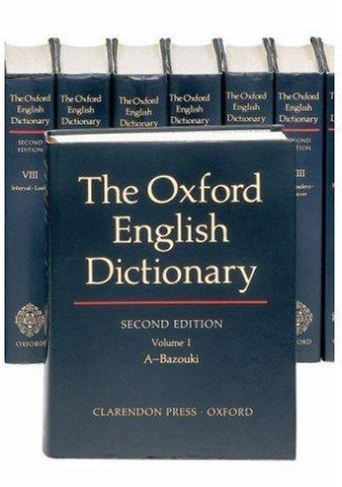
Consent and communicating risk

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"

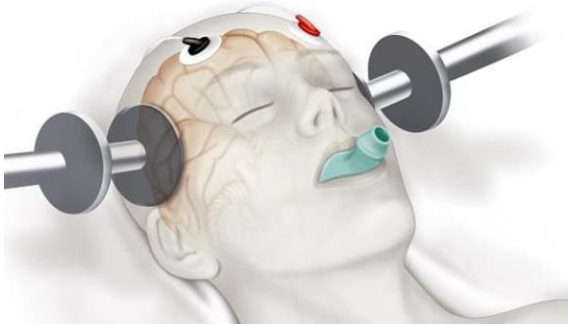
- Informed consent:
  - *Law:* permission granted in the knowledge of the possible consequences;

  - *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

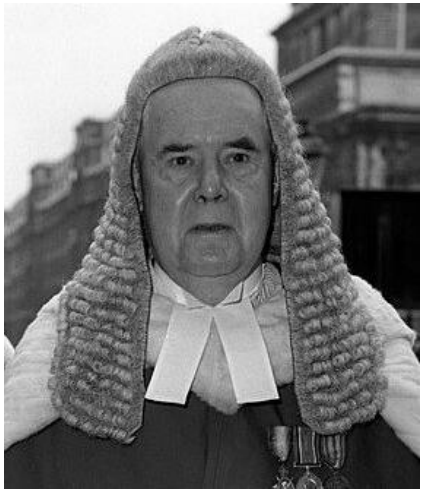
Permission granted in the knowledge of the possible consequences

What risks should be disclosed?

Bolam vs Friem Hospital Management Committee 1957: the Bolam Test



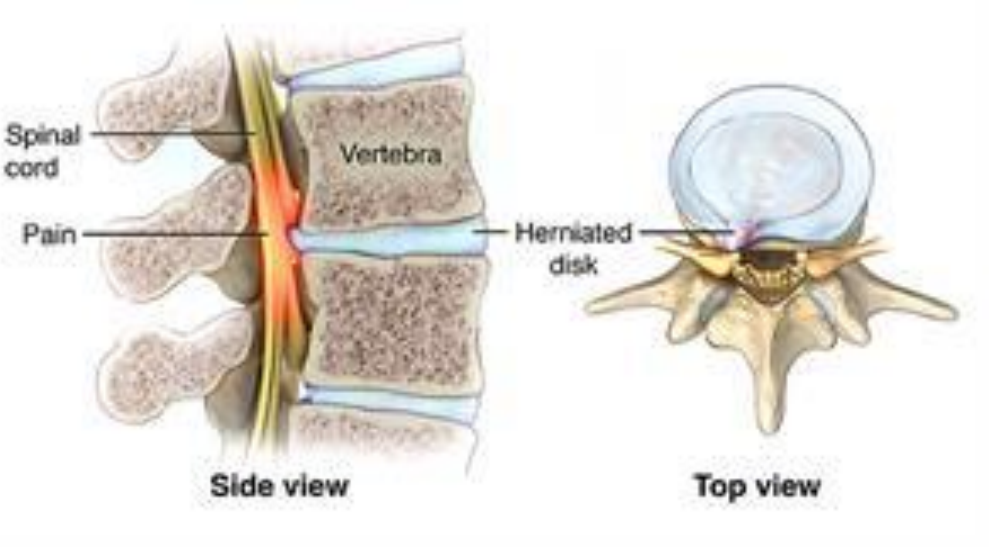
- John Bolam underwent electroconvulsive therapy without muscle relaxant and without restraint
  - He sustained many injuries including a pelvic fracture
  - He sued the hospital



- 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%



Sidaway v Board of Governors of the Bethlem Royal Hospital 1985

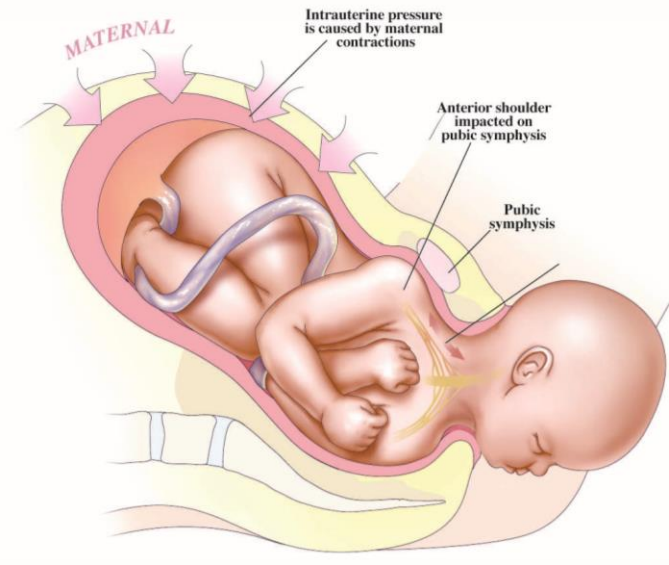
- Amy Doris Sidaway underwent cervical cord decompression
  - Neurosurgeon did not mention risk of paraplegia, which was <1%

- 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

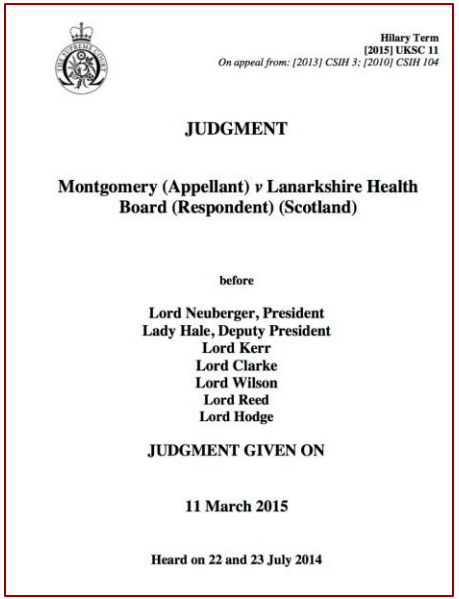
Supreme Court, Lord Neuberger presiding

- 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 secton 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.'



Hilary Term
[2015] UKSC 11
On appeal from: [2013] CSIH 3; [2010] CSIH 104

JUDGMENT

Montgomery (Appellant) *v* Lanarkshire Health Board (Respondent) (Scotland)

before

Lord Neuberger, President
Lady Hale, Deputy President
Lord Kerr
Lord Clarke
Lord Wilson
Lord Reed
Lord Hodge

JUDGMENT GIVEN ON

11 March 2015

Heard on 22 and 23 July 2014

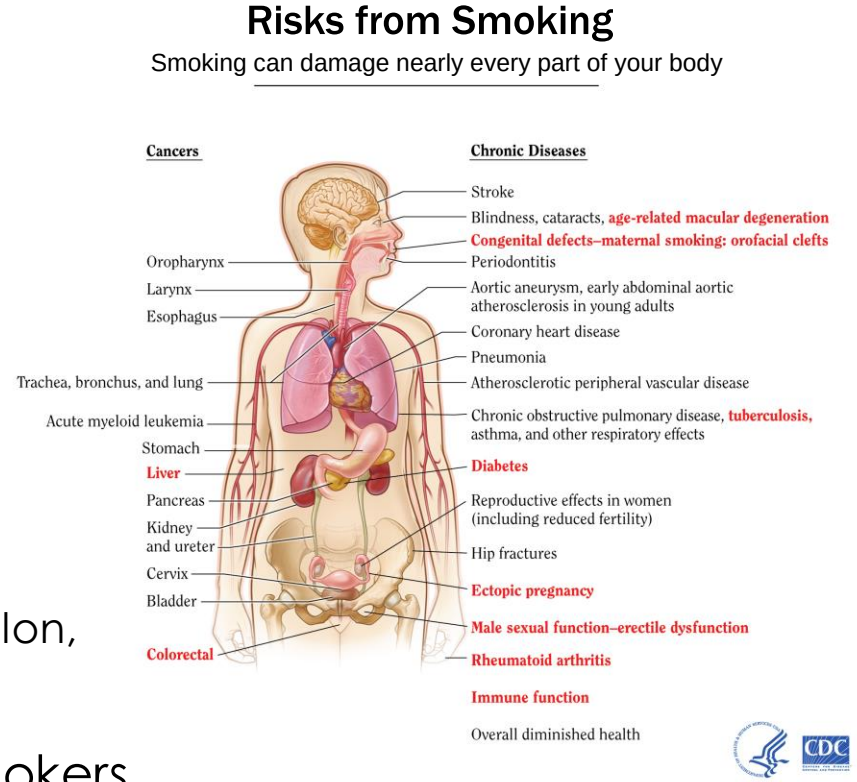
The legal position: summary

- Reasonable doctor vs. reasonable patient
- No longer sufficient to tell a patient what a "reasonable doctor" might say
  - Bolam/Sidaway
- Requirement now is to tell a patient what a "reasonable patient" would want to know
  - Montgomery

Understanding Risk

Who smokes?

- Reduces life expectancy by 7 years
- 25x more likely to get Lung Cancer
- 2-4x more likely to get 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 compications



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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.

Lynsey Scott died a few months after her lung transplant

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.

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

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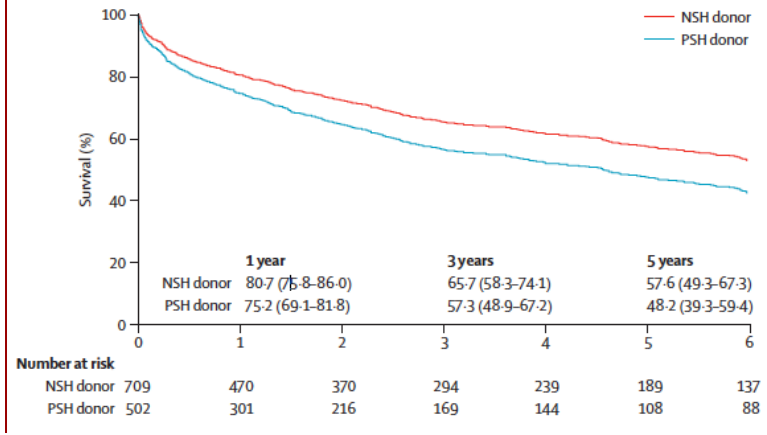
Smoking and donation: facts

- 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



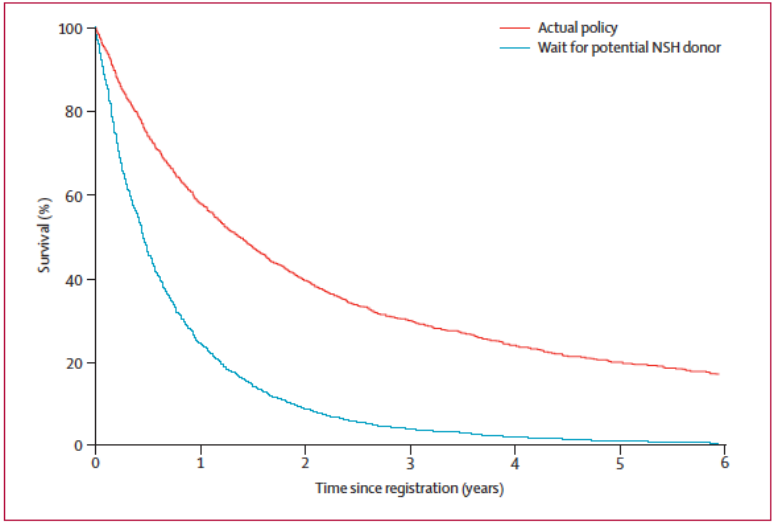
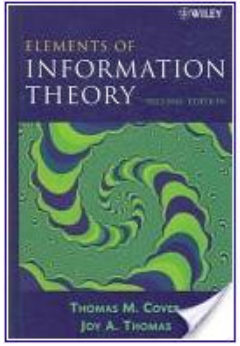


Figure 4: **Actual survival from waiting-list registration for patients with a diagnosis of pulmonary fibrosis listed between 1999 and 2003, and an estimated survival if lungs from donors with positive smoking histories were excluded from the donor pool and patients chose to wait for lungs from donors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

Bonser et al. Lancet 2012;380:747

Informed consent and risk



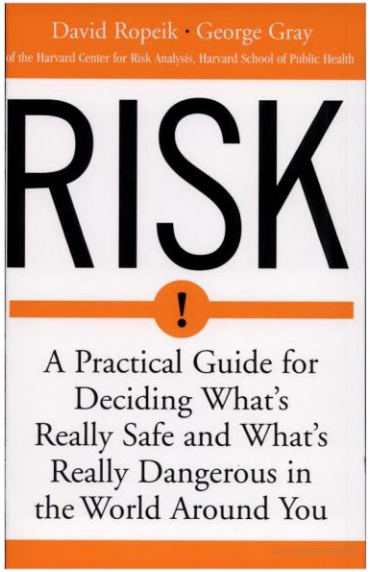
- Information
  - A reduction in uncertainty
  - Knowledge of a possible event and its likelihood

- 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,

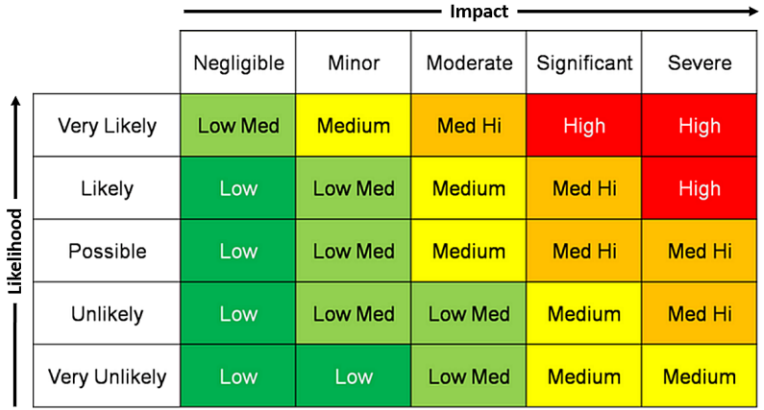
    Risk = probability x harmful consequence



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

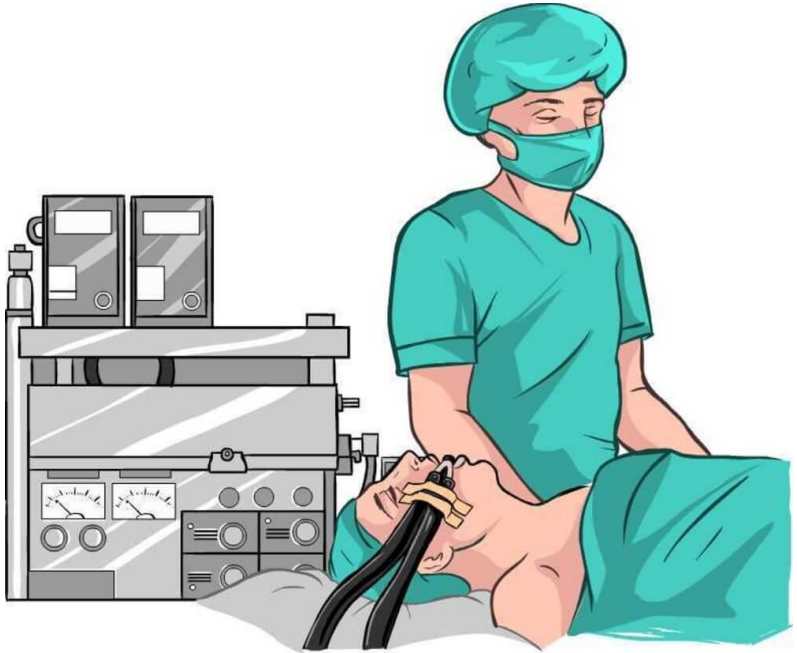
Risk = probability x harmful consequence



Perception of risk

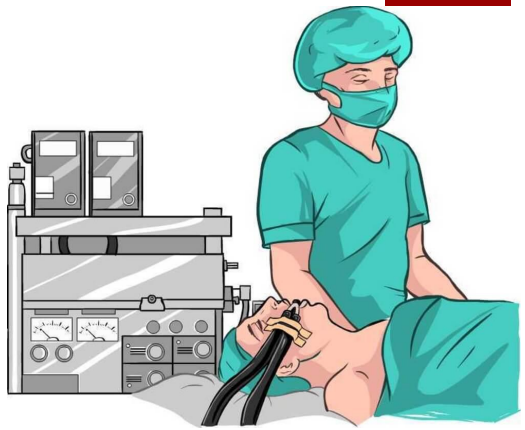
- Two sorts of risk
  - Actual risk – objective likelihood of event occurrence
  - Perceived (or emotional) risk
    - Based on belief of event occurrence,
    - Affected by emotion not fact
    - Illustrated well by gambling, where chance of winning over estimated
- Lottery risk
  - Chance of winning 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"*

Which is more likely to kill you, a routine anaesthetic or a parachute jump



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. ≤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.

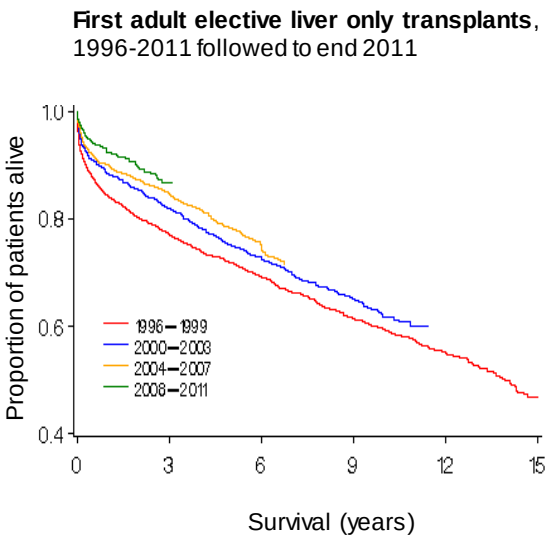
Donald Henry Rumsfeld, 1932-2021.
U.S. Secretary of Defence under Presidents Ford and Bush Jnr.
The man who started the war in Afganistan

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
- Immunosuppression

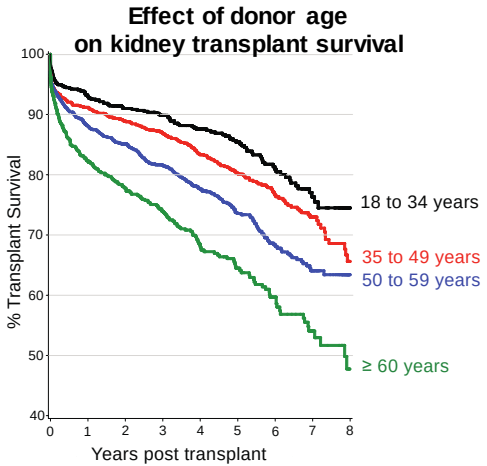
Outcome measures in transplant: Survival

- 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



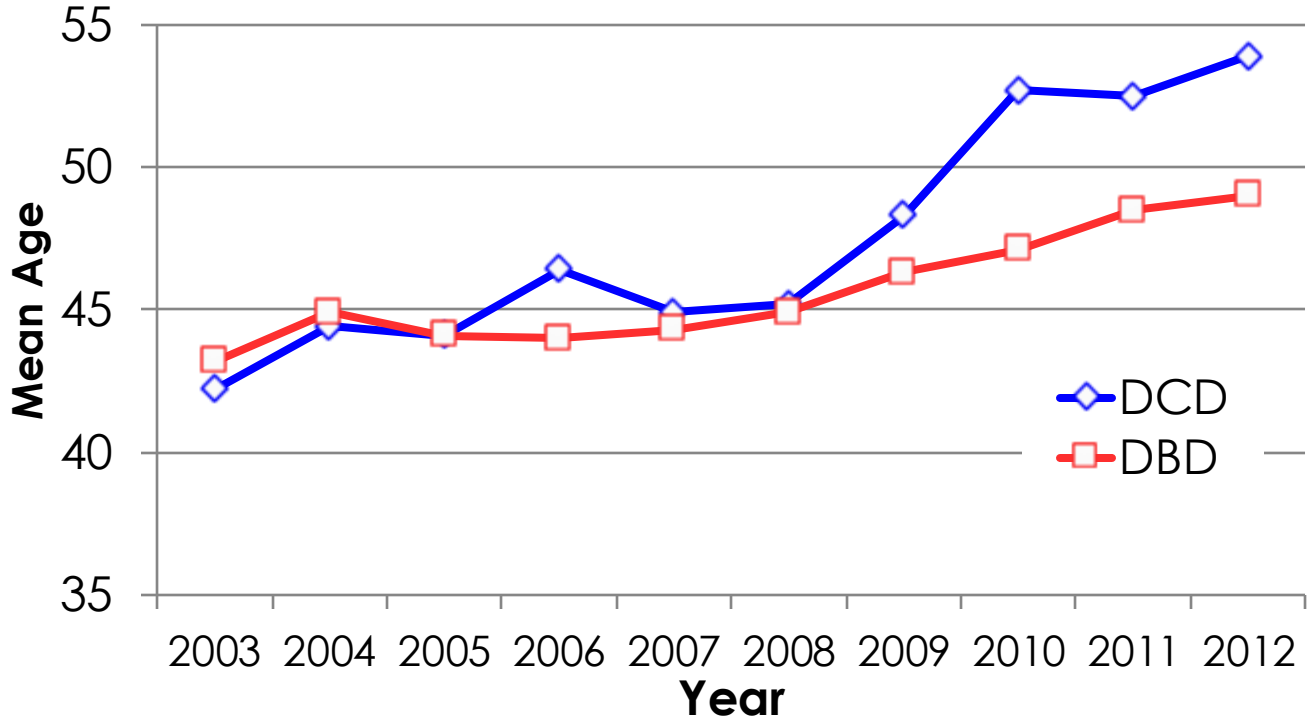
Known knowns:
Donor factors affecting outcome

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



Donors are getting older

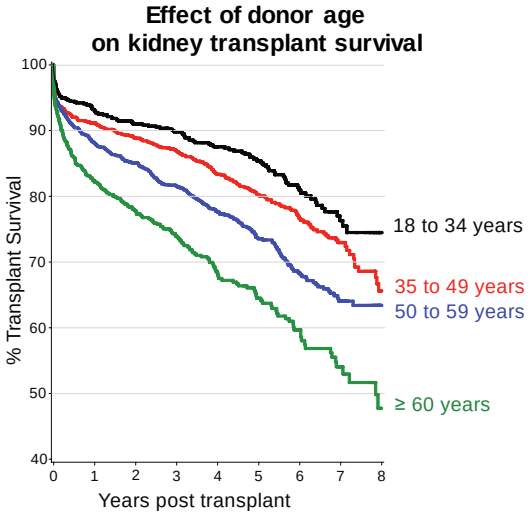
Mean age of deceased donors, 2003-2012.

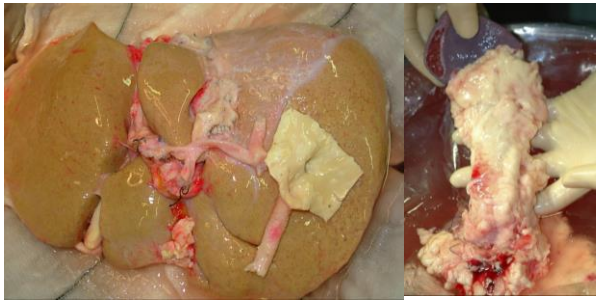


Courtesy Rachel Johnson, NHSBT

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
- "Risk" Index to aid:
  - Acceptance of donor organ
  - Allocation of donor organ
  - Audit of outcomes

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

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

CLINICAL AND TRANSLATIONAL RESEARCH

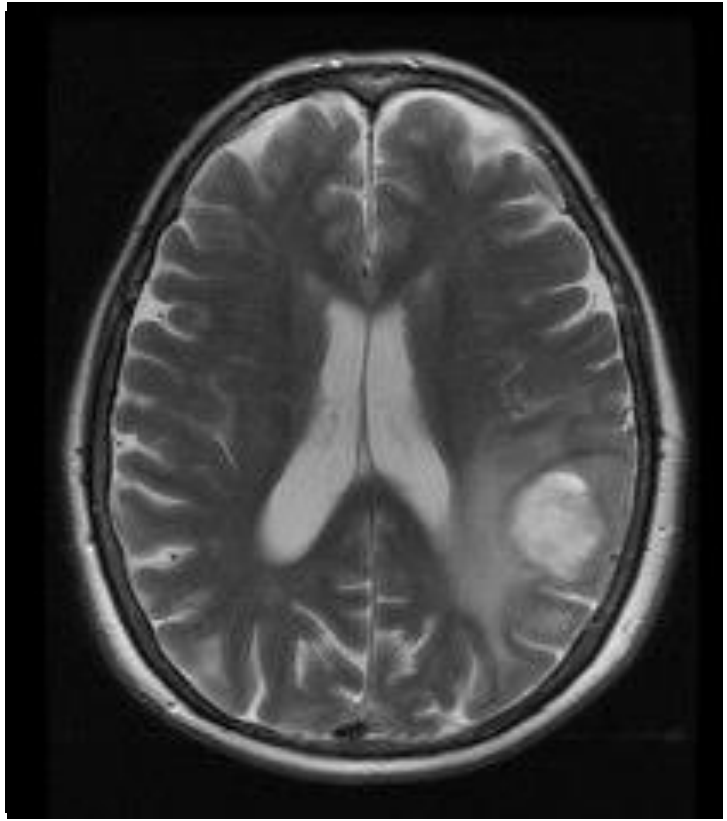
A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index

CLINICAL AND TRANSLATIONAL RESEARCH

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

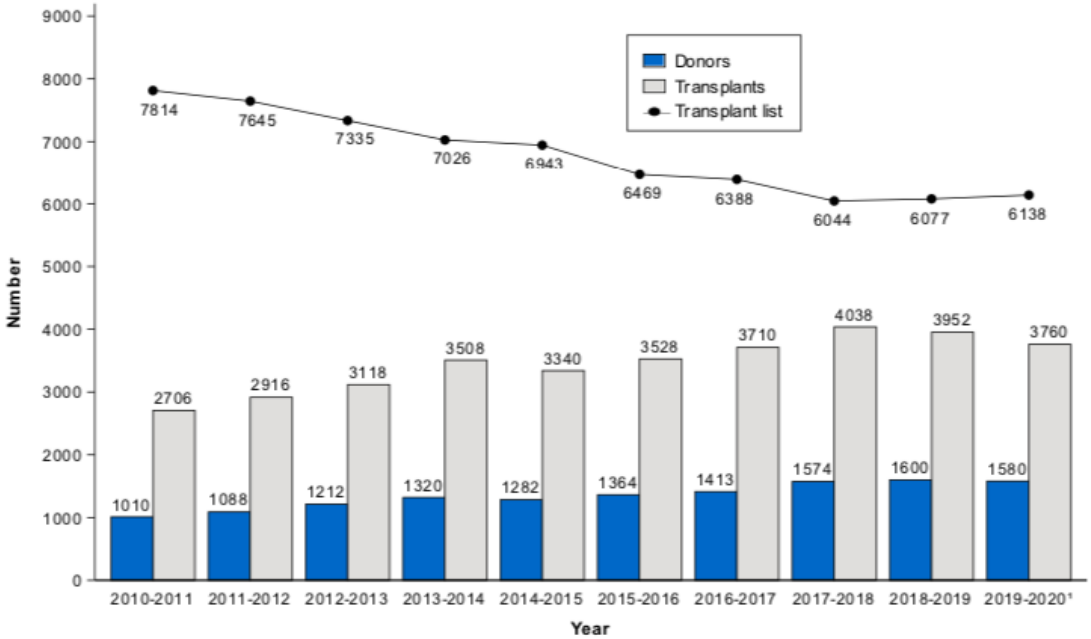
Known unknowns: Donor associated risks

- 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



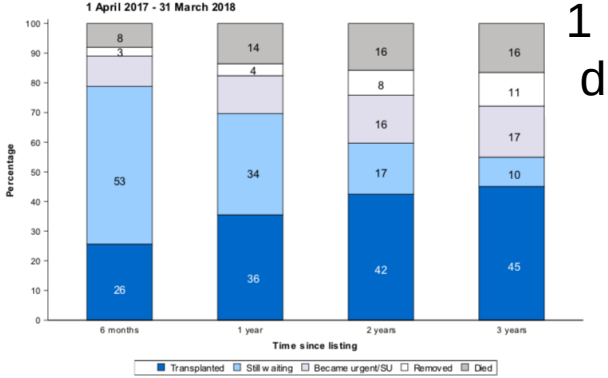
Selection of donors in an era of organ shortage

Figure 2.1 Number of deceased donors and transplants in the UK, 1 April 2010 - 31 March 2020, and patients on the active transplant list at 31 March



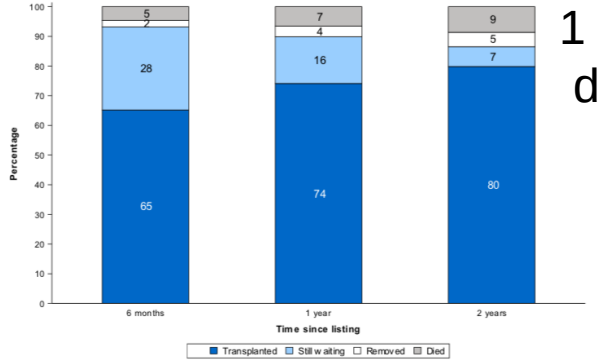
¹ Waiting list as at 29 February 2020

Figure 7.5 Post-registration outcome for 273 first lung only registrations made in the UK, 1 April 2017 - 31 March 2018



1 in 6 die

Figure 8.2 Post-registration outcome for 1066 new elective liver only registrations made in the UK, 1 April 2018 - 31 March 2019



1 in 11 die

Source: ODT Annual Activity Report, 2021. NHS Blood and Transplant.

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.

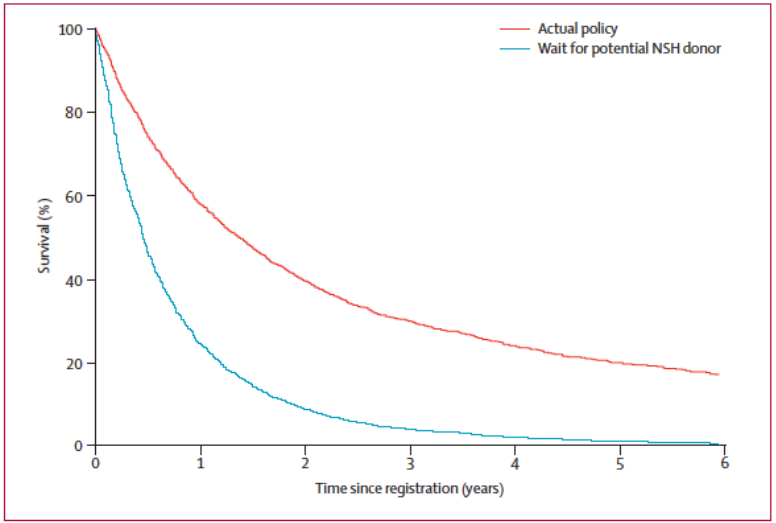


Figure 4: **Actual survival from waiting-list registration for patients with a diagnosis of pulmonary fibrosis listed between 1999 and 2003, and an estimated survival if lungs from donors with positive smoking histories were excluded from the donor pool and patients chose to wait for lungs from donors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

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

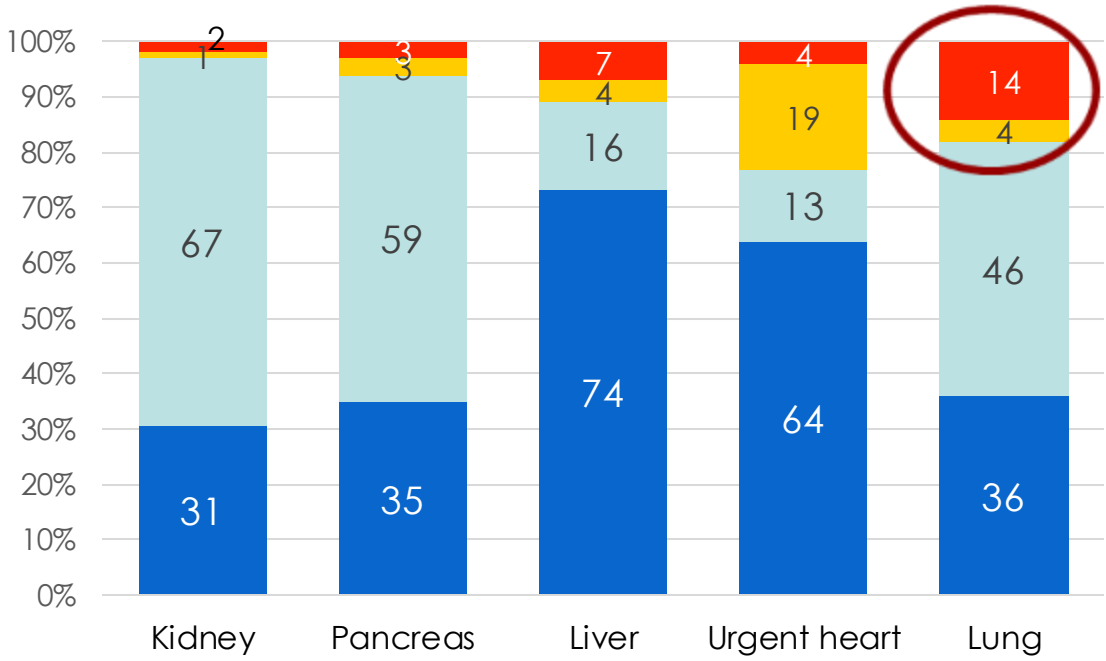
- The risks for that individual associated with waiting
- Any additional risks that the donor poses
- Chance of another transplant offer (and when) if decline the initial offer
- Risk of death while waiting the extra time

Annual Risk of Death

- Lung transplant waiting list: 160 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 yr**

*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



18% die or are removed from the lung waiting list in the first year

- Died
- Removed
- Still waiting
- Transplanted

Patients joining the waiting list in 2015/16 data. Excludes non-urgent heart patients and super-urgent liver patients

Formula 1 motor racing is safer than waiting for a lung

Mark Webber, Valencia, 2010
“Red Bull gives you wings”

Lewis Hamilton, Monza 2021
Red Bull rests on Hamilton’s head

Everyday risk: My risk of death if I travelled to Bristol 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 22 million miles
  - By light aircraft: 1 micromort per 44000 miles

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

How to present the concept of risk

Communicating risk

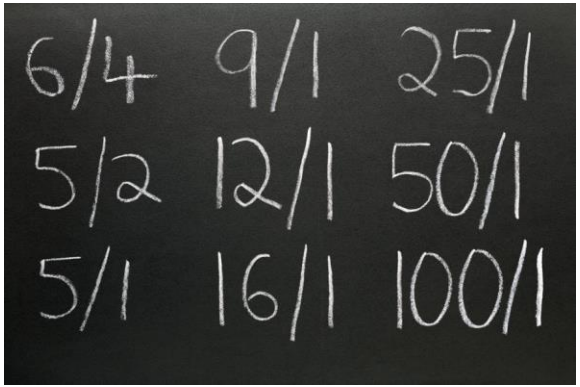
- Nothing is safe
  - There is a risk of death on waiting list
- Organs are not new
  - All donor organs are all second hand "from someone who died"
- Avoid emotive terms
  - "suboptimal"
  - "marginal"
  - "high risk"

"You're what we call 'high risk.'"

Numeric description of risk

Possible numeric formats

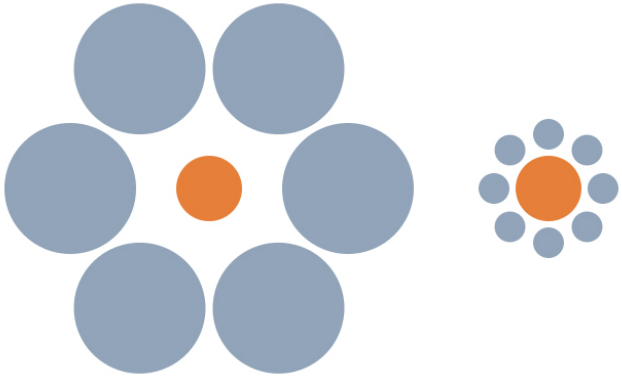
- Percentages, e.g. 10%
- Frequencies, e.g. 10 in 100
- Odds, e.g. 10 to 1
- Classical probabilities 0.0 to 1.0

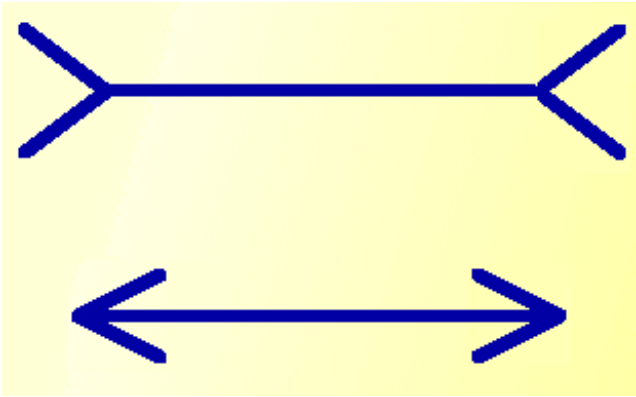


IMPLIED PROBABILITY	FRACTIONAL ODDS
99.01%	1/100
80.00%	1/4
75.00%	1/3
66.67%	1/2
55.56%	4/5
50.00%	1/1
45.45%	6/5
40.00%	3/2
33.33%	2/1
13.33%	13/2
5.00%	19/1

Which is bigger?

	A	B
1	1 in 1000	10 in 10000
2	74 in 100	3 in 4
3	20 in 50	40%
4	9 to 1 against	1 in 10
5	12% patients die	7 out of 8 patients survive



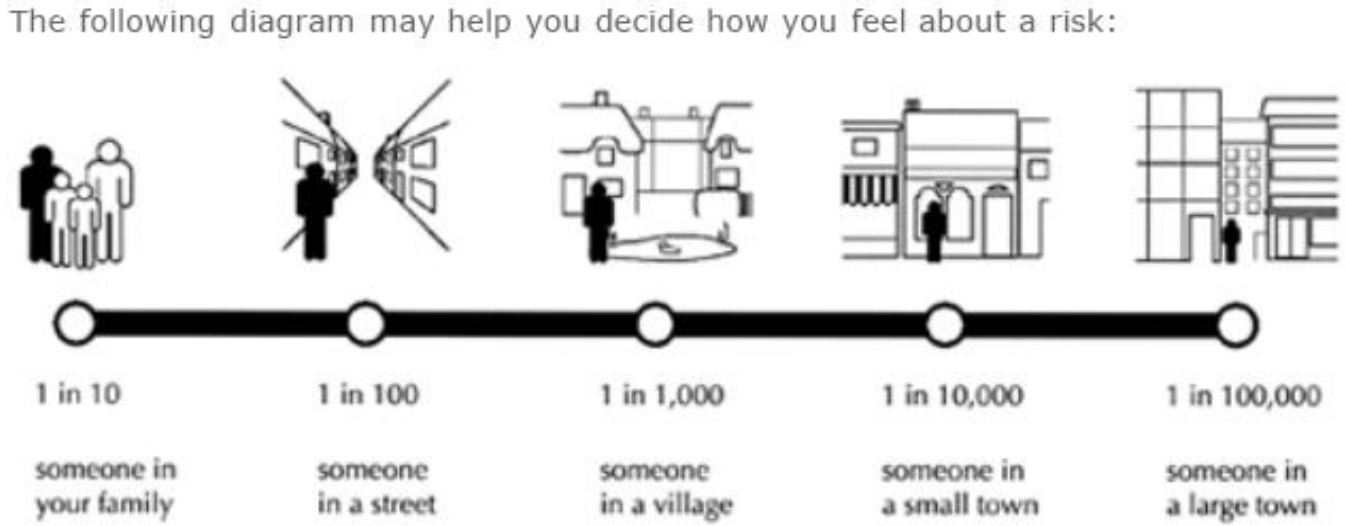


Descriptive terms

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

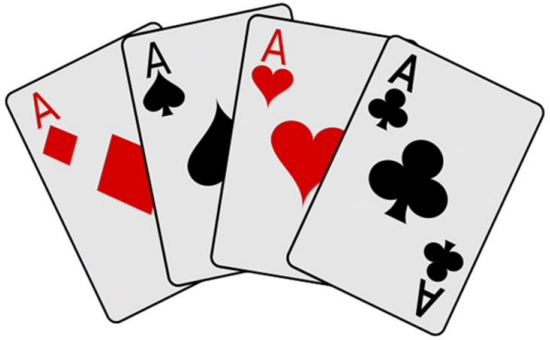
*Royal College of Anaesthetists

How common: Making frequencies meaningful



In 2018: Cambridge 129,000; Oxford 154,600; Bristol 459,300
Teversham: 3000

Making frequencies meaningful



- 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
- 1 in 100
  - The chance of your premium bond winning in a year

The National Lottery®

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

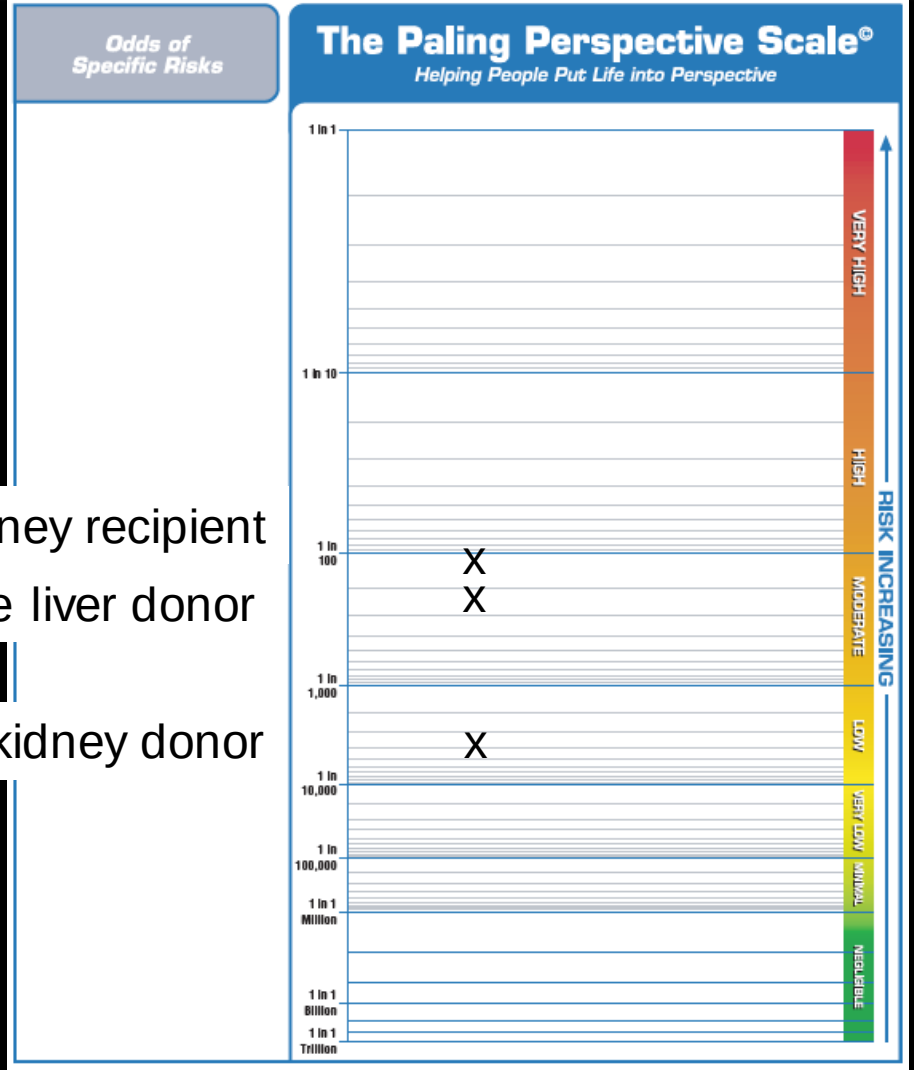
$$\frac{\text{Numerator}}{\text{Denominator}}$$

*Numeric, verbal and visual formats of conveying health risks: suggested best practices and future recommendations. Lipkus IM. Med Decis Making 2007;27:696

Kidney recipient

Live liver donor

Live kidney donor



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

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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".

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'

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.

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Education News
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UK News
Secondary education
Education
Graeme Paton

Whizz Online Maths

A-level results by s

*Elisa Gordon, Northwestern. ATC presentation.

Bar charts to display relative absolute risk

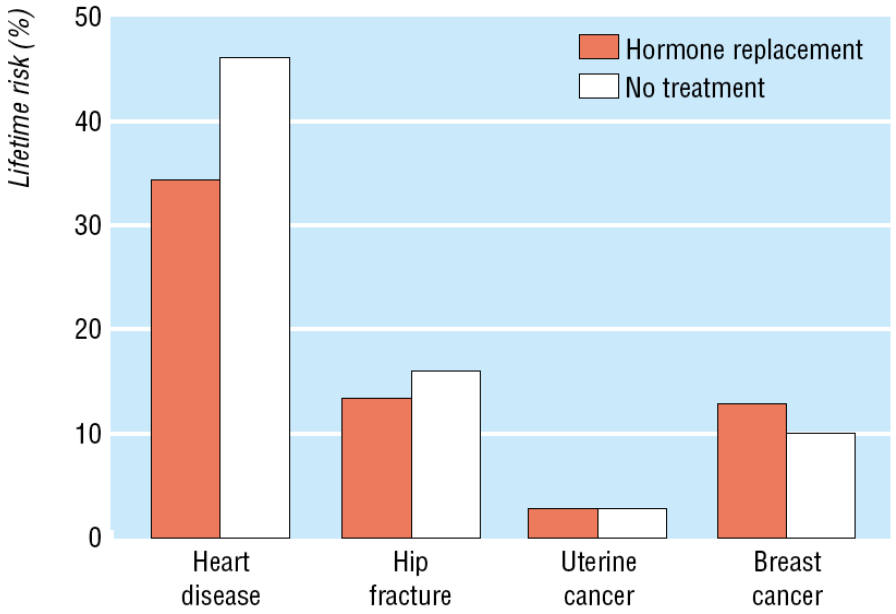


Fig 3 Portrayal of the risks and benefits of hormone replacement taken for five years[26]

Edwards et al. Br Med J 2002; 324: 827

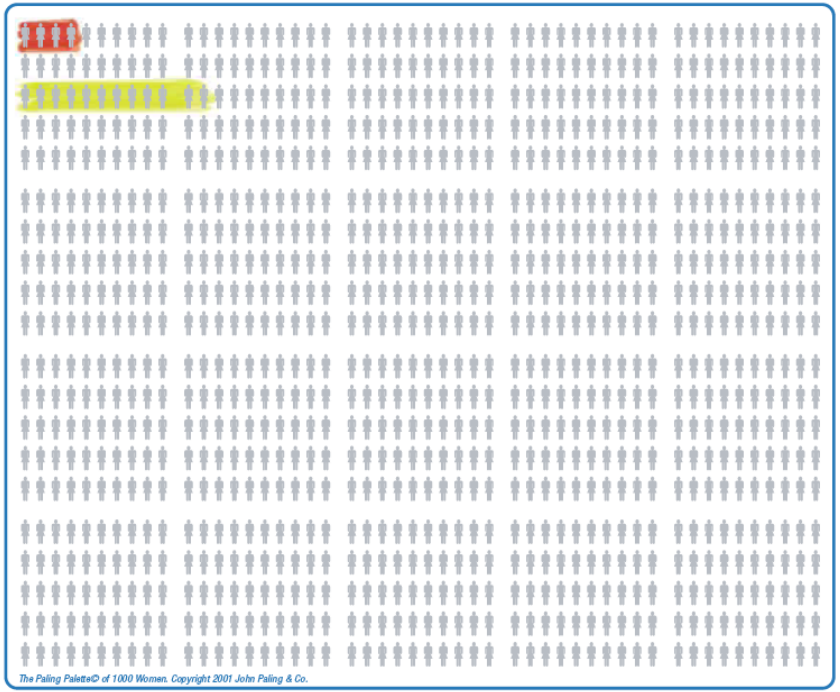
4/1000
12/1000

One Thousand People

– Pictures to Help You

See Your Odds

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



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

The Risk Communication Institute 5822 NW 91st Boulevard • Gainesville, FL 32653 • 352.377.2142 • www.trci.info

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))

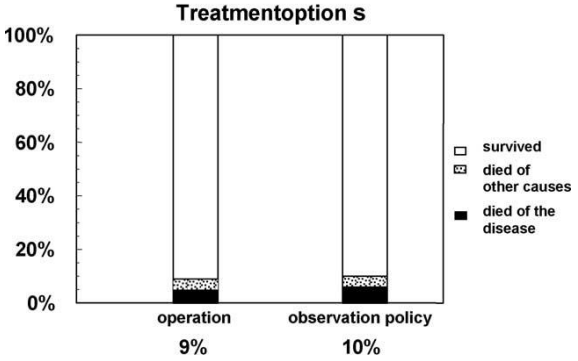
Treatment options

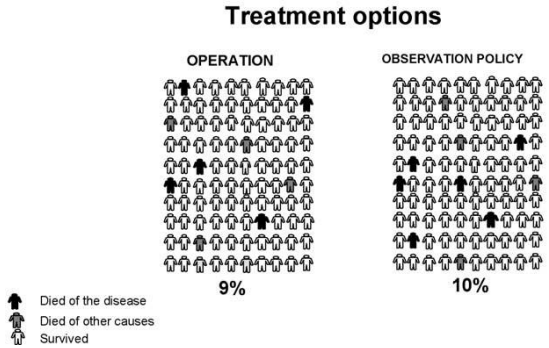
Mortality risk of operation:

9% of the patientsdie:
5% of the disease, 4% of other causes

Mortality risk of observation policy:

10% of the patientsdie:
6% of the disease, 4% of other causes





What is your age?

30

Are you male or female?

Male | Female

Calculate your life expectancy

Your average life expectancy is...

86 years

(that's **56** years from now)

However there's a chance you might live longer...

1 in 4 chance of reaching

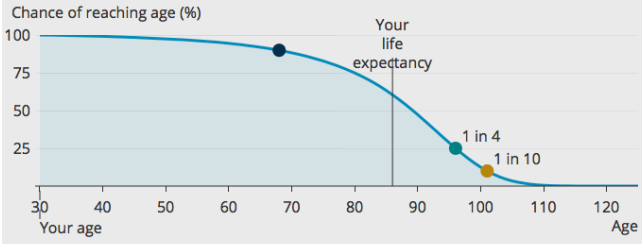
96

1 in 10 chance of reaching

101

Chance of reaching 100

12.5%



What is your age?

59

Are you male or female?

Male | Female

Calculate your life expectancy

Your average life expectancy is...

85 years

(that's **26** years from now)

However there's a chance you might live longer...

1 in 4 chance of reaching

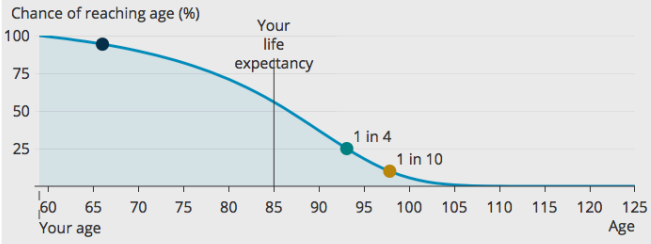
93

1 in 10 chance of reaching

98

Chance of reaching 100

5.6%



https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/bulletins/pastandprojecteddatafromtheperiodandcohortlifetables/2016baseduk1981to2066

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

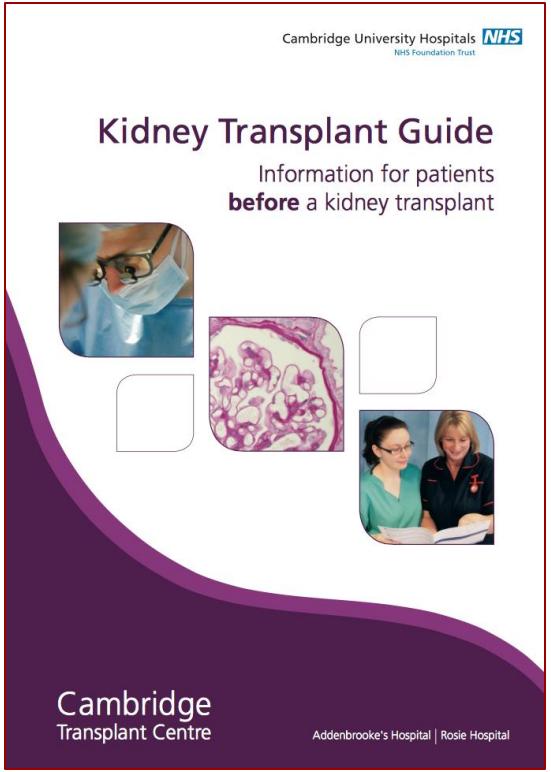
Summary

- 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

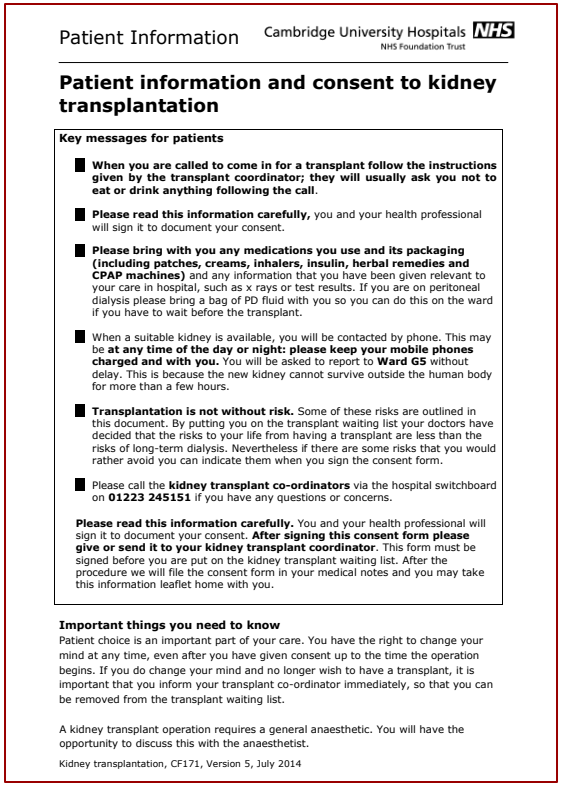
How do I do it?

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



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.

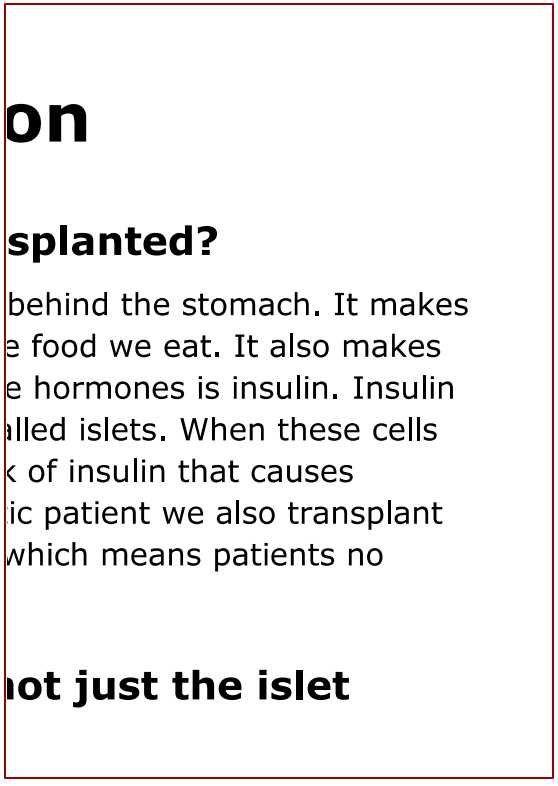
Please read this information carefully. You and your health professional will sign it to document your consent. **After signing this consent form please give or send it to your kidney transplant coordinator**. This form must be signed before you are put on the kidney transplant waiting list. After the 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



on

splanted?

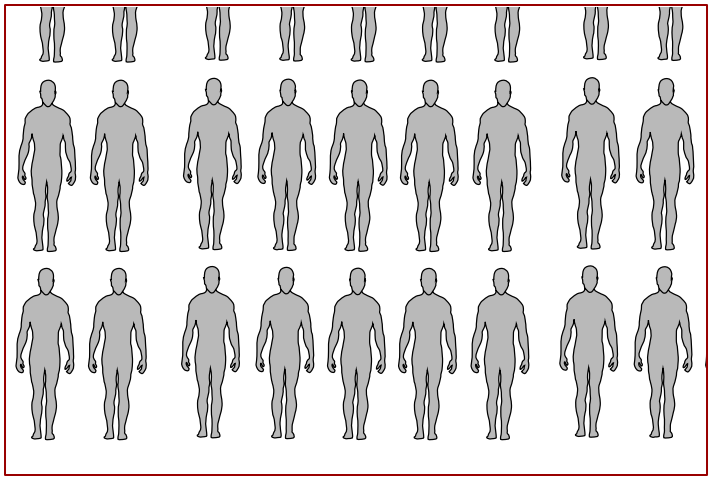
behind the stomach. It makes
e food we eat. It also makes
e hormones is insulin. Insulin
alled islets. When these cells
k of insulin that causes
ic patient we also transplant
which means patients no

ot just the islet

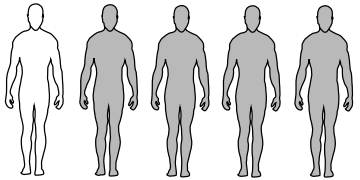
20 pages

How does the consent form convey risk?

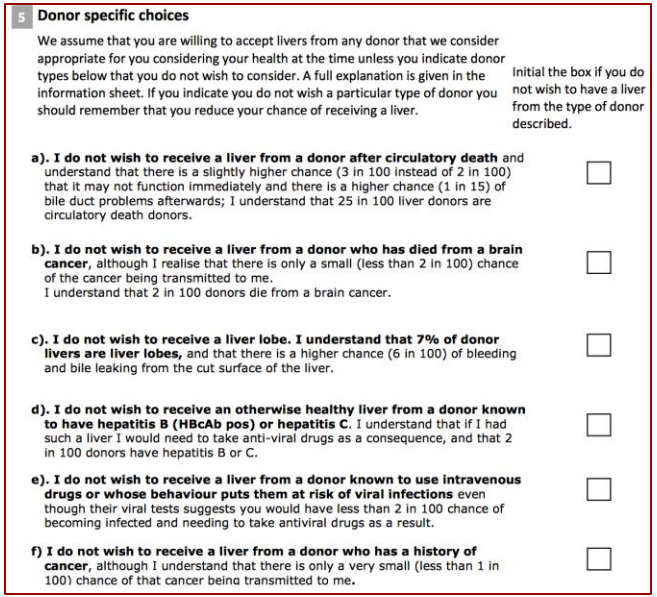
Significant, unavoidable or frequently occurring risks of this procedure
At the end of the first year after a kidney transplant around 92 out of 100 (92%) kidney transplants will still be working. To help you understand what these mean visually we have printed below a drawing showing 100 people. 92 of 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. ☐

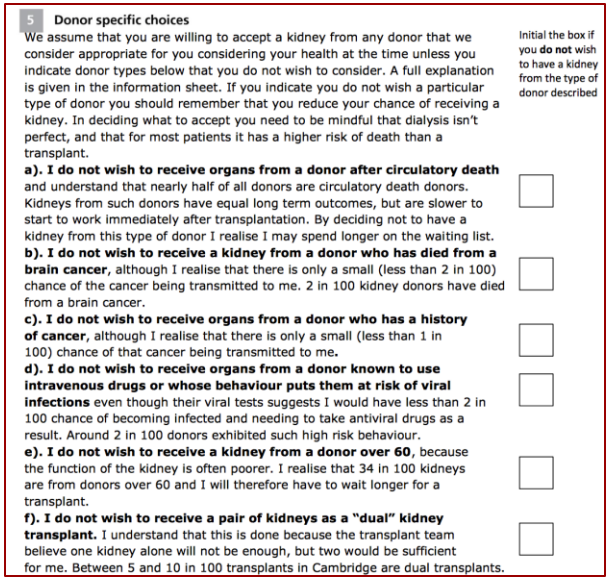
b). I do not wish to receive a liver from a donor who has died from a brain cancer, although I realise that there is only a small (less than 2 in 100) chance of the cancer being transmitted to me.
I understand that 2 in 100 donors die from a brain cancer. ☐

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. ☐

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. ☐

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. ☐

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. ☐



5 Donor specific choices

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.

Initial the box if you **do not** wish to have a kidney from the type of donor described

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. ☐

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. ☐

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. ☐

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. ☐

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. ☐

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. ☐

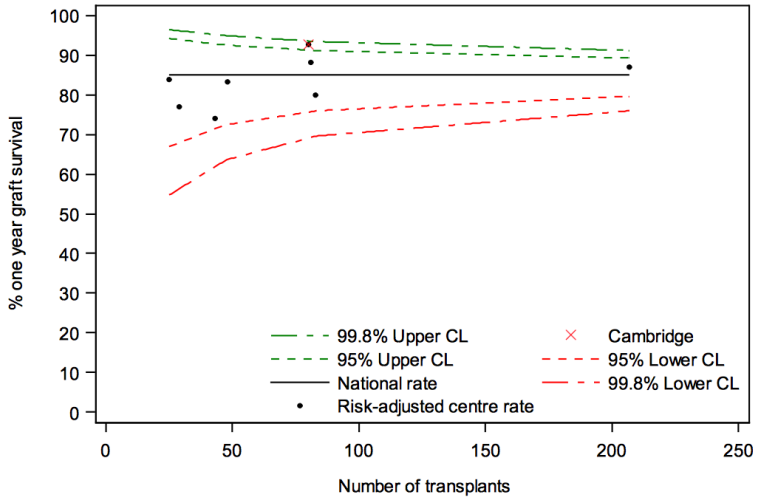
need to know?

- 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

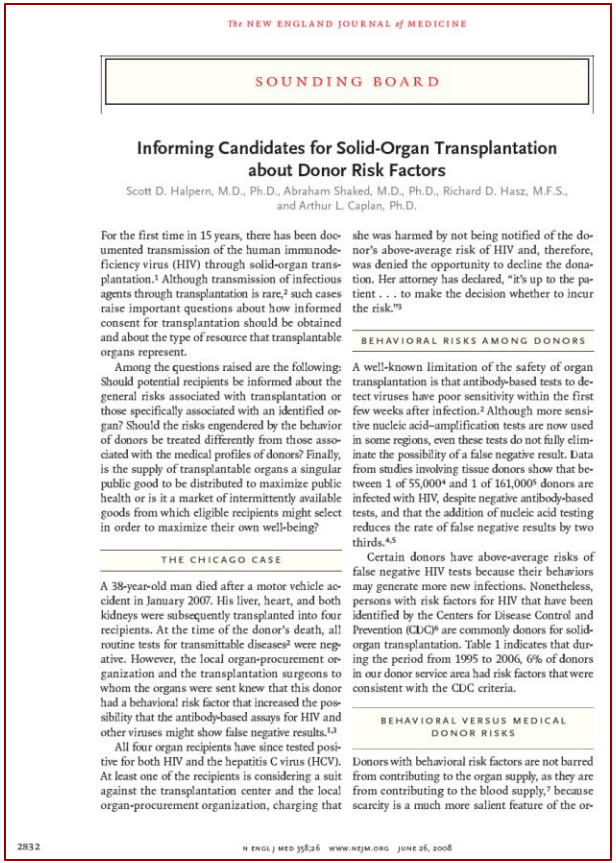
Are they listening?

Hearing, not listening

- East Anglian Renal Meeting
- Talk about pancreas transplantation, 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 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?



The NEW ENGLAND JOURNAL of MEDICINE

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 transmittable diseases[2] 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.[1,3]

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."[3]

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 55,000[4] and 1 of 161,000[5] 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.[4,5]

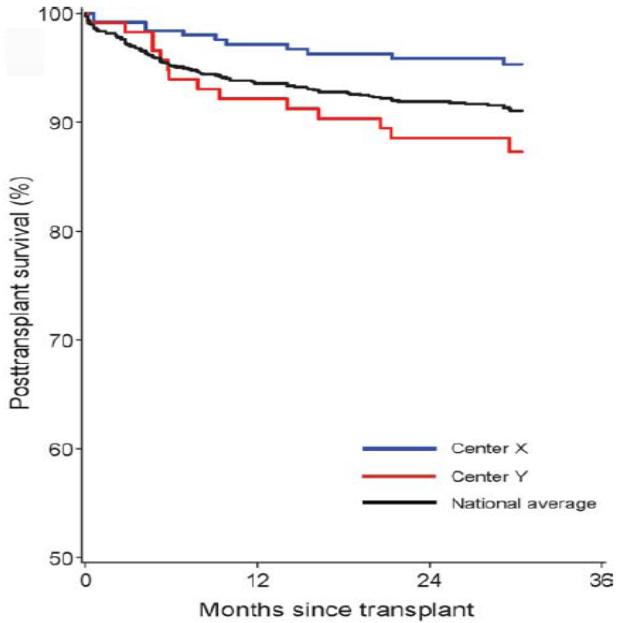
Certain donors have above-average risks of false negative HIV tests because their behaviors may generate more new infections. Nonetheless, persons with risk factors for HIV that have been identified by the Centers for Disease Control and Prevention (CDC)[6] are commonly donors for solid-organ transplantation. 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

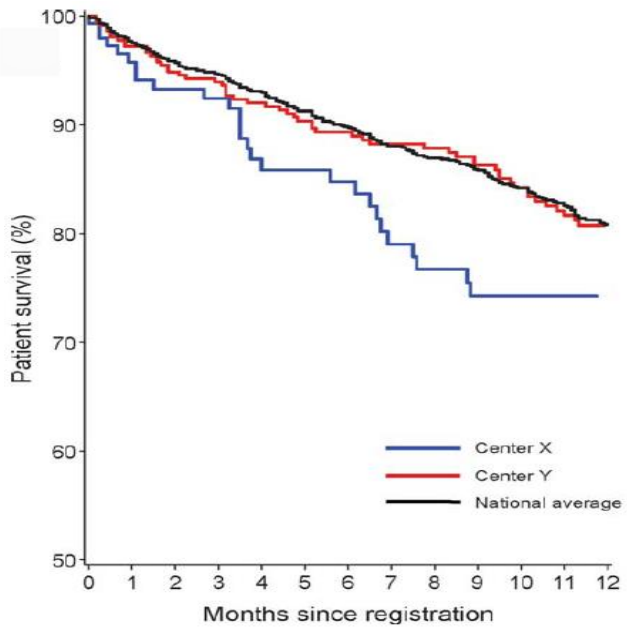
Donors with behavioral risk factors are not barred from contributing to the organ supply, as they are from contributing to the blood supply,[7] because scarcity is a much more salient feature of the or-

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



Neuberger et al. Liver transpl 2010; 16: 1119

Is it reasonable to ask a patient to make a choice

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