Ethical Considerations in Organ Transplant

Catherine Garvey RN BA CCTC
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Objectives

• Identify prioritization and organ distribution of the current organ allocation system

• Discuss patient responsibility and adherence in determining transplant candidacy.

• Review challenges of disparities in access to organ transplant

• Define ethical issues in the use of and care of living organ donors

Modern Principles of Bioethics

• Beauchamp and Childress, “Principles of Biomedical Ethics” originally 1997; now in its 7th Edition

• A Balance of 4 Basic Moral Principles
  1. Respect for Autonomy
  2. Nonmaleficense
  3. Beneficence
  4. Justice

• Beauchamp and Childress make it clear that this is not a theory of morality but principles to guide medical decision making
Allocation

• NOTA 1984

• Contract for Organ Procurement and Transplantation Network (OPTN) to maintain a national registry for organ matching.

• United Network for Organ Sharing (UNOS) 1986

Allocation

• HHS implemented a final rule 2000
  – establishing a regulatory framework for OPTN.

• Goals of OPTN
  – increase the number of transplants
  – provide equity in access to transplants
  – improve waitlisted patient, living donor, and transplant recipient outcomes
  – promote living donor and transplant recipient safety
  – promote the efficient management of the OPTN

Allocation algorithms

• Liver MELD/PELD 2002
  – Status 1A, MELD, MELD exceptions

• Lung LAS 5/2005
  – 0-100 medical urgency

• Heart status 2006 updated
  – Status 1A, 1B, 2 & exceptions

• Kidney Pancreas & Pancreas 10/2014
  – Use of insulin, c-peptide, & BMI

• Kidney 12/14
  – EPTS: Age, diabetes time on dialysis, & prior transplant
  – KDPI score for deceased donor kidney
KAS Results-6 months

- Increased transplant rate
  - in hard to match patients
  - patients with 5 or more years on dialysis
  - African Americans

- Decreased transplant of kidneys that expected to last longer than patient
  - Peds patients receive kidneys expected to last longer

- More sharing across DSA’s

Allocation-Living Donors

- KPD Programs
  - NKR
  - APD
  - UNOS

- Nondirected Donors

Allocation

- DCD Donation
  - National goal to increase
    - 15% nationally (7-30%) by regions

- Hope Act 11/15
  - Allow for study of HIV positive organs to be transplanted into HIV positive recipients
  - DD organs and living donors

- Imminent Death Donation
  - Being discussed
Allocation

- Allocation
  - The action or process of distributing something

- Rationing –
  - The controlled distribution of resources and scarce goods or services
  - there are “winners” and “losers”

Shana Alexander, Life, Nov 9, 1962
(The God Committee)

Competing priorities in organ rationing/allocation

- To maximize patient and graft survival
- To improve patient quality of life
- To minimize waiting times and death on the waiting list
- To promote equity across a range of socio-demographic dimensions
Current Kidney Allocation (Rationing) in the U.S.

- Principles-balance of
  - "equity" - every candidate has a chance to get transplanted
    - (waiting time)
  - "utility" - getting the best results from each transplant
    - (antigen matching)

What if we rationed kidneys based on social utility?

- What is social utility? How do you define it?
- Corporate executive – with/without children
- Housewife – with/without children
- Poet – with/without children
- 22 year old drug addict
- 15 year old student

What if we combined medical utility and quality of life?

- How do you measure quality of life?
- Is 5 years of quality-life the same for a 60 year old and a 17 year old?
- Should someone approaching retirement have the opportunity to enjoy their retirement? Is this different than life-years of enjoyment for a 30 year old?
What if we rationed kidneys based on medical utility (maximizing good)?

• In the US, all transplants would go to non-diabetic, White or Asian males between the ages of 25-55.
• Is this acceptable?

What if we rationed kidneys based on medical justice (fair and equal distribution of benefit and burdens)?

• 1st in line (longest waiting)
• Lottery
• Acceptable?
  – Yes?
  – No?

Ethical issues in Rationing

• What is the starting point?
  – health care provider
  – public policy debate
• My answer:
  – As health care professionals, we should advocate for transplanting every patient that we think would benefit (vs. dialysis). I believe that I should list every candidate who desires a transplant and would likely benefit.
  – However, for a public policy discussion about rationing organs, health care professionals are only 1 of many voices. When it comes to developing “rationing” algorithms, other voices must be included in the discussion.
Presumed Consent vs. Routine Removal (conscription)

- Presumed consent – a candidate is presumed to have consented if he or she had not opted out
  - assumes individuals have ownership
- Routine removal – in theory, assumes that society has a right to the deceased organs
  - the individual does not have ownership of his/her body (similar to postmortem exam)
  - does not require anyone’s consent
  - opting out systems are possible

Another Approach to Rationing

- Increase donation!!!!!!!!!!!!!
- Deceased donation
  - ECD, DCD Conscription
- Living donation
  - unrelated, nondirected, paired exchange, chains, desensitization
- Elimination of disincentives
- Provide incentives for living and deceased donation

Adherence

- “the act of doing what is required”
- Nonadherence – transplant recipients is major cause of graft failure
- Significant NA occurs 22% renal tx recipients & Component of graft loss in approx 36% patients
- Associated with increased incidence of rejection (acute & chronic) leading to need for re-tx
Adherance

• Nonadherence in pediatric K patients
  – Occurs in 5-43% patients
  – Adolescents (19-24) more NA than (24-44)
  – Major cause of graft failure

• Costs
  – Persistent low compliance associated with $12,840 increase in individual 3 yr medical costs

Interventions-NonAdherence

• Contingency plans may help patients remain adherent despite changes in daily routines

• Reminder cues, systems, and alarms can prompt patients to take their medications and to refill their medication prescriptions.

• Interventions that address “practical” barriers to adherence  Weng et al BMC Nephrology 2013 14:261

Adherence Pre-Transplant

• Missed appointments & labs
• Missed dialysis for ESRD patients
• Inadequate medication refills
• Failure to complete evaluation
• Contracts for smoking cessation, substance/ETOH use
• Failed previous transplant for NA
Adherence Pre-Transplant

- Does pre-tx NA predict post tx NA?
  - End stage organ failure debilitating
  - Transplant program not managing day to day cares
  - Definitions of referring & primary may differ from transplant program
  - No “testing” or drug levels to use

Disparities

- Cost of dialysis vs. transplant
- ESRD added to Medicare
- 1995 Transplant shown to be lifesaving

Disparities

- Access to healthcare
  - Lack of health insurance by minority groups (racial, ethnic, socioeconomic)
    - Delay care, go without care or meds
  - Lack of financial resources –
    - reduced most among minority populations.
    - plan that limits the amount of services available & number of providers

Sources:
- http://www.cdc.gov/healthyyouth/disparities/
- www.ama-assn.org/.../eliminating-health-disparities.page
Disparities

• Irregular source of care
  – ethnic or racial minorities are less likely to be able to visit the same doctor on a regular basis and tend to rely more on clinics and emergency rooms
  – have more difficulty obtaining their prescriptions and attending necessary appointments.

• Legal obstacles
  – Low-income immigrant groups are more likely to experience legal barriers. For example, insurance coverage through Medicaid is not available to immigrants who have been resident in the U.S for less than five years.

• Structural barriers – Examples of structural barriers include lack of transport to healthcare providers, inability to obtain convenient appointment times and lengthy waiting room times. All of these factors reduce the likelihood of a person successfully making and keeping their healthcare appointment.

• Lack of healthcare providers – In areas where minority populations are concentrated such as inner cities and rural areas, the number of health practitioners and diagnostic facilities is often inadequate.

• Language barriers
  – Poor English language skills difficult to understand basic information about health conditions or when to visit doctor

• Older Age
  • fixed income and cannot afford healthcare
  • transport problems or suffer from a lack of mobility
  • 15% of the older adults in the U.S lack access to the internet less likely to benefit form the valuable health information that can now be found on the internet
Disparities

- Disparities in Healthcare Quality Among Racial and Ethnic Groups: Selected Findings from the 2011 National Healthcare Quality and Disparities Reports.

Costs

- Kidney transplant & 1st year medical care averaged $89,939
- After first year, costs averaged $16,043
  - mostly for anti-rejection medication
- Dialysis costs about $44,000 per year.
- Medicare covers ESRD & transplant
  - 3 years medication if coverage is for ESRD
  - lifetime coverage if coverage due to age or disability
- Efforts at federal legislation for lifetime coverage of immunosuppression meds
  - Save money in preventing return to dialysis
Hippocratic Oath

- “First, do no harm”
  - actually, the oath does not contain this phrase, but does state: “Also I will, according to my ability and judgment, prescribe a regimen for the health of the sick; but I will utterly reject harm and mischief”
- Has been rejected as being too simplistic; it does not address numerous ethical problems in medicine: respect for autonomy, “truthfulness, privacy, distribution of health care resources, communal responsibility, the use of research subjects…."

Paternalism

- Concept in health care: “ professional has superior training, knowledge, and insight and thus is in an authoritative position to determine the patients’ best interests.”
- “intentional overriding of one person’s preferences or actions by another person, where the person who overrides justifies this action by the appeal of benefitting or preventing harm…."
- Can lead to deception, lying, manipulation or nondisclosure of information as well as coercion and force —may not allow the patient to play a role in health care decisions

- Respect for Autonomy
  "respecting and supporting autonomous decisions”

- Nonmaleficence
  “avoiding the causation of harm”

- Beneficence
  “relieving, lessening or preventing harm and providing benefits while balancing benefits against risks and costs”

- Justice
  “fairly distributing benefits, risks and costs”
Living Donation

- These 4 principles often conflict, and must be balanced as part of clinical decision making
- Example: Justification of living donation
- Facts:
  - LD tx is associated with significant better outcome (survival and quality of life) than DD
  - Earlier transplant (pre-dialysis) has better results than late
  - Risks to the donor:
    - mortality: 3 in 10,000
    - major morbidity: ~1%
    - long-term: psychosocial/financial
    - Increased risk of ESRD

Living Donation

- Justification of living donation

- Nonmaleficense (preventing harm to the donor) is balanced against beneficence (overall good) and respect for autonomy (donor’s decision)

Respect for Autonomy

- Implicit in the concept of respect for autonomy is provision of adequate information to be able to make the decision (informed consent).

  - “Informed consent occurs when a competent person makes an autonomous choice about whether or not to access medical treatment, armed with adequate information and understanding regarding risks, benefits and expected outcomes.”
  - “autonomous choice” --- voluntary
Donor Autonomy vs. Minimization of Risk

• An important discussion:
  – All decisions about proceeding with a living donor tx include this concept.

• Why?
  – The donor operation has absolutely no physical benefit to the donor; i.e., we can’t make someone healthier by taking out a normal kidney. Yet the surgery has all the risks associated with any 3-4 hour intra-abdominal operation where we are working on major blood vessels.

• How can we justify doing the surgery?

Living Donation

• Cases: donor autonomy vs. minimization of risk
  • 34 year old male with ESRD due to Inga nephropathy accepted for transplantation.
  • 39 year old sister, normal labs and a BMI of 32 wants to donate

• Fact: increased BMI is associated with increased surgical complications and obesity is a risk factor for development of ESRD

Elements of Informed Consent

• Alternate therapies for the recipient
• Success of LD transplant vs. other therapies
• Anything that, in this particular case, would
  • possibly decrease the success rate
    –(e.g., potential for recurrent disease)
• Medical and psychosocial risks of donation
• Transplant-related events could be a problem
  • Informing is not sufficient; understanding is necessary
Living Donation

• Recognizing the overall good, most U.S. transplant programs today emphasize living donation.

• Risk is minimized by a thorough medical and psychosocial exam and stringent selection criteria; and by separating donor and recipient teams; with recent addition of an ILDA to the donor team.

• However, Selection criteria have relaxed: obese donors & hypertensive donors

• Where do you draw the line?

Living Donation

• The practical question is:
  • If the individual knows and understands the risks and is still wants to proceed (autonomous choice), should the transplant team always say “OK”
  • OR
  • Are there times when the team should say “no”? ( paternalism?)

• If “no”, how do you decide? who decides?

Living Donation

• Balance between donor autonomy and minimization of risk is a daily occurrence in clinical transplant decision making

• Although the concept of minimization of risk often refers to risk to the donor, there are numerous other risks that must also be considered
Minimization of Risk: Are we only worried about risks to the donor?

• What are the consequences of a bad outcome on:
  – families and friends? (Not a legal concern but something the team needs to consider)
  • transplant team? Eval, pre-op, intra-op, post-op
    – willingness to continue LD transplantation
    – regulatory concern
  • Transplantation
    – the transplant community is small
    – when there is a bad outcome of any sort that gets into the press (and a living donor death usually does), DD drops

Important to remember:

• Although the donor can make an autonomous decision, the team is not obligated to proceed

• Veatch worries that at some point donors that are turned down because of risk may sue to be able to donate (as has happened when physicians have wanted to stop end-of-life care)

• A donor being turned down and insisting on donating should be referred to another transplant center

Vancouver Forum on Care of the Live Donor Sept. 2005

• Medical judgement versus donor autonomy

• Donor consent and autonomy is necessary, but not sufficient to proceed to donation

• Medical evaluation and concurrence are essential

• Donor autonomy does not overrule medical judgment and decision making
Living Donation

• The practical question: If the individual knows and understands the risks and is still wants to proceed, should the transplant team always say “OK” or are there times when the team should say “no”?

• If “no”, how do you decide? who decides?

Living Donation

• Donor Operation is Unique

  • It is the only operation that we knowingly do that has no potential for physical benefit to the patient

  • It is important to determine short- and long-term risks

    – e.g., for informed consent

Living Donation

• Operative risks

  – Perioperative mortality – 3/10,000 = .03%

  – Perioperative morbidity

    • reoperation <1%

    • major complications <1%

    • minor complications <10%

• Long-term risk of living with 1 kidney

  – 1. survival 2. ESRD 3. quality-of-life
Living Donor-Kidney Failure

- ESRD has been Reported in Donors

  - a) Fehrman-Ekholm et al, Transplantation, 2006:
    - 6 cases of ESKD (0.5%)
    - Age-matched expected rate, about 6 cases

  - b) Cherikh et al, AJT, 2011
    - largest series of donors with ESRD; 126 on the wait list for transplant in the U.S.
    - subset with denominator (donor outcome data was not collected nationally prior to 1995; therefore no denominator), no increase in ESKD vs population controls.

Impact of Nephrectomy on Renal Function

- Non-donor, 45 yr f/u (n =62)
  Narkun & Burgess et al, Kid Int 1993

- Non-donor, 50 yr f/u (n =111)
  Baudain et al, AJKD, 1993

- no increase in mortality or htn; no renal failure

Impact of Nephrectomy on Renal Function

- 3) Meta-analysis Kasiske et al, Kid Int 1995
  - analyzed 48 studies: 3124 patients and 1703 controls
  - both donors & nephrectomy for other reasons
  - median duration of f/u = 10.6 yrs; 20% followed > 20 yrs
  - concluded that nephrectomy does not cause a progressive decline in renal function or increased proteinuria
Living Donation - Disincentives

- Many potential (living) donors do not donate because of concerns regarding:
  - lost wages (and having no disability insurance)
  - mortality (and having no life insurance)

- no long-term health care (and future ability to get long-term health care if they change jobs)
  - 49 million uninsured in the U.S.
- costs of travel and accommodation for both the evaluation and the donation
- costs of prescriptions for post-donation medications.

Thank You

- Questions?