Guidelines to be followed by centres, services and units in order to be designated as Reference Centres, Services and Units of the National Health System, as agreed by the Interterritorial Board

44. CROSSOVER KIDNEY TRANSPLANTATION

Crossover kidney transplantation is a living donor kidney transplantation, with the particular characteristic that is performed between a donor and recipient who are not related, resulting from an exchange between two or more pairs who are incompatible. Therefore, its purpose is to offer society and patients with chronic kidney failure the possibility of living donor kidney donation and transplantation for those cases when there is not compatibility between donor and recipient, due to ABO blood-group incompatibility or because the crossover test was positive, as well as in other situations when, without having a real impossibility for the pair transplantation, there is a real benefit related to the crossover kidney transplantation procedure.

When a donor-recipient pair (pair is defined as a group of two people, who may be siblings, father-child, espouses...) are not compatibles the kidney transplantation cannot be carried out. When this happens, there is the option to sign up in the national registry of incompatible pairs and frequently during a year a crossmatching is performed among all the pairs in the pool. The resulting combinations are a priori compatible and that compatibility will be confirmed by a crossmatching test between donor and recipient. If this test is negative, the logistic means for the transplantation are started. (In every case, the donor is assessed in the hospital where the recipient will be transplanted, an ethics committee will approve the procedure, and the consent will be signed in front of a judge of the civil registry the hospital belongs to. The donor will be the one travelling). After these stages, the surgical procedures will be performed simultaneously.

A. Rationale for the proposal

transplantation.	In Spain, indication for kidney transplantation is around 100 per million population, with approximately 50 transplantation being performed per million population. Regarding <i>living donor</i> transplantation, real indication of transplantation is 7.2 per million population, given that our system's capacity to perform this therapy is approximately 15% of the total kidney activity. 36% of incompatible donor-recipient pairs for living donor transplantation are estimated, and these are included in the crossover kidney transplantation since the indication for these is of 2.6 per million population.
	per million population.

▶ Data on the use of the procedure.	In Spain, 156 living donor transplantations were performed during 2008, a rate of 3.5 per
	million population. The crossover kidney transplantation programme starts in June 2009, with
	one kidney procedure performed until now.

B. Guidelines to be followed by Centres, Services and Units in order to be designated as Reference Centres, Services and Units for crossover kidney transplantation

► Experience of the Reference Centres, Services and Units:	
 Activity: Number of procedures that should be performed in a year to ensure an adequate care. 	A minimum of 15 living donor kidney transplantations in the last 3 years.
- Other data: research on the subject, postgraduate teaching, continuing training, publications, etc.	 Being part of the National Crossover Kidney Donation Programme. Accredited postgraduate teaching: Unit participation in the internship and residency programme of the Centre. Participation in research projects and publications in the field^a. Continuing training programme standardized and authorized by the centre's board of directors. Clinical multidisciplinary sessions, at least once a month, in order to make clinical decisions and coordinate treatments.
➤ Specific resources of the Reference Centres, Services and Units:	
- Human resources required for adequate performing of crossover kidney transplantations.	In addition to those generically mentioned for authorization according to Royal Decree 2070/1999, December 30 th , establishing the general basis for clinical harvesting and use of human organs and the territorial coordination in donation and transplantation of organs and tissues, the centre must have the following human resources:

	- Medical surgical team, available at all times, with at least 3 surgeons, 1 nephrologists and 1 anaesthetist.
- Professional experience ^b :	The medical surgical team must have experience in living donor kidney transplantation and laparoscopic surgery or mini-lumbotomy.
- Specific equipment required for adequate performing of crossover kidney transplantations.	In addition to those generically mentioned for authorization according to Royal Decree 2070/1999, December 30 th , establishing the general basis for clinical harvesting and use of human organs and the territorial coordination in donation and transplantation of organs and tissues, the centre must have:
	 Nephrology unit available at all times, including the following areas: Outpatient care, performing: Pre-dialysis services, monitoring stage V renal failure, transplant recipient assessment. Hospitalization. Kidney transplantation. Depuration methods. Specialties Units: Urology unit with experience in laparoscopic surgery and mini-lumbotomy^b. Intensive Care Unit with specific isolation areas for transplantation. Radiodiagnosis with experience in transplants ^b and availability of ultrasound, MRI and CT scan techniques, including interventional radiology.
► Resources from other units and services besides those belonging to the Reference Centres, Services and Units required for adequate performing of crossover kidney transplantations.	 - Haematology, biochemistry, microbiology and clinical pharmacology services/unit. - Immunology reference services/unit. - Nuclear Medicine Services/unit. - Pathology anatomy services/unit.
► Procedure and clinical results indicators of the Reference Centres, Services and Units ^c :	The indicators will be agreed with the Units that will be designated.

► Existence of an adequate IT system

(Type of data that the IT system must include to allow identification of the activity and evaluation of the quality of the services provided) - Filling up the complete MBDS of hospital discharge.

Participation in the Spanish Registry for Living Donor Kidney Transplantation and completion of the required variables for calculation of activity and result indicators.

- The unit must have the required data which should be sent to the Spanish National Health Service Reference Centres, Services and Units Appointment Commission Secretariat for yearly reference unit monitoring.

Bibliography:

- 1. Montgomery R; et al. Clinical Results From Transplanting Incompatible Live Kidney Donor/Recipient Pairs Using Kidney Paired Donation. JAMA. 2005; 294(13): 1655-1663.
- 2. Marry de Klerk, Karin M. Keizer, Frans H. J. Claas, Marian Witvliet, Bernadette J. J. M. Haase-Kromwijk, Willem Weimar (2005) The Dutch National Living Donor Kidney Exchange Program.
- 3. Am J Trasplant 2005; 5 (9), 2302-2305.
- 4. Kim et al.Outcome of Multipair Donor Kidney Exchange by a Web-Based Algorithm. J Am Soc Nephrol 2007 18: 1000-1006.
- 5. Gentry S, Segev D, Simmerling M.,. Montgomery R. Expanding Kidney Paired Donation Through Participation by Compatible Pairs. Am J Transplant 2007; 7 (10), 2361-2370.
- 6. Gebel H, Bray R. Approaches for transplanting the sensitized patient: biology versus pharmacology. Nephorl Dial Transplant. 2008; March 25. 1-4.
- 7. Segev DL, Gentry Se, Warren DS, et al. Kidney paired donation and optimizing the use of love donor organs. JAMA 2005 293: 1883–1890.
- 8. Matas A, Bartlet ST, Leichtman AB, Delmonico FL. Morbidity and mortality after living kidney donation 1999-2001: Survey of United States Transplant Centers. Am J Transplantation 3: 830-834. 2003.

^a Criteria to be assessed by the Appointment Commission.

^b Experience will be accredited by certification from the hospital manager.

^c Clinical results standards, agreed to by the experts group, will be assessed, initially by the Appointment Commission, while in the qualification process, as more information from the Reference Centres, Services and Units is being obtained. Once qualified by the Appointment Commission, the Quality Agency will authorize its compliance, as for the rest of guidelines.

- 9. Sommerer C, Morath C, Andrassy J, Zeier M. The long term consequences of living-related or unrelated kidney donation. Nephrol Dial Transplant 19; 4: 45-47. 2004.
- 10. Ibrahim HN, Foley R, Tan L, et al. Long-term consequences of kidney donation. N Engl J Med 360; 5: 459-469. 2009.
- 11. The organ procurement and Transplantation Network. United Network for Organ Sharing (UNOS). Last retrieved on July 14th, 2009. http://www.optn.org.