STEP-programme
S-candia**T-**ransplant kidney **E-**xchange **P-**rogramme **(STEP)**

Version 1.11

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General guidelines

Purpose

To increase the likelihood of offering a suitable kidney graft to immunized (HI) recipients who are crossmatch positive against their living donor or AB0-incompatible, thus reducing their time on the waiting list.

Success criteria

- Programme launched
- Planned exchange cycles are executed without major obstacles
- Survival of grafts comparable to (or better than) than in other immunized patients with similar PRA-levels
- Donor and recipient satisfaction

Acceptance criteria

Transplants centres:

- Must be Organ Procurement and Transplantation Centre within Scandiatransplant
- Must have a designated contact for the Program
- Must agree to abide the rules for the program

Recipient criteria:

Adult patients that are eligible (or accepted to the waiting list) for a kidney transplant and are receiving care at a transplant centre within the Nordic countries can join. Patients do not have to be on dialysis to join. Patients must have a crossmatch positive (and therefore unsuitable) but otherwise medically acceptable living donor who is willing to donate a kidney within the STEP programme.

It is also possible for a center to include a ABO-incompatible couple into the programme. The couple could be included for one or several match runs

and if no match is found it could be transplanted through the ABO-incompatible programme.

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

- The donor must be fully informed and willing to take part in an exchange. Like any living donation program, all potential donors are required to complete an extensive medical and psychological evaluation to decide if they are acceptable as kidney donors.
- A GFR above 80 ml/min/1.73m2 measured by a tracer (not calculated)
- Sitting untreated BP <140/90 mmHg or 24 h BP <130/80 mmHg.
- No Diabetes.
- No Proteinuria

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

Both the donor and the recipient in both (all) exchange pairs need to be accepted by both Transplant teams involved (for important factors such as age, kidney function, prior medical conditions, anatomical details etc.)

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

Informed Consent Requirements

For candidates:

A transplant centre representative must review the components of the Program with the candidate separately from the paired potential living donor. After review, the transplant centre will ask the candidate to sign a consent form.

If the candidate chooses to accept a shipped kidney, the transplant centre must have a signed consent form showing that the candidate has been

informed of the potential risks of shipping a kidney. The consent will be valid for one year.

For potential living donors:

For any exchange, the Transplant Hospital evaluating the potential donor is responsible for receiving informed consent from potential donors (including the risk that surgery may not occur due to unforeseen events in the operating room). The consent will be valid for one year.

Match runs:

The recipient will remain on the deceased donor list even if the recipient and donor joins the STEP-programme. If the donor-recipient pair are found to have a potential exchange pair after a match run, the recipients will be temporarily deactivated on the waiting list. When a paired exchange has taken place they will be removed from the waiting list. If the paired exchange is cancelled they will be reactivated on the waiting list.

- Match runs will be performed at regular intervals and the time interval between match runs will be decided dependent of the number of participants in the program.

Coordination

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

Operative procedure, preservation and transportation:

In a kidney exchange both (all) donor operations will start simultaneously. Before start of the surgery and before vascular clamping and organ removal telephone calls will take place between the two (all) operations rooms to verify and synchronize activities. The donor kidneys will be preserved according to agreement and transported to the recipient centre as soon as possible. The start of the donor operations could be adjusted to fit regular flights.

If a kidney after explantation is deemed unsuitable for implantation, is lost during transport, or there is an early technical failure, the recipients's

transplant centre is recommended to allocate a kidney to the patient from a deceased donor at the earliest convenience.

Compensation:

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

Immunological testing of donor recipient pairs:

HLA Typing: both recipient and donors must be typed for HLA A,B,C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1 and DPB1. The resolution should be at second field level but common null alleles such as DRB4*01:03:01:02N must be identified. Information about both the genomic assignment and the corresponding serological assignment should be documented.

Immunization status must be tested with a single- antigen bead array (i.e Luminex- SAB). Data should be transferred directly with raw data to the database so accurate handling of allele specific antibodies or antibodies against certain DQA1/DQB1 heterodimers can properly be identified. There must be a mechanism for the responsible immunologist to remove or add other specificities based of previous immunization history or previous transplants.

The database used for matching should be able to 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 but be clearly indicated as such.

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

All recipients included in the STEP programme needs to be de-activated on the kidney waiting list during a scheduled run and until the resulting

exchanges are decided/planned. During the time period in between decision and transplantation, the scheduled exchange recipients will remain de-activated.

Prioritization rules:

The Matching Algorithm:
In the start of the program, only paired exchanges (2-way-exchanges) will be performed. When the program is implemented and the Nordic Kidney Transplant Group decides so, 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 (initially only 2-way exchanges will be performed)
3. Low match probability
4. Compatible blood groups, the number of ABO-incompatible transplants should be minimized in each matchrun

Note also that:

a) In the start of the program, all cycles will be of length 2 (i.e., only 2-way-exchanges will be performed). Therefore, point 2., from the above, will not be relevant, and a priority matching with only 2-way-exchanges will be performed.
b) In case a patient has several potential donors, the donor will be selected based on points 1-4, where point 4 is interpreted as the sum of match probabilities of all matched pairs for a given set of donors.

Information to patients and physicians

Benefits of joining a kidney paired donation program

For recipients:

They could receive a living donor transplant. Kidneys from live donors last longer, on average, then kidneys from deceased donors. Participants may spend less time on dialysis; they 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 member/friend. 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 actually will take place, especially when the recipient have a lot of antibodies.

To enable a kidney exchange it can take some months to do a couple of "match runs" which are necessary to do to find matching pair.