# Ethical aspects of Liver Transplantation

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### Disclosures

None

# Ethics pertaining to Recipients

Cancer, Foreign Patients, Diseases of Lifestyle

"Ethics is not always about what is absolutely right or wrong, acceptable or unacceptable, ideal or less than ideal. It is more about what is the right decision (morally speaking), in particular circumstances, what is the lesser of two evils, what is the balance between doing good and causing harm. In other words, what one ought to do."

M SLABBERT PER/PELJ 2010 (13)2

Multiple Ethical frameworks: MODERN BIOETHICS: PRINCIPALISM

- Cadaver Donor
- Living Donor
- Recipients

# The Law governing solid organ transplantation in SA

Chapter 8 of National Health Act

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Multiple Ethical frameworks: MODERN BIOETHICS

PRINCIPALISM (Autonomy; Non-maleficence; Beneficence; Justice)

Cadaver Donor: Principles involved

Living Donor: Principles involved

Recipients

**PRINCIPALISM** 

Types of donation in SA:

• Cadaver Donor Opt in: relies on altruism and informed consent

Autonomy; ethically sound

Non-maleficence: next of kin at the time of donation

Beneficence: doing good on part of (dead) donor

Justice ???

**PRINCIPALISM** 

Types of donation in SA:

Cadaver Donor Opt in

BUT "the current organ procurement method... as embodied in the National Health Act, is unsuccessful in procuring enough transplantable organs to satisfy the demand for them"

Labuschagne and Carstens, 2014

RESULT....Insufficient organs

#### **PRINCIPALISM**

Cadaver Donor: Types of donation in SA:

Opt out: presumed consent and "informed refusal" = Autonomy
 Non-maleficence & beneficence (suspicion that brain death diagnosis too early)

Justice: YES.....BUT

Requires widespread education and information sharing Ethical acceptability in SA problematic: level of education and language Brazil's experience poor

#### **PRINCIPALISM**

Cadaver Donor: Types of donation in SA:

Opt out

VERY just, provided an equal and just distribution of organs BUT mistrust "It is currently unlikely to be possible to disseminate sufficient information to constitute an 'informed' refusal owing to communication limitations posed by language and literacy barriers as well as access to information"

#### **PRINCIPALISM**

Cadaver Donor: Types of donation in SA:

Mandated choice

"every citizen would be asked to indicate his or her willingness to participate in organ donation ... by means of a mandatory check-off on applications for a driver's licence or similar"

A premeditated informed decision on the specific organs he/she would be willing to donate, should he/she choose to be a donor, is also made available by mandated choice

#### **PRINCIPALISM**

Cadaver Donor: Types of donation in SA:

Mandated choice

Principles involved: Autonomy and informed consent for individual; non-maleficence; beneficence??

Justice: YES, more organs available

BUT not everyone applies for driver's license/registers for tax, etc.

#### **PRINCIPALISM**

Cadaver Donor: Types of donation in SA:

- Opt in
- Opt out
- Mandated choice

Which is best for SA?

Combined Opt in and Mandated choice: promotes informed consent, autonomy and dignity

K Hawkins MMed Bioethics Health Law Research Report 2017

#### **PRINCIPALISM**

Living Donor donation in SA

Related and unrelated

#### Autonomous choice:

- Acting with understanding
- Acting without influence \*
- Acting with intentionality

Non-maleficence?

**PRINCIPALISM** 

Living Donor donation in SA

Related and unrelated

Beneficence:

"If related donors observe the improvement of health of their recipient and benefit, how do donors who are unrelated both genetically and emotionally benefit?"

Walton-Moss et al 2022

### Specific Recipients

Foreign Patients

Cancer patients

Diseases of Lifestyle

#### Foreign Patients

- Transplant Tourism
- Declaration of Istanbul (2018)
   On Organ Trafficking and
   Transplant Tourism

 Very limited resource: demand far outweighs supply



#### Foreign Patients

• Declaration of Istanbul (2018) expresses the determination of donation and transplant professionals and their colleagues in related fields that the benefits of transplantation be maximized and shared equitably with those in need, without reliance on unethical and exploitative practices

Ethical guidelines



### Foreign patients in SA

Limited number of organs

#### **JUSTICE**

Guiding principle 9 of WHO guiding principles on human cell, tissue and organ transplantation states:

"The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations."

Distributive justice: "fair, equitable and appropriate distribution in society determined by justified norms that structure the terms of social cooperation"

Beauchamp and Childress

### Foreign patients in SA

- Current allocation criteria are predominantly Clinical
- National waiting list of recipients
- Should have an accurate national donor list

Until more organs are available, distributive justice mandates that foreign patients should only be eligible for RLDs. (should be self-funded for procedure)

- Norwegian pilot study (2013): transplanted 21 patients with non-resectable colorectal liver metastases (CLMs): excellent outcomes with 60% 5-year survival
- Result better than chemotherapy.
- Norway has/had surplus livers.
- SA: application to Wits HREC (M) for one liver transplant.
- Agreed, providing a research protocol ensued.
- Patient (a medical doctor) to be fully informed, pay all costs and receive a marginal deceased liver IF no other suitable recipient

Wits HREC study process: SAJBL June 2017, Vol. 10, No. 1 Subsequently, two publications from WDGMC on cancer patients:

• Patients with HCC:Thirty-one cadaver liver transplants were reviewed. The most common causes of underlying liver disease were infectious, (hepatitis B virus) and diseases of lifestyle including alcoholic/non-alcoholic steatohepatitis. Median age at transplant 57, mostly male. Results:1 and 5 year recipient survival was 77% (95% CI 57–88%) and 61% (95% CI 40–76%) respectively. Twenty-five (81%) patients were deemed to be within UCSF criteria.

SAJS Sept 2019 Dempster et al.

Wits HREC study process: SAJBL June 2017, Vol. 10, No. 1 Subsequently, two publications from WDGMC on cancer patients:

• Five patients with non-resectable colorectal cancer with liver metastases; received marginal donor livers; at 36 months 80% still alive.

Exp Clin Transplant. 2020; Botha et al

Is this ethical?

Non-resectable CLMs received marginal livers: YES Distributive justice applied

Patients with HCC: recognised indication

IF Distributive justice applied to recipient waiting list

Probably YES

### A question?

What were you doing on the 13/14 March 2007?

I was dealing with an ethical conundrum

### Manto's treatment for HIV/AIDS



- South Africa's controversial Health Minister, Manto Tshabalala-Msimang is facing new calls for her resignation.
- Under her leadership, life expectancy in South Africa fell to 49 years, thanks to Aids-related fatalities which – with 4.2 million infected by the virus – saw deaths nearly double between 1999 and 2005.

### Why was Manto's transplant so controversial?



On 14 March 2007, Tshabalala-Msimang underwent a liver transplant. The stated cause was autoimmune hepatitis with portal hypertension, but the transplant was surrounded by accusations of heavy drinking.

Current Milieu: LIMITED POOL OF LIVERS; DISTRIBUTIVE JUCTICE; PERSONAL PREJUDICES

Do we have any evidence?

WDGMC: Adult transplantation 2004 - 2016

- 297 Adult orthotopic transplants: 6.4% for ALF; balance ESLD
- Mean age 51 years; 66% male; median follow up 3.2 years
- Recipient survival: 90 days 87.6%; 1 year 81.7%; 5 years 71%
- Allograft survival similar. Median Meld: 17.

Current Milieu: LIMITED POOL OF LIVERS; DISTRIBUTIVE JUCTICE; PERSONAL PREJUDICES

Do we have any evidence?

WDGMC: Adult transplantation 2004 – 2016

Causes of ESLD:

Cholestatic cirrhosis

Non-cholestatic cirrhosis: NAFELD; AFLD; Autoimmune; Hepatitis C&B

Malignancy

SAMJ. 2018. Song et al

### Recipients with Lifestyle diseases

- NAFLD (dining out/fast foods/supplements and toxins)
  - AFLD
- Viral hepatitis (unprotected sex/intravenous substance abuse)

We should deal with them as a group and draw up a fair and JUST policy using the principle of distributive justice

Current Milieu: LIMITED POOL OF LIVERS; DISTRIBUTIVE JUCTICE What about patients with severe, non-responsive Alcoholic Hepatitis?

Is management of these patients based on evidence or personal prejudices?

- Abstention for 6 months: patient may be dead by then; Is abstention for 6 months in AFLD ESLD evidence-based? "Guidelines from the AASLD, the EASL, UNOS and the French Consensus Conference declared the 6-month rule an obsolete absolute CI and should no longer be used for candidacy for Liver Transplant"

  Transl Gastroenterol Hepatol 2022 Sedki et al
- Should responsibility be used as a tiebreaker in allocation of deceased donor organs for patients suffering from alcohol-related end-stage liver disease?

  Medicine Healthcare and Philosophy 2023 Hu and Primc

Current Milieu: LIMITED POOL OF LIVERS; DISTRIBUTIVE JUCTICE What about patients with **severe, non-responsive Alcoholic Hepatitis?** Is management of these patients based on evidence or personal prejudices?

What is the evidence?

UNOS database 2012: AH transplants and ALD transplants comparable graft and patient 5 year survival

Systematic review 2018: Transplanted AH and ALD patients had similar survival and recurrence rates

Transl Gastroenterol Hepatol 2022 Sedki et al

Current Milieu: LIMITED POOL OF LIVERS; DISTRIBUTIVE JUCTICE

What about patients with severe, non-responsive Alcoholic Hepatitis?

Is liver transplantation ethical in these patients?

Alcohol addiction is considered a chemical dependence, driven by pathophysiology (as yet to be elucidated); a chronic relapsing medical disease.

J Liver Clin Res 2016

IF it is acceptable to perform liver transplants in other patients who have lifestyle-induced ESLD, why is there such a prejudice against ALD ESLD and AH? THIS is unethical.

Consideration of the role of RLD?

#### In summary

Active efforts to increase the DONOR pool:

- Opt in
- Mandated choice

Recipient-wise, ethically treat all recipients the same, whether they have biliary cirrhosis, non-cholestatic cirrhosis (lifestyle or non-lifestyle related) and malignancy

Use current evidence-based criteria, and Distributive Justice.

Thank you!!