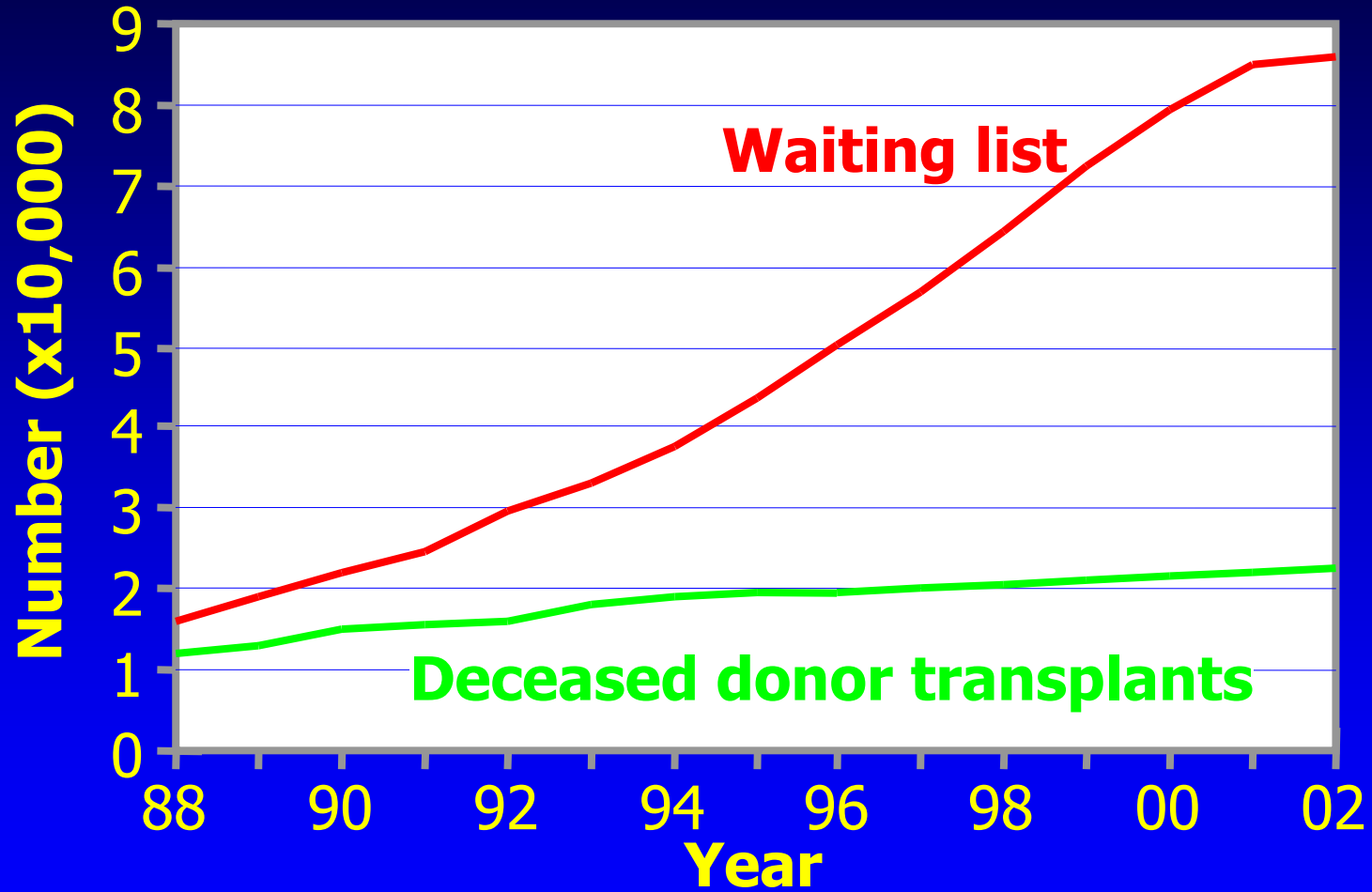


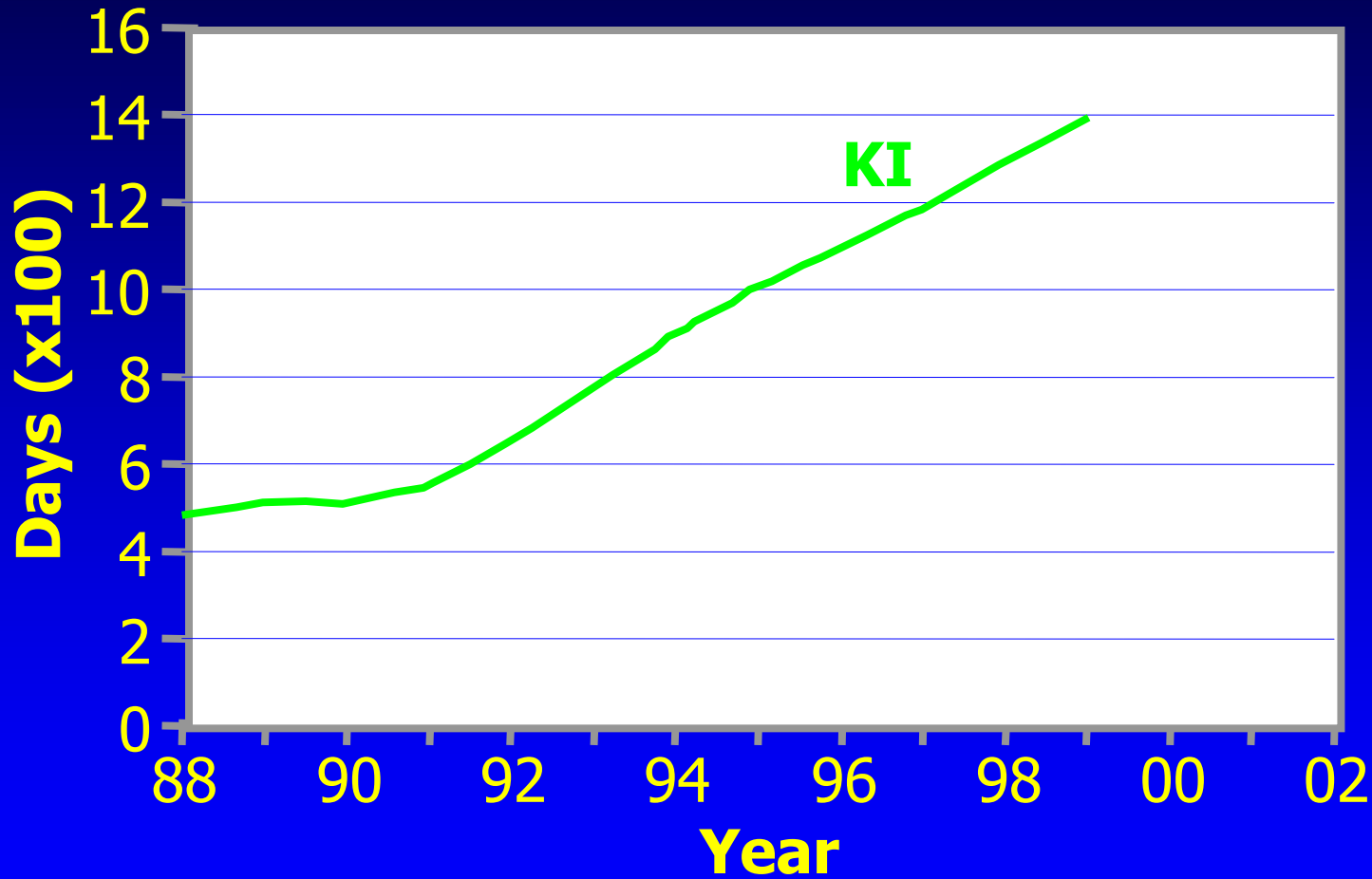
Increasing Living Donation in the USA

An answer to the organ shortage

Deceased Donor Tx and Waiting List



Median Waiting Times 1988-2002



McBride, Clinical Transplants 2003 (p.59)

Annual Death Rate on Waiting List

Ojo et al, J Am Soc Nephrol 12:589, 2001

Overall	6.3%
Glomerulonephritis	4.3%
Hypertension	4.3%
Diabetes mellitus	10.8%
Other diagnoses	4.3%

Who Dies on the Waiting List?

University of Minnesota – 2002-2004

Each year - 6.7% deaths on kidney waiting list;

Mean age: 54 ± 11 years (9 < 40; 18, 40-49; 33, 50-59; 15, 60-69; 7 ≥ 70).

70% were waiting for a first transplant

70% had PRA ≤ 10%

Avg time waiting was 1078 ± 847 days

Additional Advantages of Transplantation

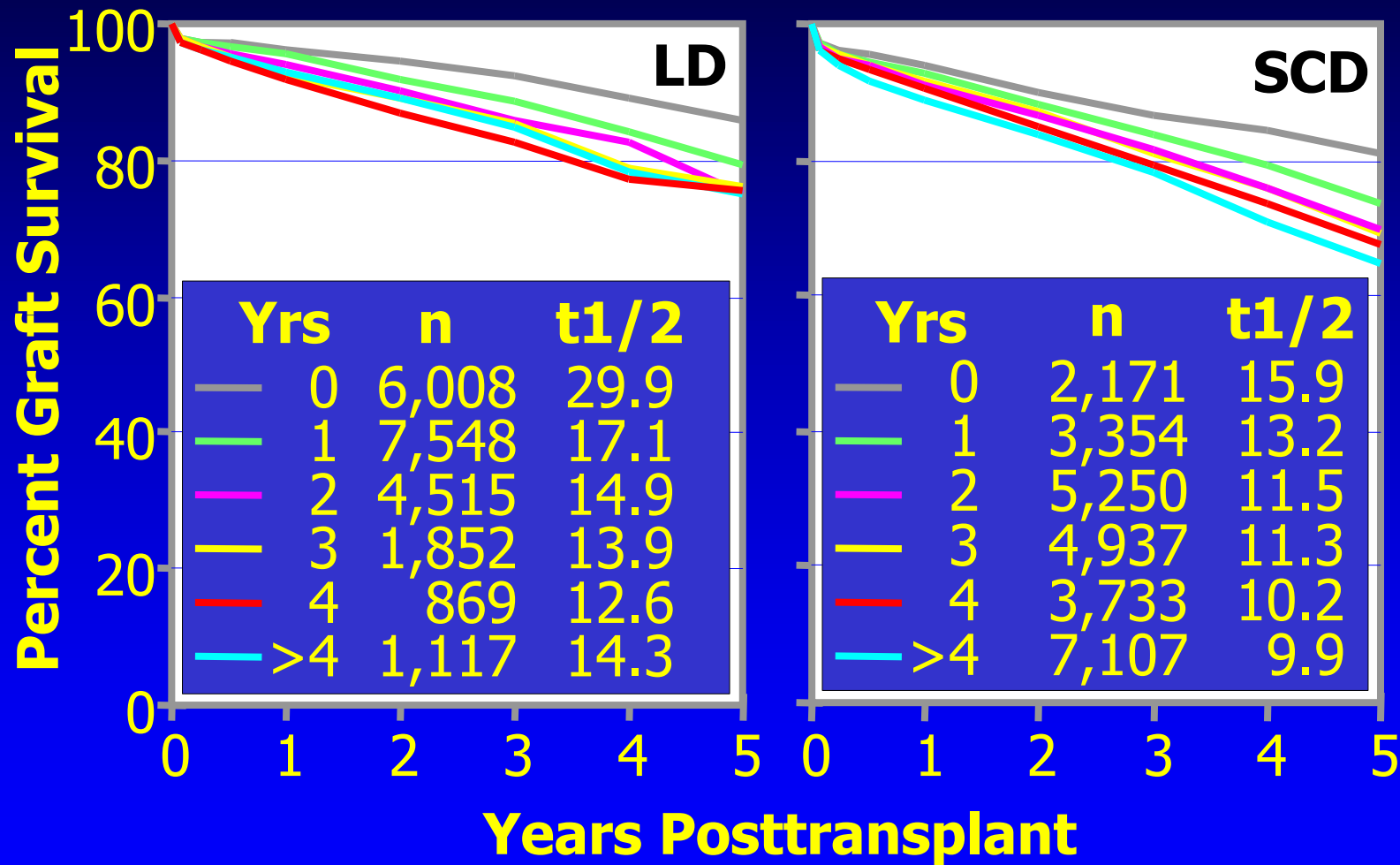
- 1) Transplantation prolongs patient survival
(vs wait listed dialysis)
- Wolfe et al, NEJM**
- 2) Early tx ↑ posttransplant survival; longer
waiting times (on dialysis) increase risk of
death and graft loss after transplantation
- Meier-Kriesche et al, Kid Int 2000**

Wait-listed vs. DD transplant*

	<u>Projected Life (yrs)</u>	
	<u>Wait list</u>	<u>Tx</u>
0 – 19	29	39
20- 39	14	31
40 – 59	11	22
60 – 74	6	10

*Wolfe, NEJM, 1999

Prolonged Dialysis ↓ Tx Graft Survival (1998-2002)



Cecka, Clinical Transplants 2003 (p.7)

Organ Shortage - Potential Solutions

1) Increasing Deceased Donors

If all potential donors became actual donors, the waiting list would still grow annually

Sheehy et al, N Engl J Med 349:667-74, 2003

2) Increasing living donors

Donor Concerns

Mortality - .03%;

**bleeding, infection,
pulmonary embolus**

**Bay & Herbert; Najarian et al, *Lancet*, 1992; Bia et al,
Transplantation, 1995; Matas et al, *AJT*, 2003**

Donor Concerns - Morbidity

	<u>Open</u>	<u>HA LN</u>	<u>Non-HA LN</u>
Reoperation	0.4%	1.0%	0.9%
Readmits	0.6%	1.6%	1.6%
DVT/PE	0.02%	0.09%	0.1%
Bleeding	0.1%	0.45%	0.2%

Matas et al, AJT, 2003

Donor Concerns

Quality-of-life

**comparable to general population;
96% say they would do it again**

**Long-term outcome – renal function
cardiovascular**

Impact of Nephrectomy - Meta-Analysis

48 studies with 3124 patients and 1703 controls

- both donors and Nx for other reasons
- median duration of f/u = 10.6 yrs; 20% followed > 20 yrs

Concluded that Nx does not cause a progressive decline in renal function or increased proteinuria

- may cause slight increase in BP

Kasiske et al, Kid Int 1995

3 Long-term studies (≥ 20 yr f/u)

Najarian et al, Lancet, 1992

57 donors from 1/1963 - 12/1970 were compared to 65 siblings ; no diff in Cr, proteinuria, BP

Goldfarb et al, J Urology, 2001

BP & Cr higher than pre-donation, but still in the normal range; Incidence of Htn comparable to general pop;
Proteinuria \uparrow , but appears to be no clinical consequence

Ramcharan & Matas AJT, 2004

Cr, BP, and proteinuria by current donor age (20-37 yrs after donation)

Living Donors in Need of a TX

Ellison et al; Transplantation 2002

56 previous living kidney donors had been listed for tx
43 had received tx (36 functioning)
2 died while waiting
(no denominator; controls)

86% donated to a sibling

55% male

55% black

cause of renal failure

47% hypertension

17% focal sclerosis

13% CGN

There is no formal mechanism for long-term donor follow-up; mixed message

Currently, NIAID and NHLBI have a RFA for long-term follow up of kidney donors

Goal is complete follow-up of a cohort

Potential sources ↑ LDs

a) living unrelated donor

huge potential; currently > 30%

b) swap – exchange programs

limited potential; ethical issues

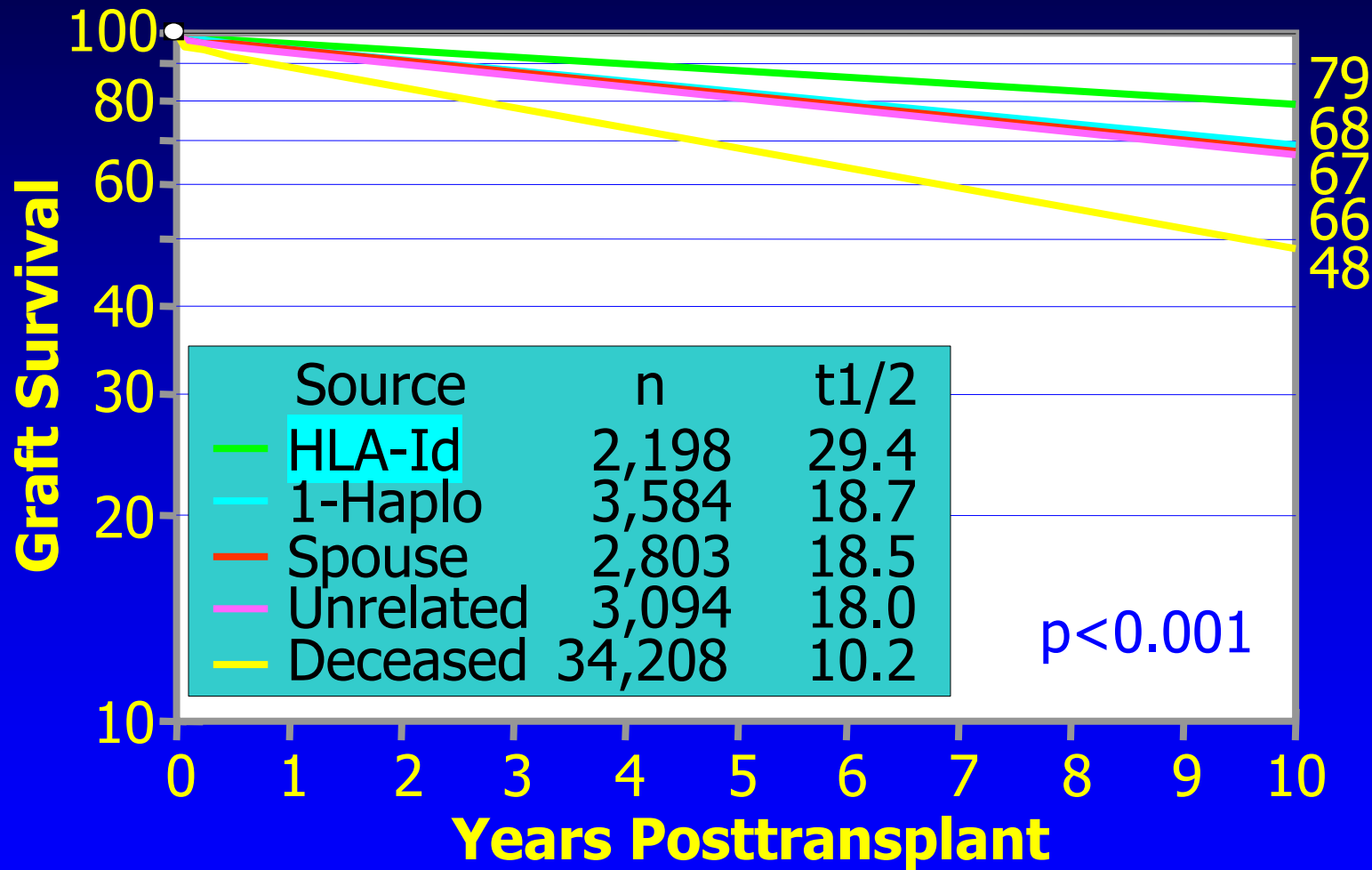
c) ABO incompatible; **limited potential**

d) positive XM; **limited potential**

e) nondirected donors; **limited potential**

f) vendors

LURD - Graft Survival by Donor Source 1998-2002



Cecka, Clinical Transplants 2003 (p.4)

A Regulated System of Sales

Proposed System:

- 1) Payment is by government or private insurance co;
- 2) Fixed price to the vendor;
- 3) Allocation by pre-defined algorithm (everyone on the list has an opportunity);
- 4) Thorough screening evaluation;
- 5) Informed consent;
- 6) Vendor safeguards

Payment

Fixed price - tax free

**- no impact on other benefits
(e.g., welfare)**

Could include:

Life and long-term health insurance

Could include a menu of choices

**Bellagio Task Force on Transplantation,
Body Integrity, and the International
Traffic in Organs found no ethical
principle that would justify a ban on sales
under all circumstances**

Transplantation Proceedings 29:2739, 1997

**International Forum for Transplant Ethics
concluded that the discussion of organ
sales needs to be reopened**

Lancet 351: 1950, 1998

“If donating a kidney is legal, and if the only difference between donating and sales is monetary self interest, and if monetary self interest does not in itself warrant legal prohibition.....”

Gill and Sade, Kennedy Inst of Ethics 2003

“it is legal for persons to sell parts of their bodies (blood, sperm, eggs)”.

(Surrogate mothers).

Thus “monetary self interest alone does not warrant legal prohibition”

Egg Donors...

WE CAN COMPENSATE YOU,
BUT NEVER REPAY YOU.

Earn \$5000 **compensation**. And a couple's undying gratitude. Drawing on my experience as a former egg donor, we are uniquely qualified to offer you a level of professionalism, understanding and respect beyond other services. Make a donation. Make a life. Make a difference.



Nazca I. Fontes,
Founder, Egg Donor.

If we want to oppose kidney sales (vs. sperm or eggs) because nephrectomy is more dangerous, then we should also oppose donation.

If we want to oppose kidney sales because people should not sell body parts, then we should also oppose sale of sperm or eggs.

Gill and Sade, Kennedy Inst of Ethics 2003

Sales Are Economically Feasible for the Health Care System

Markov model developed*:

**calculated the expected average costs
and outcome benefits by adding vendors
to the pool of organ donors (20 yr time-
frame)**

(U.S. data)

***Schnitzler, Amer J Transplantation 4:216-21, 2004**

Waiting list

Vendor kidney

Wait on dialysis
P(death)

D: \$, QALY

P (function)

A: \$, QALY

P(DwF)

B: \$, QALY

P (return dialysis)

C: \$, QALY

P (Cad Tx)

E:

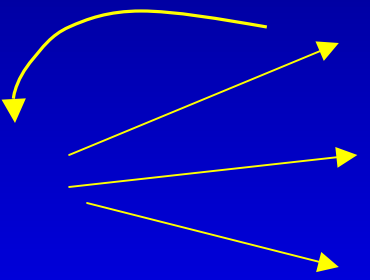
P (Death)

F:

P (remain on dialysis)

G:

10 Year Model



**Expected average savings to the (U.S.)
health care system using a vendor
(donor) = **\$94,579****

**Cost neutral to pay a vendor about -
\$94,579**

**(or could pay less but provide health care, life
insurance, etc)**

***Matas & Schnitzler, Amer j Transplantation 4:216-21, 2004**

The (13) Usual Arguments Against Sales and Why They are Wrong

We accept donation: Any successful argument against sales must distinguish between sales and donation

“If any aspect of organ selling is against the interests of the vendor, it is not the getting of money but the loss of a kidney”

Prohibiting the poor from selling a kidney still leaves them poor (and removes 1 possible option to improve their lives)

Thus those who are protecting the poor by prohibiting sales – simply remove one option for the poor to better themselves

- 1) The organ shortage is an artificial crisis;**
- 2) Other systems of “sales” have failed to protect the vendor**
- 3) Sale of blood failed**
- 4) “Commodification”**
- 5) Exploitation of the poor**
- 6) Financial Offer is Coercion**
- 7) There can be no genuine consent**

8) Harm to the vendor

9) Collateral damage

- to the government

- to the health care profession

10) The church will object

11) Donation will decrease

12) Should be altruistic

13) Possibility of abuse

Richards, JR, Nepharious Goings On – Kidney Sales and Moral Arguments. The Journal of Philosophy and Medicine, 21:375-416, 1996

Wilkinson, S, Commodification Arguments for the Legal Prohibition of Organ Sale, Health Care Analysis 8:189-201, 2000

Gill MB and Sade RM, Paying for Kidneys: the case against prohibition. Kennedy Inst Ethics 12: 17-45, 2002.

Matas, AJ, The case for living kidney sales: rationale, objections and concerns. American Journal of Transplantation 4:2007-17, 2004.

What does the public think?

Guttman and Guttman, J Med Ethics, 19:148-53, 1993; **general public > 60% in favor**

Medical students >50%; Doctors and nurses 25%

Kittur et al, Lancet, 1991; Responders asked if some form of financial or nonfinancial compensation should be offered in the USA to increase the # organs (? Cad)

52% said yes: 68% of those 18-34

49% of those 35-54

31% of those >55

A Testable Hypothesis

A regulated system can be developed and will:

- 1) Increase # available organs**
- 2) Not increase disease transmission**
- 3) Protect the vendor**
 - no increase risk vs donor**
 - same quality of life as donors**
- 4) Not decrease altruistic donation**
- 5) Not decrease dignity of vendor or the medical profession**

Can it be tried in a limited geographical area?

Principles - The Center

Potential vendors:

- evaluated twice over a 6 mo interval (including psychosocial exam)
- have an advocate

Transplant centers – meet developed qualifications

Allocation - algorithm (to all on list)

Payment - fixed price
(life and health insurance)

Follow-up - Annually, including psychosocial and quality of life

Registry - To report outcomes

Practical Concerns

Determining criteria for vendors

a) minimum age

b) defined geographic area

- 2) Providing long-term health care for vendors
- 3) Following vendors long-term
- 4) Distributing payment
- 5) Verifying health status of vendors
- 6) Handling logistics
- 7) Designating price
- 8) Drawing the line at kidneys (vs other organs)

Conclusions

- 1) From a recipient perspective, LD tx is best
- 2) The donor operation is associated with mortality and morbidity
- 3) LURDs have equivalent outcome as LRDs
- 4) While helpful, swaps, exchanges, nondirected, etc, #'s are small
- 5) A regulated system of sales may help, but numerous issues need to be addressed



Vendor Risks

**Same as
donor risks**

Vendor Benefits

**\$ = Improved life
Respect for
autonomy**

Recipient Benefits

**Increased survival
Improved Tx
survival**



1) The organ shortage is an artificial crisis

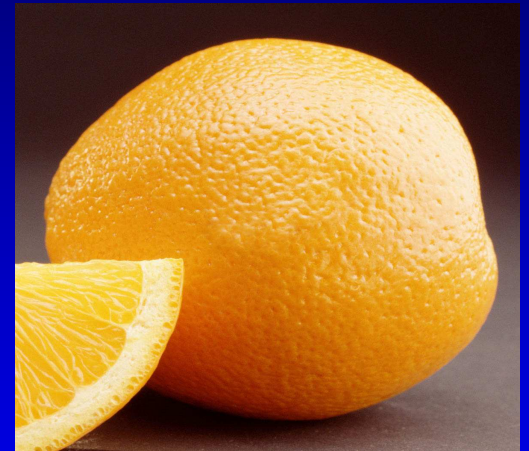
Scheper-Hughes

“organ scarcity is...an artificially created need, invented by transplant technicians, for an ever-expanding sick, aging, and dying population.” “Organ scarcity..is invoked like a mantra in relation to the long waiting lists...”

But, outcome of tx is better than outcome of alternative therapies; patients are choosing tx

2) Other systems of “sales” have failed to protect the vendor

But, the fact that unregulated systems elsewhere (without oversight and without care of the vendor) have failed, is not an argument against a **regulated system**. (The system would have to be limited to geographic areas where vendor interests could be protected.)



3) Sale of blood failed

Blood donors lied about their health; blood transfusion transmitted hepatitis and HIV

But, at that time, screening tests did not exist for these viruses

Today, vendors can be effectively screened

4) “Commodification”

“commodification” is just an emotionally charged term to describe “sales”; should have the debate without use of this word

Implied seems to be that a vendor will, in some way, lose human dignity, and be seen as a provider of spare parts; but there is no data to suggest that sperm or egg vendors or surrogate mothers have any loss of human dignity

“my kidney is not my humanity”

**treating people as commodities,
with no say in their own destiny,
is totally different than letting
them decide for themselves what
to do with their own bodies**

Also implied in some “commodification” arguments is that body integrity is highly valued; and that vendors would have some longstanding damage because of a break in body integrity

But all surgery – including optional plastic surgery - involves a break in body integrity; and there does not seem to be long-lasting effects

Those who have this concern can opt to not be vendors

5) Exploitation of the poor

Core of this argument:

- a) nephrectomy has risks
- b) poor are more likely to be vendors
- c) the financial offer will override their better judgment

Numerous problems with this argument:

first, “nephrectomy has risks” - we allow sale of other body parts; if risks of nephrectomy (vs sale of other body parts) justify a ban on sales, they should justify a ban on donation

Second, “poor are more likely to sell a kidney than the rich”. But is this exploitation? (i.e., deriving wrongful advantage from the calamity of others)

a) poor and rich on the waiting list would benefit; and their lives prolonged

b) the vendor would be making an autonomous decision; would receive a substantial payment that could improve his or her quality of life

A regulated system is not necessarily exploitative if it includes procedural safeguards to ensure the vendors know what they are doing and are acting voluntarily (and, in the cases of kidney sales, the system would not be seeking the typical exploiter’s “wrongful gain”)

Third, “the financial offer will override their better judgment”

- a) fundamental tenet of Western liberalism that people should be allowed to control their own destinies (autonomy)**
- b) the fact of payment does not necessarily mean that the vendor’s choice was not free and voluntary (no one argues against the rich being vendors)**
- c) there is a difference between a “hard choice” and an “involuntary choice”; being poor does not remove the ability to make rational decisions (we do not have legal guardians to protect the poor from every decision they**

- one cannot confuse a limited range of options with an inability to choose between options

Does not distinguish from donation;

“if the possibility of (financially) pressuring the organ seller is sufficient to warrant a ban on organ sales, the possibility of (emotionally) pressuring the related donor must be sufficient to warrant a ban on organ donation”

- Wilkinson, 1966

Finally,

**Prohibiting the the poor from selling a kidney still
leaves them poor (and removes 1 possible
option to improve their lives)**

**Thus those who are protecting the poor by
prohibiting sales – simply remove one option
for the poor to better themselves**

6) Financial Offer is Coercion

“persuasion (of an unwilling person) to do something by using force or threats” (New Oxford American Dictionary)

Financial offers may be seductive but they are not subtle threats

In fact, no potential vendor can be coerced by the opportunity to sell an organ

7) There can be no genuine consent

This is in conflict with the concept of autonomy

“Vendor volunteers may be underprivileged and uneducated”

a) can be corrected by education

b) even if true for some, doesn't mean we should limit the freedom of all

- applies to donors also; therefore should we prohibit donation?

8) Harm to the vendor

Does not distinguish from donation

We allow the poor (and nonpoor) to take risks for payment (jobs – coal miner, fireman, policeman, bomb disposal, oil-rigs)

We allow all (poor and nonpoor) to pursue other activities with greater risk than donation – hang gliding, bungee jumping, rock or mountain climbing - smoking

9) Collateral Damage

**a) If government is “buyer” of kidneys,
erosion of trust in the government**

**Government might “exploit” the poor; No
evidence**

**There are many examples of different arms of
government having conflicting priorities (in
this case - saving lives of patients with ESRD
vs concern of exploitation):**

**e.g., protection of environment vs dependence on
foreign oil; development of the economy vs
raising minimum wage**

9) Collateral Damage

**b) Health profession would be tarnished;
doctor-patient relationship would suffer;
“corruption of sensibilities and general
moral decline”**

**No evidence; (and does this rhetoric override
death and destitution)**

**In fact, surrogate mothers have not created these
effects (and, in fact, get excellent physician
care)**

**“mutual respect for all persons will be slowly
eroded”**

- slippery slope argument; no evidence

10) The “church” will object

This may be true for some religions

but

We (are supposed to) have separation of church and state; the church can have an opinion but should not set public policy

11) If sales, donation may decrease

This is a hypothesis to be tested

- and powerful reasons to believe not true
(desire to know the donor; benefit of
preemptive tx)**

12) “Donation should be altruistic”

Why?

- historically true, but not necessary**

13) System will be abused

a) Potential vendors will lie about their health

- 2 evaluations @ 6 month intervals

b) Physicians will relax acceptance criteria

- rigid standards

Possibility of abuse is not a reason for prohibition; (because there is tax abuse, should we end taxation?)

- doesn't distinguish from donation