MEDICAL AND DENTAL PRACTITIONERS COUNCIL OF ZIMBABWE

GENERAL REQUIREMENTS FOR DIAGNOSTIC CORONARY ANGIOGRAPHY AND PERCUTANEOUS CORONARY INTERVENTIONS (PCI)

Preamble

In line with the government thrust on economic turnaround strategies that include promotion of international investors, the Ministry of Health & Child Care requested Council to develop a Policy that will guide practitioners wishing to enter into partnerships with international investors to establish a Human Transplant Facility in Harare that provides inter-alia Diagnostic Coronary Angiography and Percutaneous Coronary Interventions (PCI). In line with the mandate of the Council of defining and enforcing ethical practice, as provided in Section 30(1)((i) of the Health Professions Act(Chapter 27:19) Council developed the following guidelines :

1. GENERAL REQUIREMENTS FOR DIAGNOSTIC CORONARY ANGIOGRAPHY AND PERCUTANEOUS CORONARY INTERVENTIONS (PCI)

- Proper hospital infrastructure
- Equipment
- Critical mass of appropriately trained work force
- On-site cardiac surgery or formalised link to a cardiac surgical unit

1.1 INFRASTRUCTURE AND EQUIPMENT

INFRASTRUCTURE

Specifications for CCL have to be met and these include:

- Theatre to be of a minimum certain international standard dimensions as the theatre must be able to house the imaging equipment.
- For safety the theatre has to conform to Radiation Protection Association guidelines (hereto appended).
- The theatre must be approved by the RPAZ and should be hospital based.

1.2 SPECIALISED EQUIPMENT

- Specialised radiographic imaging equipment mounted in the CCL
- Haemodynamic monitoring equipment
- Physiological data acquisition
- Radiographic equipment
- Electrical power back up of the appropriate size to operate the equipment (generator of at least 100 kilowatts)

- Contrast injectors
- Adequate supply of support equipment (consumables) i.e. catheters, intra aortic balloons, guide and pacing wires, radio contrast
- Emergency trolley
- Cardio pulmonary resuscitation equipment
- If performing paediatric procedures specialised paediatric equipment will be required.
- Any other equipment as per best international practice

1.3 CRITICAL MASS OF APPROPRIATELY TRAINED WORKFOCE

KEY PROFESSIONALS:

1.3.1 Specialist Practitioners

- Cardiologists or a Physician who has had training in Coronary Angiography and PCI
- Radiologists with training in Vascular and Interventional expertise
- Cardiothoracic Surgeons with open heart surgery expertise
- Anaesthetists with cardiovascular expertise
- Paediatric Cardiologists (if performing paediatrics procedures)

1.3.2 Other Experts

- Catheterisation laboratory Nurses with specific training
- Radiographers (including Radiation Safety Officer) with special training in operating the equipment
- Critical Care Nurse or Theatre trained Nurse

Nursing and Technical Staff Training should include

- A didactic component
- On site observational training
- Hands on experience as assistant operator

1.4 CARDIAC SURGICAL UNIT

- There must be an on-site surgical unit or there must be a formalised link to a cardiac surgical unit.
- Access to a surgical unit should be achieved within an hour.

1.5 CORONARY CARE AND ICU SERVICES

- These facilities must be in house.
- The diagnostic coronary and cardiac catheterisation laboratory shall be hospital based units.
- The hospital should have a fully equipped diagnostic radiology unit which include ICT, Ultrasound

2. REQUIREMENTS FOR SAFE PERFORMANCE OF PROCEDURES

- Careful Patient Selection
- Comprehensive Staff training
- Structured clinical protocols

2.1 CAREFUL PATIENT SELECTION

Careful patient selection meeting the international Classification Standard

- Ambulatory and;

- In house patients
- Emergency cases

SPECIAL GROUPS

1. PAEDIATRICS

2. CONTRAINDICATIONS

Among others these include:

- High risk vascular complications
- Peripheral vascular disease morbid obesity
- Prosthetic valves
- Low injection fractions (less than 35%)
- Bleeding disorders
- Uncontrolled hypertension
- Uncontrolled diabetes
- Chronic steroid treatment
- Allergy to contrast media
- Chronic airway disease
- Recent stroke
- Transient ischaemic attack
- Severe pulmonary hypertension
- Complex congenital heart disease

2.2 PCI IN A UNIT WITHOUT ON SITE SURGICAL BACK UP

- Should have a Diagnostic Coronary Angiography service with acceptable rate of complications for at least 12 months.
- Potential delay of obtaining cardiac surgery for complications should be explained to the patient.
- There must be an informed consent
- There should be an on call team post procedural for at least 24 hours
- High risk patients should ideally be in a facility with on-site surgical back up but those with large ST elevations and cardiogenic shock can benefit from early intervention (emergency category)
- There should be formal liaison with a high volume PCI Centre with on-site cardiac surgery.
- Centres with more than one hour travel from the Cardiac Surgical Unit should not perform elective high risk PCIs.
- Quality assurance documentation of outcomes is required.

2.3 CROSS CUTTING ISSUES FOR THE UNIT

- All specialists should be accredited to perform these procedures. That includes appropriate training and meeting a minimum number of procedures per year. (ELC Subcommittee to define the details of accreditation)
- Ideally there should be two appropriately trained Cardiologists per PCI centre.
- Availability of ICU/CCU facilities (with ECG).
- Individual hospitals should have written policy