MEDICAL AND DENTAL PRACTITIONERS COUNCIL OF ZIMBABWE

GUIDELINES FOR HUMAN TRANSPLANT

PREAMBLE

In the Zimbabwean system, organ donations are guided by the Anatomical Donations and Post-Mortem Examinations Act 15 01 which is administered by the Ministry of Health and Child Care. This Act is the equivalent of the Human Tissue Act in other jurisdictions'. Although the Anatomical Donations and Post-Mortem Examinations Act 15 01 is not comprehensive enough, it offers guidance from living to cadaveric tissues.

PURPOSE OF THE GUIDELINES

The purpose of these guidelines is to define ethical practices in the practise of Human Transplant in Zimbabwe as well as define the Committees which will be critical in overseeing the transplant process. These guidelines are generic and apply to all organs.

1. NATIONAL TRANSPLANT COMMITTEE

The role of this Committee is to establish the broad principles governing transplantation including the criteria for accepting patients for transplant. Issue of equity, justice and access must be a high guiding principle for the Committee.

Composition of the Committee

- Specialist Health practitioners
- Lawyers (to assist in determining, for example, whether the legal definition of consent was fulfilled)
- Religious and traditional leaders (representing lay people)
- Ministry of Health & Child Care

(The Health professionals must outnumber the non-health members)

2. TRANSPLANT COMMITTEE/TECHNICAL ASSESSMENT COMMITTEE

This will be a Medical and Dental Practitioners Council of Zimbabwe (MDPCZ) Committee which will be responsible for setting up the parameters that govern the transplant. The Transplant Committee will be responsible for the scientific assessment of patients as well putting patients on the waiting list but will not make decisions on individual care of patients. The Committee will be able to recommend its decisions to Council.

Composition of the Committee

- Specialist Transplant doctors
- Specialist Psychiatrists and Psychologists
- High risk Obstetricians

- Specialist Transplant Nurses
- Social workers
- Ethics professionals

3. STAGES/PHASES OF TRANSPLANT

There are three phases in the transplant process, that is, pre-transplant stage, transplant stage and post-transplant stage.

3.1 PRE-TRANSPLANT STAGE

3.1.1 Who Qualifies for organ transplantation?

- A patient with progressive and irreversible disease which has reached end stage as defined by the Transplant Committee of the MDPCZ.
- The patient should not have any active malignancy or infection.
- There should be absence of other systematic diseases that may limit rehabilitation.
- The patient should have life expectancy of greater than 5 years with a successful transplant.
- There should be willingness to comply with treatment and follow up and have effective family or social support.
- For renal, the patient should have end stage disease (Stage 5) and transplant can be done even before the patient starts dialysis.

3.1.2 Patient Assessment

Information to potential recipients which should be in writing should cover the following:

- Medication regimes
- Lifestyle adjustments required
- Short and long term outcomes of the procedure
- Risks and benefits
- Effect of transplant on existing medical conditions

3.1.3 Who may not be a recipient?

A patient with the following may not qualify as a recipient:

- Active substance abuse
- Severe cognitive impairment
- Severe peripheral vascular disease
- Active malignancy
- Non adherence to therapy (to be considered on merit)

3.1.4 Patient Investigation (Laboratory)

- Full blood count
- Tissue capacity
- Multi-screen for electrolytes
- Liver and renal function tests
- Lipid profiles
- Cultures especially urine
- Serology – hepatitis B, Hepatitis C, HIV
- Compatibility (HLA etc.)
- Gender specific tests:
  - Papsmear for adult females (within the last 6 months)
  - PSA for men over 45 years
  - Pregnancy tests

- Any other as per best international practice'

3.1.5 Radiology

- Ultrasound done by a Radiologist
- Chest x-ray, MRIs
- Coronary artery disease history
- Coronary angiography
- Echocardiography
- CT abdomen
- Other appropriate investigations
- Any other as per best international practice'

3.1.6 Pre-Transplant Immunisation

These will include:

- Influenza
- MMR
- Varicella
- Meningococcal
- Pneumococcal
- Any other as per best international practice'

3.1.7 Donor Selection: Who Qualifies to be a Donor

Living Donor assessment

- Donation is voluntary – no payment should be made
- No minor donors – they have no capacity to make decisions
- Initial cross match and HLA typing, virology
- Medical (genetic disorders) and social history, extensive and detailed
- Any other as per best international practice'

Cadaveric (Deceased Donors)

- Should be guided by the Anatomical Donations and Post Mortem Examinations Act 15 01
- There is need for advocacy to get societal commitment so that numbers are increased as this is an essential component of maintaining the skills of the transplant team.

3.8 Patient Status while waiting

- At the beginning of the year the Physician should provide an annual assessment report on the status of the patient.
- In between when there is a material change in the patient's condition including death, the Physician is obliged to disclose. In the absence of that there is no need for a report.

3.9 On Hold Status

- A patient is put on hold when there is a new medical condition or when something major happens.

3.9 Removing patients from the waiting list

- This will be done when something unexpected happens and the condition is no longer suitable for transplantation.

4. TRANSPLANT STAGE

An institution wishing to carry out transplants should have the following:

4.1 Infrastructure

- Holding wards
- Renal/liver support units
- Pathology/Laboratory and Radiology services
- Pharmaceutical services
- Nephrology/Hepatology/Cardiology units
- Operating theatre

All these units should be under one roof.

4.2 Competencies for Professionals

- Adequate number of Physicians in that specialty
- Credentialed Transplant Nephrologists, Transplant Hepatologists, Cardiologists, Pulmonologists
- Transplant surgeons
- Transplant Nurses
- Transplant Coordinators (with post basic qualification in Transplants)
- Intensivists and Anaesthetists
- Intervention Radiologists
- Pathologists/Immunologists
- CPD to maintain competencies

All Physicians must have post fellowship training in Transplants and must have residential practical mentoring in an approved institution. The core transplant team should be resident in the country for at least 12 months'.

4.3 Equipment

4.3.1 Nephrology

- Basic ward structures
- Dialysis
- Plasma exchange equipment
- Ultrasound scan (for bedside renal biopsy)
- Point of care radiology
- Radiology services should include; Angiography, CT/MRI scans

4.3.2 Anaesthetic

- Standard anaesthetic and monitoring equipment

4.3.3 Surgical

- Well equipped functional theatre with lamina floor

4.3.4 Laboratory

- Proper immunopathology laboratory
- Functional electronic microscope
- Toxicology

- Dissecting microscope
- Therapeutic drug monitoring

4.4 Supplies

- Essential medicines to be held at 3 months stock level
- Antibiotics
- Immunisations
- Vaccines
- Immunosuppresants
- Consumables for dialysis
- Protected (isolated) dialysis unit with 2 beds for rejected transplants.

5. Specimens for Export /Import

- The Medical Research Council of Zimbabwe regulates the shipment of tissues out of the country especially living tissue.

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1. POST-TRANSPLANT STAGE

1.1 COMPLICATIONS IN EARLY POST- OPERATIVE PHASE

Major complications which can occur in the early post-operative phase include:

i) Delayed Graft Function (GDF)

Investigations

- Ultrasound plus Doppler to exclude possible arterial or venous or ureteric occlusion.
- Laboratory tests

Management

- Interventional radiology
- Urgent reoperation

ii) Graft Rejection

There are four main types of rejection experienced by transplant recipients

a) Hyper acute

This is antibody mediated and should not happen if the transplant screening of antibodies has been done well. It usually occurs immediately after transplant.

b) Accelerated

This occurs when the transplant recipient possesses pre-existing antibodies and occurs within the first week following surgery.

c) Acute

This can occur within the first three months of transplant. Acute rejection should be confirmed by a biopsy.

d) Chronic

This is a T-cell mediated rejection can either be cause by donor specific antibodies.

Management

Ultrasound guided biopsy
Blood clotting profile – INR, PTT, Platelet count
Monitor for post biopsy bleeding

iii) Infection

Look out for opportunistic infections, bacterial, viral or fungal.

a) Viral

These are usually seen between 4 to 26 weeks after transplant and include Cytomegalovirus (CMV), Herpes Simplex Stomatitis (HSV), BK Polyoma Virus (BKV) and Epstein-Barr virus (EBV).

b) Fungal

These include candidiasis, Cryptococcus, mucormycosis or aspergillosis.

c) Bacterial

These include urinary tract wound, lung infections and sepsis.

iv) Diarrhoea

Diarrhoea is a frequent problem in post-transplant patients. It can be infectious or non-infectious.

v) Leukopenia

- Review immunosuppresants and other drugs
- Investigate for infections

Management

Stimulate with G-CSF
Treat accordingly

vi) Follow Up

a) Ambulatory Care Phase

RECOMMENDED FREQUENCY OF FOLLOW-UP AT TRANSPLANT OUTPATIENT CLINIC	
Time, Post-Transplant (months)	**Frequency of Routine Outpatient Visits**
0 to 1	Twice every week
1 to 2	Once every week
2 to 3	Once every 2 weeks
3 to 6	Once every 3 weeks
6 to 12	Once every 4 weeks
Greater than 12	Patient should have mini bloodwork done every 4 to 6 weeks between clinic visits Clinic visits once every 12 to 16 weeks.

b) Standing Laboratory Orders

Routine tests

- Potassium
- carbon dioxide
- Phosphate
- Calcium
- Blood glucose (fasting)
- Haemoglobin
- Liver function

- Urine & Albumin – creatinine ratio
- T & B cell profiles
- Lipid profiles
- Virology tests
- Therapeutic Drug Monitoring

c) Long-term Immunosuppression Regimen

- Immunosuppression for life but with progressive reduction
- Reduction is especially for steroids in view of their complications.
- There are some organs where the recipient may be weaned from immunosuppressants completely

d) Long-term Additional Medication

- Cotrimoxazole
- Dapsone
- Pentamidine
- Antiviral drugs

e) Treatment of Failed Transplant Organ

Depends on clinical scenario:

- Re-transplant
- Withdraw immunosuppression schedule

f) Evidence of chronic indices

- Creatinine has gone up
- Lungs cannot saturate
- Heart cannot pump – below 30%

g) Prophylactic Dental Coverage

- Prosthetic cardiac valves
- Previous infective endocardiatis
- Congenital Heart Disease
- Cardiac transplant recipients who develop cardiac valvupathy

h) Surgical Prophylaxis

If they are going for any other surgical procedure – penicillin, cephalosporins

i) Dyslipidemias

Starting therapy may interact with CNI.

j) Phlebotomy

In post transplant polycythemia (17g/dl for males and 16.5g/dl for females)

k) Immunisation

There is potential serious illness and death for immune compromised people. Before deciding to immunise check whether it is necessary to immunise. If necessary follow these guidelines:

- Avoid live vaccines
- Delay vaccination
- Consider passive immunising agents

l) Contraception

Generally fertility for females increases greatly after transplant. Within the first year of transplantation women should avoid pregnancy.

- Use barrier methods (condoms, diaphragm)
- Avoid oral contraceptives
- Avoid IUDs and other hormonal methods.

m) Pregnant Transplant Recipients

- Pregnancy must be carefully planned with the Transplant Team to change some of the immunosuppresants
- There should a high risk Obstetrician to work with the transplant team
- The Obstetrician should watch out for the following:
  - Birth defects
  - Spontaneous abortions
  - Premature and low birth weight
  - Diabetes
  - Hypertension and pre-eclampsia

n) Erythrocyte Stimulating Agents

- Investigate the causes of anaemia first
- If so indicated use ESAs (Erythropoietin or darbepoitien)
- Laboratory monitoring for (FBC, Vitamin B_{12}, RBC folate, iron, TIBC, % saturation, ferritin, reticulocyte count, CBC, differential, BUN, creatinine, electrolytes)

o) Screening for other Cancers

- One of the post transplant complications in malignancy.
- A yearly cancer screen for those cancers that can be screened should be done.

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