

# Standards Document for Evaluation of Emerging Pediatric Transplant Programmes

## IPTA Outreach Committee

### **Introduction:**

One objectives of the IPTA is to facilitate worldwide access of children with end stage organ failure to safe, ethical and high quality solid organ transplantation. The IPTA Outreach Programme is aimed at engaging centres worldwide who wish to initiate a new solid transplant programme for children, or expand the quality or capacity of an existing transplant programme. Support available from the Outreach Programme is mostly directed toward providing training, organizational support and establishing guidelines and procedures. Limited resources necessitates prioritizing those programmes that have the greatest chance of successful implementation/expansion.

This document outlines basic guidelines for a regulatory framework, accessible infrastructure and expertise needed in order to establish or expand a pediatric solid organ transplant program. As part of the intake process, applicant programmes must complete a needs assessment based on these criteria. It is expected that a programme application addresses each of the standards in this document. Where the standard is not yet met at time of initial application, comments must be provided to explain existing barriers, potential solutions and the role that the Outreach Programme may play in helping achieve the standard. Applicant programmes will be prioritized for support based on the feasibility of both establishment and sustainability of the proposed transplant program development, based on these standards.

IPTA upholds the principles of the Istanbul convention against organ trafficking and transplant tourism and will not support any programme that does not abide by these principles.

### **1. Regulatory and ethical requirements**

- 1.1.** Organ trafficking and transplant tourism: IPTA will not provide resources or support toward any programme that participates in or benefits from commercialization of organ donation. The Director of the Transplantation Programme and the Director of the Hospital must sign a declaration stating their programme will abide by the principles of the Istanbul declaration.
- 1.2.** Commerce in organ allocation: Financial considerations of any party involved in the transplant process must not influence the application of allocation rules.
- 1.3.** Equity of access: Barriers to access for transplantation for patients (e.g. financial, transportation, geographic distance, language) should be identified and minimised where possible.
- 1.4.** Ethical allocation: Organs need to be allocated in an equitable and transparent manner. Written allocation protocols/algorithm need to be provided and publicly accessible.
- 1.5.** Legislation supporting organ donation: If the programme intends to accept organs from deceased donors, legislation in that country must exist that supports the recovery of organs from deceased do-

nors and subsequent transplantation into children. If the programme intends to accept living donation, legislation in that country must exist that supports the recovery of organs for living donors and subsequent transplantation into children.

- 1.6. Regional organ procurement agreements: If the programme intends to accept donation from deceased donors, written agreement with organ procurement organization, tissue banks and/or donor referral centres will be required to establish the terms of agreement with the transplant centre.
- 1.7. Hospital policy: The programme must have a policy statement that is authorized by hospital administration that specifies support to maintain the transplant programme at the institution and specifies which types of organ transplantation will be permitted in children at the institution.
- 1.8. Hospital accreditation: The hospital hosting the transplant programme must meet national regulatory requirements for hospital accreditation. If there are specific/separate standards for transplant programme accreditation, these standards must also be met.
- 1.9. Adult hospital referral centre collaboration : The programme must identify a regional adult transplant centre (organ specific) willing to accept transfer of pediatric transplant recipients at an agreed upon transition age in adolescence/adulthood.

## **2. Facility/resource Infrastructure**

- 2.1. Hospital facility: Access to intensive care unit, operating theatres and an identified area post-transplant for ward care.
- 2.2. Acute dialysis services: On-site acute dialysis facilities should be available on a daily basis for all organ transplant programmes.
- 2.3. Outpatient clinic: A designated outpatient clinic area is identified and adequately resourced to provide outpatient assessment of transplant recipients after discharge.
- 2.4. Allograft biopsy services: Access to percutaneous biopsy resources (e.g. interventional radiology) for liver and kidney transplant, and cardiac catheterization for endomyocardial biopsy for heart transplant recipients.
- 2.5. Radiology services: On-site and timely access to x-ray and ultrasound required in the pre/post-operative management of transplant recipients. For heart transplantation, similar access is required to echocardiography.
- 2.6. Histopathology services: Timely access to histopathology services for diagnosis of organ complications. In urgent situations, tissue processing must be available within one week (desirable would be 24 hours of biopsy).
- 2.7. Blood bank: On-site access to blood compatibility testing and blood products for transfusion (e.g. packed red blood cells, IVIG, plasma products).
- 2.8. Tissue typing laboratory: Access to an established tissue typing laboratory accredited to national standards. The laboratory must routinely provide the following services: HLA tissue typing of donor

and recipient, pre-transplant HLA antibody testing, donor/recipient cross match testing and post-transplant HLA antibody testing.

- 2.9. Diagnostic test laboratory: On-site access to biochemistry and haematology available 24 hours a day for the transplant services . Blood gas machine or point of care testing that provides access to electrolytes and creatinine 24 hours a day would be a reasonable alternative. Access to therapeutic monitoring of immunosuppressant medications should be specified and available at minimum on a weekly basis.
- 2.10. Microbiology and virology laboratory services: On-site or closely available access to serologic testing and identification of infectious pathogens that are common in transplant medicine and/or endemic to the region serviced by the transplant programme.

### **3. Expertise/knowledge infrastructure**

- 3.1. Leadership: The Director of the Transplantation Programme should be identified and have a minimum of 12 months experience in the management of all aspects of transplantation.
- 3.2. Surgical expertise: A minimum of one surgeon qualified to perform the transplant operation and manage complications arising from transplant surgery, either within the programme or in partnership with the programme. The surgeon should have specific and demonstrated competency with the transplant surgery according to national standards in transplant surgery (either adult or paediatric) and be qualified or have demonstrated competence in performing surgery in children. Previous training and experience (e.g. number of transplants performed) should be detailed.
- 3.3. Medical expertise: A paediatric physician (e.g. nephrologist, hepatologist, cardiologist) who will be responsible for medical management of organ failure and medical complications of transplantation. The physician should be qualified according to national accreditation standards for pediatric medicine and the relevant specialty. Previous transplant training/experience should be detailed.
- 3.4. Immunology and immunosuppression expertise: A clinician (may be either the identified physician or surgeon) with expertise in the immunological aspects of transplantation, including interpretation of HLA typing, immunosuppression and monitoring of immunosuppressant medications.
- 3.5. Nursing and hospital care: Nursing and associated hospital in-patient support personnel that have been trained or will be trained in care of transplant patients, and are available to provide 24-hour care of transplant recipients admitted to hospital for the transplant procedure or for management of complications after transplantation.
- 3.6. Allograft biopsy expertise: Access to clinician qualified or has demonstrated competence to perform diagnostic biopsy of the transplanted organ.
- 3.7. Histopathology expertise: Access to pathological interpretation of allograft histopathological testing.
- 3.8. Adult programme expertise: For new programmes, agreement with a regional adult transplant center providing the same organ transplant service, to provide clinical support to the pediatric program and qualified to accept care of pediatric transplant recipients who will transfer to adult care.