

General guidelines

Purpose

To increase the likelihood of offering a suitable kidney graft to recipients who are HLA and/or ABO-incompatible with their living donor, thus reducing their time on the waiting list and/or pre-treatment.

Success criteria

- Programme monitored, evaluated and continuously improved
- Planned exchange cycles/chains are executed without major obstacles
- Survival of kidney grafts comparable to (or better than) other patients with similar PRA-levels within Scandiatransplant

Acceptance criteria

Transplant centres:

- Must be a Scandiatransplant member hospital
- Must have a designated contact for the program
- Must agree to follow the rules of the program

Recipient criteria:

Patients who are eligible (or accepted to the waiting list) for a kidney transplant and are receiving care at a transplant centre within Scandiatransplant can join.

Patients must have one or more medically acceptable living donors who are willing to donate a kidney within the STEP programme.

Indications for participation in STEP:

- ABO incompatible
- HLA incompatible (DSA)
- Suboptimal age match
- Suboptimal ABO match
- Suboptimal HLA match
- Suboptimal size match
- Compatible pair that wants to participate in order to benefit the program

If an ABO-incompatible pair is included in the program, the pair can be included for one or several match runs and if no match is found the recipient can be transplanted through the local ABO-incompatible program.

Donor criteria:

(recommended under normal circumstances, may be discussed in specific cases)

- The donor must be fully informed and willing to participate in an exchange. Like any living donation program, all potential donors are required to complete an extensive medical and psychological evaluation to determine whether they are acceptable as kidney donors.
- If a living donor is accepted for donation at a local centre, the donor can enter STEP.
- Non-directed/altruistic donors can be included in the program.

No specific information on donor identity can be provided to the recipient; however general medical donor information may be provided during the consent process. All donors will receive a Scandia donor number that can be used for traceability in the recipient medical files.

The donor must be accepted by both the donor and the recipient centre and the recipient by the recipient centre (for important factors such as age, kidney function, prior medical conditions, anatomical details, etc.).

Donors must be reported to the YASWA living donor database and followed up after donation according to local and best-practice guidelines.

Informed Consent Requirements

Donors and recipients should be informed of the possible complications and difficulties that may be encountered during kidney exchange and how this is managed according to local routines.

Written informed consent is obtained by the local recipient centre.

Match runs

The recipient can remain on the deceased donor waiting list even if the recipient and donor join the STEP-programme. If the donor-recipient pair are found to have a potential match after a match run, the recipients will be temporarily deactivated on the waiting list by the Scandiatransplant office. During the period between evaluation and transplantation, recipients will remain de-activated.

When a paired exchange has taken place, the recipient will be removed from the waiting list and linked to the donor.

If the paired exchange is cancelled the recipients will be reactivated on the waiting list, which is done by the recipient centre.

Match runs will be performed 3-4 times per year, and results are communicated by e-mail to all the transplant centres by the Scandiatransplant office.

One week after the match run the first clinical and immunological evaluation must be completed, and status update must be reported to the Scandiatransplant office. Information about broken chains and cycles must be reported a.s.a.p. to the Scandiatransplant office. A re-run is executed when relevant, within 1-2 weeks after the primary run. Matches found in the primary run (for instance nested two-way after broken three-way) have priority over those found in the re-run.

Coordination

Coordinating teams from all Transplant units involved need to communicate, plan and coordinate all required exchange activities (such as immunological evaluations, surgical operations, communication, transport etc.) well in advance.

Operative procedure, preservation and transportation

All significant intraoperative events are discussed and planned prior to surgery by the transplantation units involved. Donor operations will start simultaneously or according to specific agreement. Before starting surgery, and before vascular clamping and organ removal, direct communication will take place between all operating rooms to verify and synchronize activities. The donor kidneys will be preserved according to the agreement and transported to the recipient centre as soon as possible. The start of the donor operations can be adjusted to fit the availability of transportation.

Compensation

All costs for both the recipient and donor (including necessary immunological work-up etc.) are covered by the local Transplant unit. Each country provides compensation according to its own rules for the donor that the recipient brings to the exchange program. The cost of transport are covered by the receiving Transplant unit.

Immunological testing of donors and recipients

ABO and HLA typing:

Both the recipient and donor must be primary typed at the recipient centre for ABO and HLA-A, -B, -C, -DRB1, -DRB3/4/5, -DQA1, -DQB1, -DPA1 and -DPB1. The HLA typing resolution should be at second field level but common null alleles such as DRB4*01:03:01:02N must be identified. The genomic assignment should be documented in YASWA at second field resolution. When ambiguities common and well-documented(CWD) HLA-alleles must be reported.

Information about unacceptable ABO antigens to the recipient must also be registered in YASWA.

When a potential exchange has been identified the recipient center must perform confirmatory ABO and first level resolution HLA typing on the donor as well as a crossmatch.

Recipient and donor centre must coordinate the shipment of blood samples from the donor. Sample blood volume, coagulants, and labelling are clearly specified in separate guidelines: 'Guidelines on STEP donor blood samples required by each laboratory'.

Immunization status:

The recipients must be evaluated with a single-antigen bead array (Luminex SAB). Data should be transferred directly with raw data to the database so that accurate handling of allele specific antibodies or antibodies against certain DQA1/DQB1 heterodimers can be properly identified. Responsible immunologist may remove or add other specificities based on previous immunization history and/or previous transplants. See separate YASWA manual for further details.

Match run results will indicate if donors are carrying alleles that are not tested for among the SAB in the recipients. In this case the matching should be on a generic level.

Antibody testing should be repeated quarterly (HLA and if relevant anti-A and -B) or after potential sensitizing events (e.g. blood transfusion).

Prioritization rules

2-way-exchanges, 3-way-exchanges, chains and altruistic donors will be allowed in the matching algorithm.

The algorithm will prioritize:

- 1. The number of transplanted patients
- 2. Short cycles
- 3. Low match probability*
- 4. Compatible blood groups (minimized number of ABO-incompatible transplants)

There is no upper limit of pairs involved in a chain.

The prioritization rules will be evaluated and modified when needed by the STEP-steering committee and changes will be presented to the Nordic Kidney Group.

* Calculation of 'Low match probability': $(1/(100\text{-cPRA})) \times 30$ where cPRA is taken from the latest sample before match run

Information to patients and physicians

Benefits of joining a kidney paired donation program

For recipients:

They can receive a living donor transplant. Kidneys from live donors last longer, on average, than those from deceased donors. Participants may spend less time on dialysis and may receive a transplant before starting dialysis. They may not have to wait as long for a transplant.

For donors:

You may help your family members/friends. It can be a rewarding experience, as more families are helped by your donation.

Risk of joining a kidney paired donation program

For recipients:

There is a limited possibility that the program will find a matching kidney for the recipient and a paired exchange will take place, especially when the recipient has many HLA antibodies.