Organ Transplantation, 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%</p>
- 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.'



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

Risks from Smoking

Smoking can damage nearly every part of your body



Overall diminished health



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ngland Northern Ireland	Wigan transplant patient given lun	gs of 30-year smoker	
Cootland Vales Jusiness Politics Health Education Science & Environment Science & Enviro	The rather 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 noncess eufferen 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.	 SEE ALSO Woman dies after lung transplant 13 January 10 Kent Organ transplants' hidden risk 24 November 09 Health RELATED BBC LINKS Cystic fibrosis RELATED INTERNET LINKS UHSM NHS Blood and Transplant The BBC is not responsible for the content of external internet sites 	
lagazine n pictures	The University Hospital of South Manchester (UHSM) NHS Trust said it had followed national guidelines.	TOP MANCHESTER STORIES + How to contact us	
ountry profiles pecial reports	Ms Scott, 28, who was born with cystic fibrosis, underwent the surgery in February 2009 to prolong her life after her condition deteriorated.	Other local news Goodbye Frank I News feeds	
Related BBC sites Sport Weather	She died a few months later in July. Tests later concluded the primary cause of death was pneumonia.	MOST POPULAR STORIES NOW	

Smoking and donation: facts

- 50% of deceased donors are smokers
 - That's why they die young
- Smoker's lungs do less well than nonsmokers 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



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 e.g. risk of catching coronavirus



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"

Ambrose Bierce

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.





Fatality rates for 49607 deaths mentioning COVID-19 in E & W, 7/3/10 to 26/6/20



BMJ 2020; 370 doi: <u>https://doi.org/10.1136/bmj.m3259</u>

RISK WITH AGE

A person's age is the strongest predictor of their risk of dying of COVID-19. The risk increases from the age of 50.



VULNERABLE MEN

A study in Spain found that men are at higher risk of dying from COVID-19 than are women.



Nature 28-8-20



TAKING RISK

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



CORONAVIRUS FOOTBALL NEWS - CELEBS TV POLITICS SPORT - MORE - 1 2 0 0 0 0



'further measures'



warns of 'further

measures





key employee after row

about Charles's 'special

pudding'



defensive' and displaying

'signs of anger' in latest

Boris Johnson warns of as hospital outbreak blamed on 'superspreading event'

News + US News + Coronavirus

Dad who protested against lockdown dies after catching coronavirus himself

interview

In posts shared across Facebook, dad John W. McDaniel criticised Ohio governor Mike DeWine for closing businesses and denied coronavirus was real





London 16th May 2020

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



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

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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 7.5 Post-registration outcome for 340 first lung only registrations made in the UK, 1 April 2016 - 31 March 2017



Figure 8.2 Post-registration outcome for 1010 new elective liver only registrations made in the UK, 1 April 2017 - 31 March 2018



Source: ODT Annual Activity Report, 2020. 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
 - we use the pavement rather than walk in the middle of the road

■But

- Transplantation involves risk
 - as demonstrated previously
- Delaying transplantation involves risk
 - Having organ failure is not without 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
- COVID in UK
 - 5 in 1000 if 45 to 64
 - 30 in 1000 if 65-74
 - 116 in 1000 if ≥75

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"

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

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
 - I micromort per 7 miles
- By car: 1 in 1,000,000
 - I micromort per 333 miles
- By train or commercial plane: 0.045 in 1,000,000
 - I micromort per 7500 miles
 - By light aircraft: 23 in 1,000,000







Someone waiting for a lung transplant

- 25 in 100 chance of dying250 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
 - The patient has to make a choice, and doing nothing is a choice
- Organs are not new
 - They are all second hand "from someone who died"
- Avoid emotive terms
 - "suboptimal"
 - "marginal"
 - "high risk"



[&]quot;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. 9 to 1

Classical probabilities, e.g. 0.1



R	8
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?





Which is bigger?

	Α	В
1	1 in 1000	10 in 10000
2	3 in 4	74 in 100
3	21 in 50	40%
4	10 to 1 odds against	1 in 10 chance
5	1 in 8 patients die	12% patients die

Descriptive terms



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

Very common	Common	Uncommon	Rare	Very Rare
1 in 10	1 in 100	1 in 1,000	1 in 10,000	1 in 100,000

*Royal College of Anaesthetists

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 in the first year 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

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

Numerator Denominator

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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Bar charts to display relative absolute risk



Fig 3 Portrayal of the risks and benefits of hormone replacement taken for five years²⁶

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

Everyday risk: The Paling scale

Risks from Blood Transfusions

The Paling Perspective Scale©



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4/1000 12/1000



Figure 1: Rofecoxib (Vioxx) risk characterization theatre. The 16 darkened seats represent the number of additional people who will experience cardiovascular events when taking rofecoxib, as compared to the 1000 individuals not taking this antiinflammatory over a 9-month period. Merck & Co. pulled rofecoxib off the market on Sept. 30, 2004, due to increased risk of heart attack and stroke.

CMAJ 2008; 178(11): 1512

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



Treatment options

Died of the disease Died of other causes	OPERATION A A A A A A A A A A A A A A A A A A A	OBSERVATION POLICY ↑↑↑↑↑↑↑↑↑↑↑↑↑↑↑ ↑↑↑↑↑↑↑↑↑↑↑↑↑↑↑↑↑↑↑
Survived		

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))



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

Age

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 Foundation Trust
Patient informatio transplantation	n and consent to kidney
Key messages for patients	
 When you are called to com given by the transplant co eat or drink anything follow 	e in for a transplant follow the instructions ordinator, they will usually ask you not to ing the call.
 Please read this information will sign it to document your or 	a carefully, you and your health professional onsent.
 Please bring with you any u (including patches, creams, CPAP machines) and any inf your care in hospital, such as p dialysis please bring a bag off if you have to wait before the t 	ardications you use and its packaging inhalors, insulin, herbal remedies and mation that you have been given relevant to crays or test results. If you are on peritoneal D haid with you so you can do this on the ward transplant.
 When a suitable lidney is avait be at any time of the day or charged and with you. You y delay. This is because the new for more than a few hours. 	iable, you will be contacted by phone. This may night: please lazep your mobile phones nill be asked to report to Ward G5 without kidney cannot survive outside the human body
 Transplantation is not with this document. By putting you decided that the risks to your1 risks of long-term dalysis. Ne rather avoid you can indicate t 	out risk. Some of these risks are outlined in on the transplant waiting list your doctors have life from having a transplant are less than the entruless if there are some risks that you would hern when you sign the consent form.
 Please call the kidney transpl on 01223 245151 if you have 	ant co-ordinators via the hospital switchboard any questions or concerns.
Please read this information or sign it to document your consent, give or send it to your kidney (signed before you are put on the i procedure we will file the consent this information leaflet home with	arefully. You and your health professional will After signing this consent form please transplant coordinator. This form must be iciney transplant waiting list. After the form in your medical notes and you may take you.
Important things you need to i	ian oner
Patient choice is an important part of	your care. You have the right to change your
mind at any time, even after you hav	e given consent up to the time the operation
regimes at you do change your mind a important that you inform your trans	nu no kinga wish to nave a transpiant, it is plant co-ordinator immediately, so that you can
be removed from the transplant wait	ing list.
A kidney transplant operation require on writingly to diarass this with the a	s a general anaesthetic. You will have the

Kidney transplantation, CF171, Version 5, July 2014

20 pages



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.

Pancreas transplantation Page 1 of 5

Innovation and excellence in health and care Addenbrooke's Hospital | Rosie Hospital

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 Initial the box if you do types below that you do not wish to consider. A full explanation is given in the not wish to have a liver information sheet. If you indicate you do not wish a particular type of donor you from the type of donor should remember that you reduce your chance of receiving a liver. 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. Lunderstand 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.

Donor specific choices

Initial the box if We assume that you are willing to accept a kidney from any donor that we you do not wish consider appropriate for you considering your health at the time unless you to have a kidney indicate donor types below that you do not wish to consider. A full explanation from the type of is given in the information sheet. If you indicate you do not wish a particular donor described 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. 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.

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 Cambridge 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, but she did not hear or read it
- 10 years after transplant
 - Qualified as a nurse
 - Married
 - 1 child



The NEW ENGLAND IOURNAL of MEDICINE

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?

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 doc- she was harmed by not being notified of the doumented transmission of the human immunode- nor's above-average risk of HIV and, therefore, ficiency virus (HIV) through solid-organ trans- was denied the opportunity to decline the donaplantation.1 Although transmission of infectious tion. Her attorney has declared, "it's up to the paagents through transplantation is rare,² such cases tient . . . to make the decision whether to incur raise important questions about how informed the risk."3 consent for transplantation should be obtained BEHAVIORAL RISKS AMONG DONORS

and about the type of resource that transplantable organs represent.

in order to maximize their own well-being?

Among the questions raised are the following: A well-known limitation of the safety of organ Should potential recipients be informed about the transplantation is that antibody-based tests to degeneral risks associated with transplantation or tect viruses have poor sensitivity within the first those specifically associated with an identified or- few weeks after infection.² Although more sensigan? Should the risks engendered by the behavior tive nucleic acid-amplification tests are now used of donors be treated differently from those asso- in some regions, even these tests do not fully elimciated with the medical profiles of donors? Finally, inate the possibility of a false negative result. Data is the supply of transplantable organs a singular from studies involving tissue donors show that bepublic good to be distributed to maximize public tween 1 of 55,0004 and 1 of 161,0005 donors are health or is it a market of intermittently available infected with HIV, despite negative antibody-based goods from which eligible recipients might select 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

THE CHICAGO CASE

A 38-year-old man died after a motor vehicle ac- may generate more new infections. Nonetheless, cident in January 2007. His liver, heart, and both persons with risk factors for HIV that have been kidneys were subsequently transplanted into four identified by the Centers for Disease Control and recipients. At the time of the donor's death, all Prevention (CDC)6 are commonly donors for solidroutine tests for transmittable diseases² were neg- organ transplantation. Table 1 indicates that durative, However, the local organ-procurement or- ing the period from 1995 to 2006, 6% of donors ganization and the transplantation surgeons to in our donor service area had risk factors that were whom the organs were sent knew that this donor consistent with the CDC criteria. had a behavioral risk factor that increased the pos-

sibility that the antibody-based assays for HIV and other viruses might show false negative results.13 All four organ recipients have since tested posi-

organ-procurement organization, charging that scarcity is a much more salient feature of the or-

N ENGLI MED 158:26 WWW.NEIM.ORG JUNE 26, 2008

BEHAVIORAL VERSUS MEDICAL DONOR RISKS

tive for both HIV and the hepatitis C virus (HCV). Donors with behavioral risk factors are not barred At least one of the recipients is considering a suit from contributing to the organ supply, as they are against the transplantation center and the local from contributing to the blood supply,7 because
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?

