantation is that antibody-based tests to detect viruses have poor sensitivity within the first few weeks after infection.² Although more sensitive nucleic acid-amplification tests are now used in some regions, even these tests do not fully eliminate the possibility of a false negative result. Data from studies involving tissue donors show that between 1 of 55,000⁶ and 1 of 161,000⁶ donors are infected with HIV, despite negative antibody-based tests, and that the addition of nucleic acid testing reduces the rate of false negative results by two thirds.^{6,7}

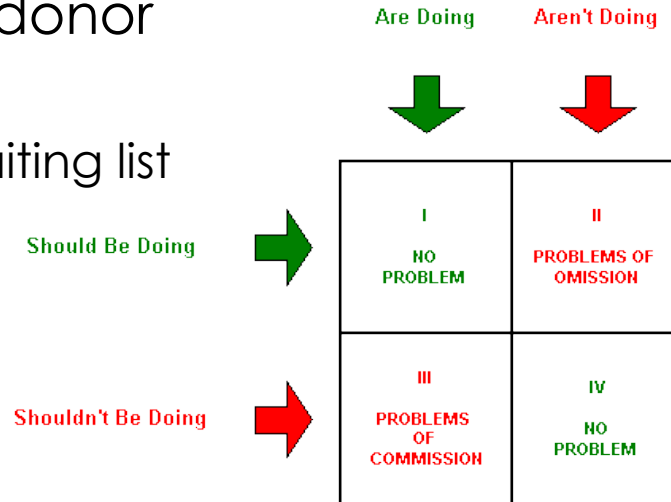
Certain donors have above-average risks of false negative HIV tests because their behaviors may generate more new infections. Nonetheless, persons with risk factors for HIV that have been identified by the Centers for Disease Control and Prevention (CDC)⁸ are commonly donors for solid-organ transplantation. Table 1 indicates that during the period from 1995 to 2006, 6% of donors in our donor service area had risk factors that were consistent with the CDC criteria.

BEHAVIORAL VERSUS MEDICAL DONOR RISKS

Donors with behavioral risk factors are not barred from contributing to the organ supply, as they are from contributing to the blood supply,⁷ because scarcity is a much more salient feature of the or-

The transplant surgeon's dilemma

- Use organs from a less than ideal donor
 - Higher chance of failure
 - Death from failure is the surgeon's fault
- Wait for organs from an ideal donor
 - Less chance of failure
 - More chance of death on the waiting list
 - But its not **my** fault...



Is it reasonable to ask a patient to make a choice

- when medical professionals cannot agree on the magnitude of a risk?

