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GloACT

**Toolkit on the Investigation
and Prosecution of
Trafficking in Persons
for Organ Removal**



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MODULE 4: THE TRANSPLANT PROCESS

LEGITIMATE TRANSPLANT PROCESS AND RED FLAGS

I. INTRODUCTION

The aim of this module is to provide a basic understanding of what organ transplantation is, and of the processes designed to safeguard the legitimacy of transplant systems and to protect organ donors from exploitation. Organ donation and transplantation involve complex adaptive systems. These systems can be abused but, when they are abused, traces will be left that can produce admissible evidence. When implemented properly these systems can prevent illicit organ removal. This module describes the different phases of the evaluation process of organ recipients and donors, with particular attention to the use of illicit means to obtain the cooperation of donors as found in cases of trafficking in persons for organ removal (TIP for OR).

When illicit organ removal is disguised as a legitimate donation, the evaluation process and surgical intervention are essentially the same as in legal organ removal and transplantation. Throughout this module 'red flags' are placed to

indicate where exactly rules regarding legally valid and ethical organ donation can be manipulated and organ donors may be exploited.

Before discussing in detail the two most common types of organ transplantation, namely kidney and liver, it is important to provide a short explanation about the legal measures and safeguards that are in place for any legitimate organ transplant. It is important to note that the transplant evaluation process and the medical assessments of organ donors and recipients might differ from country to country, from region to region, and even from center to center. These discrepancies are the result of the diversity in transplant systems and rules, different ways of interpreting the applicable rules, differences in the organizational structure of medical facilities, and the availability or lack of trained professionals. Despite these differences, minimum safeguards exist in almost any country offering transplant services.

2. LEGAL FRAMEWORK FOR ORGAN TRANSPLANTATION: SHORT RECAP

A. Prohibition of organ trade

All countries, with the exception of one¹, prohibit paid donation, or commercial dealings in human organs. Who exactly is criminalized (e.g. donor, brokers, medical professionals or recipient) may vary.

Living organ donations are very closely controlled and subject to specific national regulations, which are modelled on the international principles regarding organ donation and transplantation (for more information see Module 2).

B. Key differences among transplant systems

The first aspect of a transplant evaluation process that may vary among states is the psychosocial assessment of organ donors and recipients. Psychosocial screening in living organ donation is a highly recommended practice to ensure voluntary, informed and safe organ donation. Although the 2017 Kidney Disease: Improving Global Outcomes guideline² recommends that all candidates receive an in-person psychosocial evaluation, not all states mandate psychosocial evaluation as a part of the pre-transplant organ donor evaluation. The same recommendation has been issued for living liver donations which carry more risks for both organ donors and recipients. Very often in states that do not require a compulsory psychosocial evaluation, only a psychiatric assessment is carried out to ensure that organ donors and recipients are legally competent and do not suffer from a psychiatric disorder. Domestic evaluation procedures that do not routinely conduct a formal psychosocial evaluation may do so if underlying problems were identified or suspected during the medical evaluation, or if the donor was unrelated to the intended recipient. Moreover, there is no standardized or uniformly accepted format for conducting psychosocial evaluation. Methods of conducting such screening differ between states, regions and medical facilities. The second point of difference among transplant systems and the evaluation processes is the involvement of an ethics committee or transplant authority in approving the organ removal and transplantation. Such a committee exists in most countries, either at the national, regional or hospital level. The ethics committee's role is to guide the policies and procedure related to organ donation, removal, allocation, and transplantation to ensure that they are in accordance with legal and ethical principles. The ethics committee will review transplant documentation and the assessment of the organ donor and the recipient before approving the organ removal and transplantation. For non-

related living donors, the ethics committee might also interview the organ donor to ensure that the consent is valid and there is no payment involved. The ethics committee comprises physicians (who are independent from the transplant team), other care providers, an ethicist, and a legal expert. When it concerns a dedicated committee at the national or regional level it can also include a judge or a member of law enforcement, such as an anti-trafficking officer.³

NOTE: In some countries, the ethics committee, upon assessing if a planned transplant aligns with the ethical principles, can recommend to stop the transplant. But it is ultimately left to the transplant team whether to proceed or not. It is challenging to go ahead with the transplantation when a negative recommendation is given by the ethics committee but there is no obligation to follow the decision of the ethics committee.⁴

C. Donation from living donors: who can donate?⁵

- a. Related organ donation: this is an organ donation from a person who is genetically or emotionally related to the (intended) recipient.
 - Genetically related organ donation: In all countries having in place a living organ donation program, living organ donation is allowed by a close genetic relative (ranging from the first to the fourth degree of consanguinity, depending on the national transplant law) and a spouse and, where applicable, registered partner, fiancée or person who can provide proof of long-term cohabitation.
 - Emotionally related organ donation: In some countries the range of permissible relationships has been extended to also include persons who stand in a close personal and emotional relationship with the recipient. Often, approval by an ethics committee is required for this category of donor.
- b. Unrelated organ donation: this is an organ donation by a donor who is genetically or emotionally unrelated to the (intended) recipient. These persons (also known as 'good Samaritans') are in some countries allowed to donate, and are as a rule subject to psychosocial assessment and the approval by an ethics committee. Generally, there are two categories:
 - Unrelated directed donation occurs where the donor might designate an unrelated recipient (e.g. contact through social networking or media campaigns). These are very

uncommon.

- Unrelated non-directed donation involves donation to an unspecified recipient (unknown to the donor).

NOTE: Not all national laws define what a close personal relationship is and, in such scenarios, they may only be considered when the national law sets out the conditions under which such circumstances may be permitted. Those conditions may include a requirement for an independent body (ethics committee) to consider and approve each case.



The majority of TIP for OR cases involve organ donation by unrelated donors, where financial and other benefits are offered as inducement, and in some instances coercion or force is used to obtain the donors' consent to organ donation. This, however, is not always straightforward to detect as the donor will pose as an altruistic, related organ donor to comply with national transplant requirements⁶.



It is not always possible to determine whether a donation is truly altruistic and/or takes place between relatives. Even in living organ donation between relatives there might be elements of coercion and undue pressure that could amount to TIP for OR. As to organ donation from an (alleged) spouse, trafficking can occur when a person (often a young woman) is lured or sold into a forced marriage only to be later forced to donate an organ. The purpose of the marriage is to obtain an organ in formal compliance with national transplant rules on permissible relationships to donate an organ.

D. Documentation

Information regarding the potential donor and the recipient is usually documented and kept in separate files or charts in medical facilities where the organ removal and transplantation is performed. As for organ donors, the documentation includes: medical results, written reports by professionals who have assessed the potential donor, attesting to the potential donor's capacity to make a decision about donation, understanding of the proposed procedure and of its risks and potential benefits, the disclosure process, and the potential donor's voluntariness and motivation for donation. It should also state clearly if the potential donor is medically and psychologically suitable to donate. Similar documentation and evaluation reports are done for organ recipients. If an organ is donated by a relative, proof of kinship

should be included in the official documentation (e.g. marriage certificate, birth certification, passport, embassy confirmation).

NOTE: By examining this documentation it is possible to determine: 1) whether the medical facility under investigation has followed the existing transplant procedure and domestic transplant regulations; 2) who was responsible for the evaluation of donor(s) and recipient(s); 3) who is the donor and the recipient, what type of transplant was performed and when; and 4), where applicable, the composition of the ethics committee and its process of approval.

E. Which organs are transplanted?

Organs that may be donated by a living donor are: a kidney and, much less frequently, a liver lobe or segment. Very rarely, also a lung, corneas (tissue), skin, small intestine, and pancreas might be donated by a living donor.

Vital organs, such as a heart, can only be removed from a deceased donor. This module focuses on living kidney and liver donations specifically.

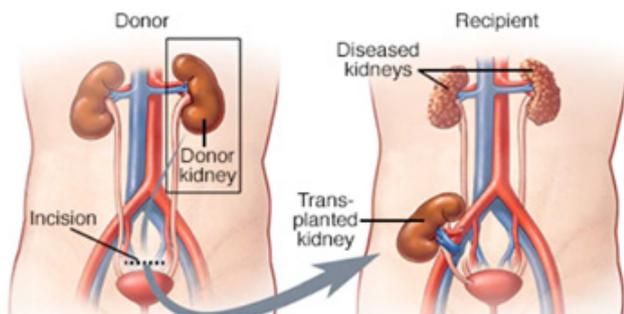
NOTE: In cases of lung, liver, pancreas, and intestine donation similar guidance might be found in: "A Report of the Vancouver Forum on the Care of the Live Organ Donor: Lung, Liver, Pancreas, and Intestine Data and Medical Guidelines".⁷

3. KIDNEY TRANSPLANTATION OVERVIEW

A. What is a kidney transplantation?⁸

- A kidney transplant is a surgical procedure to replace a diseased kidney with a healthy kidney. Kidneys remove various toxins from the blood, passing the waste materials out of the body as urine. As kidneys become diseased, they lose their ability to function properly.
- Kidneys can come from deceased donors or living donors. This module only discusses living organ donation. Unauthorized organ removal from a deceased person will not fall under the scope of TIP for OR, unless that person was trafficked and has died as a result of organ removal. The investigation and prosecution of such a case would be conducted in an almost identical manner as where a living donor survived.

The transplanted kidney is placed in the lower belly on the front side of the body (see image below).



(Mayo Clinic, “Living-donor transplant”, Mayo Foundation for Medical Education and Research (MFMER), 25 February 2020. Available at <https://www.mayoclinic.org/tests-procedures/living-donor-transplant/about/pac-20384787>)

- Organ removal from a living donor can be performed in two ways: ‘hot’ and ‘cold’.

A ‘hot’ operation is one where the kidney is removed from the donor and implanted into the organ recipient shortly after. This requires both the donor and the recipient to be anaesthetized and their surgeries coordinated at the same time. It also requires them to be in close proximity in the hospital. The advantage of this technique is that it does not require any sophisticated cooling equipment or solutions. The disadvantages are that the surgeon must work relatively fast and the risk of complications is higher.

Currently, a more common approach is a ‘cold’ operation, where the kidney is removed, chilled in a similar way to that described for deceased donors and then placed in the recipients’ body sometime later. The advantages of this method are that it reduces the workload and the time pressure on the surgeon and medical team, allowing a slower and possibly less risky approach. The main disadvantage is that it requires more advanced surgical techniques and cooling solutions and medical equipment.⁹

B. Why someone needs a kidney transplant

Most frequently, a kidney transplant is carried out for patients suffering from end stage renal disease. This is a permanent condition of kidney failure. Other conditions, such as diabetes, high blood pressure, various hereditary diseases and congenital defects of the kidneys may result in the need for a kidney transplant. Kidney disease may be treated by medication but in some cases this may no longer be possible. In such a case, a kidney transplant is the best and sometimes the only treatment option.

People suffering from late stage kidney disease are put on dialysis. Dialysis is a mechanical medical process that removes toxins from the blood. There are various types of dialysis, but the one most commonly used requires patients to go to hospital for three four-hour sessions a week on the dialysis

machine. Some kidney patients consider a transplant after beginning dialysis, others consider it before starting dialysis. In some circumstances, dialysis patients who also have severe medical problems such as cancer or active infections and may not be suitable candidates for a kidney transplant.

C. How someone becomes a transplant patient

- A nephrologist (i.e. a physician specialized in kidney disease) typically refers a sick patient for a kidney transplant evaluation within its own medical facility or to a transplant clinic. Kidney patients can also contact transplant centers directly (located within their country or abroad) to start the evaluation process. After a medical facility receives the referral, or an official inquiry, it usually assigns the patient a transplant coordinator. This coordinator assists and guides the patient through the entire process, scheduling appointments, collecting necessary medical records and providing information about transplantation.
- When the transplant team determines that the organ recipient is a good candidate for kidney transplant, and if there is no available living kidney donor, he/she will be added to the national transplant waiting list. The waiting time for a suitable donor varies for each individual case. If a donor recipient has a living kidney donor (a person willing to donate a kidney), the transplant might be scheduled as soon as the medical suitability and compatibility of donor and recipient have been established.

When an organ recipient was on a national transplant waiting list and travelled to obtain a transplant abroad, upon returning with a new organ and after medical consultation, he/she might be taken off the waiting list. Patients who were taken off the waiting list without having received an organ through the domestic transplant system will likely have received the transplant illegally and may be of interest to law enforcement.

In the case of an illegitimate organ transplant, organ recipients might seek kidney brokers directly to circumvent domestic transplant processes and national waiting lists, or they might seek advice from their physicians as to where and how they could arrange a transplant illegally. Organ recipients might also seek the assistance of brokers and traffickers domestically to assist in finding a paid donor, falsify documents to show kinship, and to

prepare an unrelated donor posing as a 'good Samaritan' for the assessment process. Brokers often operate online, or they might be referred to organ recipients by medical staff, or other recipients who have received a kidney transplant in this way. Brokers who operate internationally, facilitating illicit transplants in third countries, take on a range of tasks, including finding a transplant clinic and a kidney donor, and organizing medical evaluations to assess medical compatibility with the recipient. Domestically, brokers might 'hover' around dialysis centers and engage with patients, or recipients' families to try to convince them to consider obtaining a kidney illegally.

receive and their general health prior to donation. For this reason, donor protection should always be taken into account during the selection and assessment of a living donor.

There are a number of reasons why transplantation with a kidney from a living organ donor has better results as compared to transplantation with a kidney from a deceased donor. First, living donors are usually younger and carefully selected on the basis of their overall good health.¹⁰ Second, living organ donation often means a much shorter ischemic time (a restriction in blood supply to tissues, causing a shortage of oxygen that is needed for cellular metabolism to keep tissue alive), with the time from donation to the re-perfusion of the kidney in the recipient.

D. Who is eligible to be a living kidney donor?

A person can become a living kidney donor if he/she has a relationship with the intended recipient which under national transplant law would allow living organ donation. As a rule, living organ donation involves a close family member, including parents, siblings, children (18 years or older), uncles, aunts, cousins, or a spouse or close friend. When allowed under national law, a kidney donation might exceptionally also be accepted from an unrelated donor. Based on the (unsubstantiated) assumption that unrelated donors are less capable of altruism, more corruptible or vulnerable to coercion than related donors, additional protective measures are often introduced to ensure that organ donation is voluntary and altruistic and that the donor is not under any form of coercion or other form of undue influence.

Every country will have a set of rules and procedures to verify the legitimacy of the donation process and to ensure that organ donation is safe for the organ donors. A potential living donor will undergo a medical evaluation consisting of medical tests to ensure that the donor and recipient are compatible. Moreover, a potential organ donor will be informed about the risks of organ removal, undergo psychosocial evaluation, if applicable, and finally will give informed consent. Each stage of this evaluation is discussed under subsection - Evaluation Process for Organ Donation and Transplant.

Living kidney transplants are possible because everybody has two kidneys. When one kidney is removed the other kidney continues to function. The remaining kidney will increase in size to compensate for the loss of the donated kidney. In many cases the person donating the kidney will lead a normal life with normal life expectancy. However, the consequences for organ donors differ and depend on factors like the work they do, the aftercare they

E. What are the risks involved in kidney donation and transplantation?

Kidney donation and transplantation may carry risks for the organ recipients and organ donors. In recipients, complications can occur including bleeding, infections, blockage of the blood vessels to the new kidney, leakage of urine or blockage of urine in the ureter, lack of function of the new kidney. Importantly, the transplanted kidney may be rejected. Rejection is a normal reaction of the body to a foreign object or tissue. The immune system responds to what it considers as a threat and attacks the new organ. To prevent rejection of the transplanted organ, most transplant recipients must take medication called immunosuppressants.¹¹

For kidney donors there are both short- and long-term risks involved in living donation. Surgical complications can include pain, infections, blood loss, blood clots, allergic reactions to anesthesia, pneumonia, injury to surrounding tissue or other organs, and even death. However, as transplant surgeries are becoming more common and surgical techniques are getting more sophisticated, risks involved in living donation continue to decrease. Some long-term problems might be experienced, including pain, nerve damage, hernia or intestinal obstruction, high blood pressure, proteinuria, or reduced kidney function.¹²

EVALUATION PROCESS FOR KIDNEY DONATION AND TRANSPLANTATION

The living donor evaluation process will follow a different schedule than the one involving the organ recipient. Importantly it will be modelled so as to comply with domestic transplant regulations and the assessment procedure adopted by the medical facility where it is conducted. As such it might differ between states, regions and even transplant centers.

Irrespective of these variations, the evaluation process should have the same stages and key elements. The evaluation process can be divided into three parts:

- **FIRST STAGE - Initial screening**

During this stage, which is usually a first visit in a medical facility, a non-invasive and low-cost test is conducted to identify the medical suitability of donors and recipients. Information regarding the donor's health is requested (medical history), and the first assessment of the motives of donation might be conducted. A financial evaluation of organ recipients might also be conducted (depending on the state).

- **SECOND STAGE - Pre-transplant assessment**

During this stage the donor's medical and psychosocial conditions are assessed. Very often this stage requires a report with information about the results and consent for donation developed by an independent transplant team. Formal consent to organ donation from an organ donor is often required at this stage.

- **THIRD STAGE - Transplant approval**

This stage, shortly before the organ removal and transplantation, requires a final crossmatch test between the organ recipient and the donor. All formalities for valid consent must be completed in accordance with domestic transplant regulations and the removal and transplantation must be approved by an ethics committee.

A. Initial screening¹³

The initial screening begins with a basic medical assessment of the living organ donor, which might include gathering basic health information (for example, requesting medical history if available and filling in a medical and social questionnaire if applicable). If there are no immediate and obvious medical conditions that would rule out organ donation, compatibility tests are performed.

i. Compatibility testing

The compatibility tests are special blood tests required to determine the blood and tissue type of potential donors and recipients. These tests allow to better match a kidney donor to a recipient.

Blood Type Testing

The first test establishes the blood type. This test is conducted in a transplant hospital where the procedure takes place or can be carried out in a private hospital or laboratories that are not affiliated with the transplant hospital. There are four

blood types: A, B, AB, and O. The recipient and donor should have either the same blood type or compatible ones, unless they are participating in a special program that allows donation across blood types. The AB blood type is the easiest to match because that individual accepts all other blood types. Blood type O is the hardest to match. People with blood type O can donate to all types, but they can only receive kidneys from blood type O donors. For example, if a patient with blood type O received a kidney from a donor with blood type A, the body would recognize the donor kidney as foreign and attack it.

The list below shows compatible types:

- If the recipient blood type is A the donor blood type must be A or O.
- If the recipient blood type is B the donor blood type must be B or O.
- If the recipient blood type is O the donor blood type must be O.
- If the recipient blood type is AB the donor blood type can be A, B, AB, or O.

NOTE: ABO mismatch in organ donation is becoming an accepted practice especially in case of children where the donor is usually one of the parents.

Tissue Typing

The second blood test for human leukocyte antigens (HLA) is called tissue typing. Antigens are markers found on many cells of the body that distinguish a person as unique. To receive a kidney where the recipient's markers and the donor's markers are the same constitutes a "perfect match" kidney. Perfect match transplants have the best chance of long-term kidney functioning. Some degree of "mismatch" between the recipient and donor is accepted.

Crossmatch

When a donor kidney is available, a third test called a crossmatch is conducted to ensure that the recipient does not have pre-formed antibodies to the donor. During an infection, pregnancy, or during a blood transfusion or transplantation the human body makes substances called antibodies that act to destroy foreign materials. If there are antibodies to the donor kidney, the body may destroy the kidney.

The crossmatch requires mixing the recipient's blood with cells from the donor. If the result is positive, it means that there are antibodies against the donor. The recipient should not receive kidney from this donor unless a donor undergoes treatment before transplantation to reduce the antibody levels. Crossmatches are performed several times during preparation for a living donor transplant, and a final crossmatch is performed within 48 hours before this type of transplant.

Serology

Additional tests are also done for viruses, such as HIV (human immunodeficiency virus), hepatitis, and CMV (cytomegalovirus) to select the proper preventive medications after transplant, and/or prevent spread of these diseases.

ii. Financial consultation

Organ transplant is an expensive medical procedure and even when the social security system covers the costs, medical facilities would want to ensure that the cost of the medical tests and the removal and transplantation will be reimbursed. Nonetheless, this will depend on the domestic health care system. In states that provide nationwide health coverage, the medical facility might check if the recipient is registered and in fact benefiting from the health insurance. Some countries might cover only a percentage of the cost. In this case the patient's capacity to cover the rest will be evaluated, including covering the cost of necessary medications. Private medical facilities, especially those located abroad will check with international or domestic insurance companies to make sure that there is sufficient coverage. Generally, if the donation is to a family member or friend, the recipient's insurance will pay for donor testing and surgery expenses. This is also applicable to unrelated donors. However, the donor might need to cover travel expenses and follow-up care, in addition to suffering lost wages.

B. Pre-transplant evaluation

When the donor and the recipient are a match, they are evaluated from the psychosocial and legal perspectives. Additional pre-transplant medical tests are also conducted.

i. Medical test¹⁴

In addition to blood and tissue matching, the organ donor will also undergo a comprehensive medical health evaluation, and psychosocial screening. Medical test might include:

- chest X-ray and electrocardiogram (ECG) to check for heart or lung disease;
- radiological testing to assess the state of kidney, including its blood vessel supply;
- urine testing, specifically a 24-hour urine sample is collected to make sure good kidney function. If it is found that the kidney function is low, donors most likely will be advised against donation;
- gynecological examination, specifically for female donors; and
- cancer screening when appropriate which may include a colonoscopy, prostate exam, and skin cancer screening.

ii. Psychosocial evaluation¹⁵

Organ donors should be interviewed by an independent expert (a psychiatrist, a psychologist, or a social worker) regarding the donor's personal life and financial situation. The evaluation could include psychometric testing conducted once or during several meetings. This will depend on the applicable assessment guidelines and the donor's case.

The psychosocial evaluation aims to:

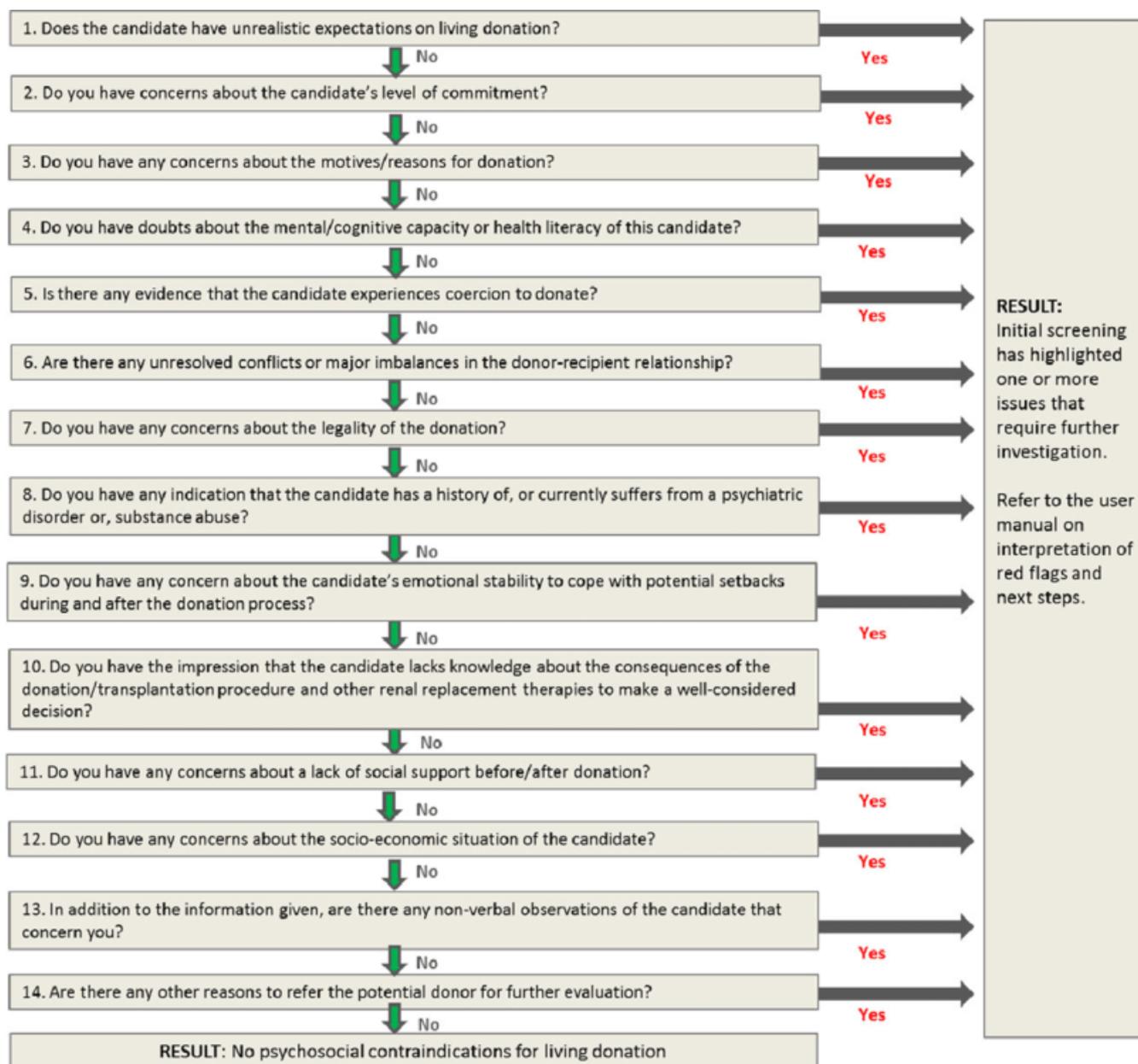
- determine if there is any history of mental illness;
- evaluate the mental state of the donor and determine that person's motivation;
- identify risk factors for problematic post-operative course;
- detect any irregularities, doubts, possible coercion or other signs that could indicate that the organ donor is not donating organ voluntarily, or that some form of benefits has been offered to the donor;
- support conscious and informed decision; and
- provide emotional support and information to the donor, and to provide the donor with an opportunity to express him or herself more fully than he/she might to the physician, or in the presence of the recipient or family members.

Importantly, if at any point in the process, the potential donor does not want to donate, the transplant team can help the donor to decline in a way that preserves the family relationships, usually by stating that the donor had been found to be medically unsuitable.

This process is especially vital in unrelated organ donation, which might involve false claims of family kinship, coercion, or financial inducement. It is common practice to forge documents to show a close relation (genetic or emotional) and to coach the donor on how to respond to questions so as to preserve the impression of an informed and voluntary decision.

It is also possible for a related organ donor to be coerced and forced into organ donation. This might be especially relevant in states where social norms deepen gender inequality, for example, when it is assumed that or pressure is exerted on women in a family to donate their organ to a husband, father or son, irrespective of their wish.

Figure 1 (below) entails questions for professionals after conducting the psychosocial assessment (EPAT) to identify red flags regarding vulnerability, non-suitability or increased risk for psychosocial complications.



iii. Giving formal consent

Informed consent for the kidney donation may be obtained during this stage, which gives the donor some time to take in all the information regarding the transplant procedure, risks and consequences. Verbal and written information should be offered about donation including the alternative treatment options for the potential recipient. It is important that the offer of information should not imply any pressure to donate. Some countries might require for consent to be obtained during the first meeting at the medical facility. However, it is good practice that this must be obtained before performing any test that is invasive or poses any health risks. How the consent is collected, and its form, differs from country to country. In case of an unrelated organ donor, consent is often obtained orally before an ethics committee, a judge or a notary. For example, in Costa Rica consent is given in front of the notary. In Spain, the policy on living donation requires

a report with information about the consent for donation given before an independent board (ethics committee) as well as about the consent given at the civil registry.

It is required that the organ donor be legally competent to give consent. No minor or person incapable of fully understanding the information provided should be accepted as a living donor other than, in some countries, narrow exceptions allowed under national law (e.g. small children donating a kidney to a sibling as a last resort). Organ donors should also have a sufficient level of intelligence and understanding, allowing them to comprehend the information on the risk and benefits. Importantly, they should be donating the organ out of their own free will (not being forced, coerced or deceived into the decision) and without expecting any material reward. Donors should be informed about the possibility of withdrawing their consent at any point prior to organ removal.

C. Transplant approval

Usually both the donor and the recipient are admitted to the hospital the night prior or the morning of the surgery. Immediately before the transplant the crossmatch test is repeated to confirm that organ donors and recipients are a match. Before the surgery commences all the legal procedures to approve the transplant must be completed and valid consent to organ donation must be obtained. Usually this will be verified by the ethics committee prior to the transplantation (depending on the type of medical facility, it might convene once a month, or once a week).

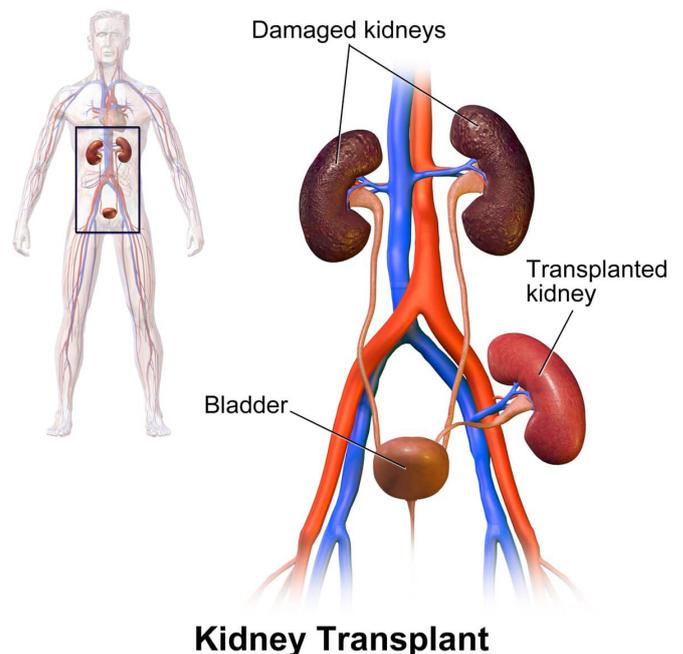
In some cases, brokers or traffickers might gain access to an authorization committee and convince, or bribe its member(s) to collaborate in the TIP for OR by approving illicit organ transplantations. There are also cases where the function of an authorization committee (ethics committee) is purely formalistic, or symbolic. Organ donation might be approved simply by asking: "are you willing to donate your organ?" and upon receiving a positive confirmation from an organ donor. This might occur in states with weak oversight system, and transplant systems lacking transparency and a proper monitoring mechanism. Only by interviewing an organ donor about the nature and the scope of the questions asked will it be possible to determine if the ethics committee fulfils its role, and if its member(s) might be involved in illicit transactions.

Transplant Surgery¹⁶

- Organ removal and organ transplantation are often carried out in short succession.
- The transplant surgery, nephrectomy, is performed under general anesthesia and may last from two to four hours.
- There are two methods to remove a kidney from a living donor: surgical incision and laparoscopy. The surgical incision was a common method used in the past, currently occasionally used in cases when individual anatomic differences in the donor suggest that this might be the best method. In this procedure the kidney is removed through an open incision in the flank region. It involves a 12-18 cm incision on the side, division of muscle and, in some cases, removal of the tip of the twelfth rib. The operation typically lasts 3 hours and the recovery in the hospital averages 4-5 days with time out of work of 6-8 weeks. The second method, laparoscopy, uses small incisions and a scope or camera, to remove a kidney. The procedure has a shorter recovery period and the complication rate is very low. Patients

undergoing laparoscopic surgery are required to stay at in the hospital for only 2-3 days. Donors are often able to return to work within 3-4 weeks after the procedure.

- As for organ recipients, the transplanted kidney is placed in the front part of the lower abdomen, in the pelvis. During this procedure recipients' own kidney will not be removed unless recommended. Organ recipients are encouraged to leave the bed and move 12 to 24 hours after surgery. Recovery in the hospital is usually 3-7 days. Complications can occur as with any surgery and may require another operation to address them.¹⁷



Kidney Transplant

(University of California San Francisco Department of Surgery Transplant Surgery, "Kidney Transplant". Available at <https://transplantsurgery.ucsf.edu/conditions--procedures/kidney-transplant.aspx>)

Post-transplant care

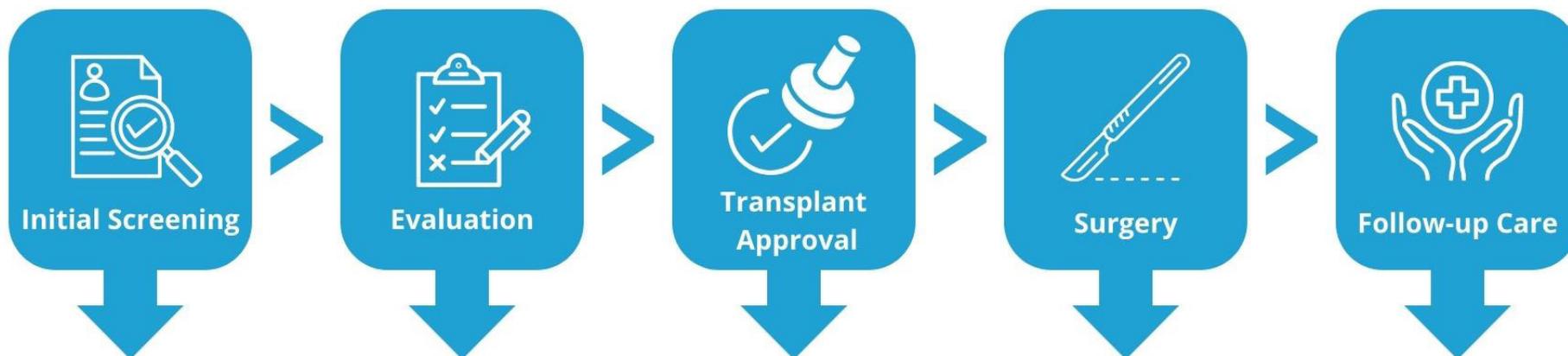
Organ donor

After the procedure the organ donor will be administered pain medication to address any discomfort. The postoperative recovery requires monitoring the donor's recovery until he or she is stable, including the provision of care for morbidity that may arise as a result of donor nephrectomy. After discharge from the hospital, the donor should be invited for follow-up check-ups and require lifelong monitoring of their overall health, blood pressure and kidney function. It might also require treatment of the donor with preexisting or acquired conditions (related to uninephrectomy) that are thought to represent a health risk (e.g. hypertension, obesity, diabetes, and proteinuria).

Organ recipient¹⁸

The post-transplant period requires close monitoring of the kidney function and early signs of rejection. Anti-rejection medications (immunosuppressive agents) help to prevent rejection. They are necessary for the “lifetime” of the transplanted organ. If these medications are stopped, rejection may occur, and the kidney transplant will fail. There might be some adjustments required of the medications, and vigilant monitoring for the increased incidence of immunosuppression-related effects such as infections and cancer.

Prior to a live kidney donation to a potential recipient (known or unknown to the potential donor in the circumstance of unrelated donation) the transplant assessment process should be followed to ensure safe, voluntary and legally valid donation. The process is divided into five key stages, including evaluation of the living organ donor and the recipient. Each stage might include either a specific medical and psychological assessment and fulfilling administrative/legal requirements. They are described in general terms below, but the exact steps may differ between countries depending on their legal framework. Each stage highlights areas vulnerable to manipulation¹⁹.



Upon first visit to the medical facility an organ donor should:

- be informed about the procedure and the evaluation process;
- provide a medical history (if applicable);
- possibly undergo a basic physical examination as for the suitability of his/her health; and
- possibly undergo initial assessment of attitude and motivation.

Medical

- A non-invasive, low-cost test is conducted to verify if the donor and recipient are a match.
 - ▶ Compatibility test (blood and tissue)
- Crossmatch and Serology test.

Medical test might include:

- chest X-ray and electrocardiogram (EKG);
- second set of laboratory test;
- urine testing, specifically a 24-hour urine sample is collected to ensure good kidney function.
- gynecological examination, specifically for female donors;
- cancer screening, when appropriate;

Psychosocial*

- ▶ Organ donors should be interviewed by an independent expert regarding their personal life and financial situation to ensure donation is free, voluntary and no pressure is detected.

Legal

- ▶ Informed consent to kidney donation should be obtained;
- ▶ Consent should be provided in writing, and could be given before an official body (if applicable) e.g. judge or in a civil registry office;
- ▶ Documents regarding kinship in case of related donation should be provided and verified.

- ▶ Approval of transplant by an official body (ethics committee, or transplant authority) *

Repeat of crossmatch test immediately before the surgery.

***Consent must be obtained!**

The transplant surgery, nephrectomy, is performed under general anesthesia and may last from two to four hours.

After the procedure, the organ donor will be administered pain medication to address any discomfort.

The organ donor should stay in the hospital for an average of 3 days, depending on health condition and the method used to remove the kidney.

Overseeing and monitoring the postoperative recovery process of the donor until that individual is stable, including provision of care for morbidity.

After discharge from the hospital, the donor should be invited for follow-up check-ups and require lifelong monitoring of their overall health, blood pressure and kidney function.

The donor might also require treatment for preexisting or acquired conditions (related to uninephrectomy) that are thought to represent a health risk (e.g. hypertension, obesity, diabetes, and proteinuria).

Initial Screening or during the evaluation stage

The donor should be informed of the risks of nephrectomy (kidney removal), including: the risk of death, surgical morbidities, changes in health and renal function, impact upon insurability/employability and unintended effects upon family and social life; the expected transplant outcomes (favourable and unfavourable) for the recipient and any specific recipient conditions which may impact upon the decision to donate the kidney, disclosure of recipient-specific information which must have the assent of the recipient (if applicable); alternative renal replacement therapies available to the potential recipient.

***Consent:** The potential donor should be capable of understanding the information presented in the consent process. The decision to donate should be voluntary, including the freedom to withdraw from the donation process at any time before removal; and the assurance that medical and individual reasons for not proceeding with donation will remain confidential.

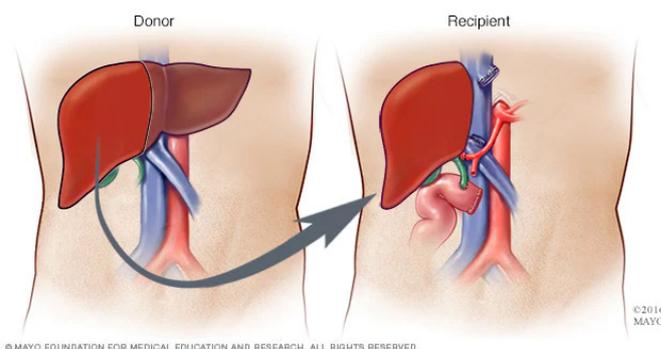
***Psychosocial Assessment:** Not all countries have introduced mandatory psychosocial screening of prospective organ donors. This task to inquire about motives and the consent prior the surgery is often outsourced to physicians or the transplant surgeon. It is required, however that the donor is screened for any mental disorders and to determine that he or she is psychologically stable.

***Ethics committee or transplant authority:** Most countries will have some form of a committee, either at the national, regional or hospital level, to approve the organ removal and transplantation. The ethics committee's role is to guide the policies and procedure related to organ donation, removal, allocation, and transplantation to ensure that they are consistent with legal and ethical principles. With regard to living organ donations, the ethics committee will review the transplant documentation, and the comprehensive assessment of the organ donor and the recipient before approving the organ removal and transplantation. For unrelated living donors the ethics committee might also interview the organ donor to ensure that the consent is valid and there is no payment involved.

4. LIVER TRANSPLANT - OVERVIEW²⁰

A. What is a liver transplant?

- Liver transplantation is a surgical procedure to remove a diseased or injured liver from one person and replace it with a whole liver from a deceased donor, or a segment or lobe (up to 60%) of a liver from a living donor.
- The liver is the only organ able to regenerate. A transplanted segment of a liver can grow to normal size within a few months. Similarly, the liver in a living donor will begin to regenerate immediately after surgery and will be back to normal size in three to six months. Because of this regenerative ability living donors are accepted to donate a portion of the liver.
- Liver transplantation is a complex operation which requires a stricter selection of the recipient and the donor in contrast to kidney transplantation.



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(Mayo Clinic, "Liver transplant", Mayo Foundation for Medical Education and Research (MFMER), 15 July 2020. Available at <https://www.mayoclinic.org/tests-procedures/liver-transplant/about/pac-20384842>)

Given the shortage of available organs, liver transplantation from a living donor is an alternative that may be considered. For example, it is not possible for non-EU resident patients suffering from liver disease in need of a transplant to be registered on the Eurotransplant waiting list. For these patients, living liver donation might be the only option. This is also the case for patients suffering from liver failure living in a country without a well-developed liver transplant programme, and for those who might have been waiting for transplantation for a long time, or who might not even qualify to be put on the transplant waiting list.

What is the function of the liver?

- The liver is a vital organ that performs many critical functions including metabolism of medication and toxins, removing degradation

products of normal body metabolism (for example clearance of ammonia and bilirubin from the blood), and synthesis of many important proteins and enzymes (such as factors necessary for blood to clot).

- A person cannot survive without a healthy and functional liver. As there is no other therapeutic option in case of a liver failure (as compared to dialysis in case of kidney failure), transplantation may be the only therapeutic option available.

B. Why someone needs a liver transplant

- Liver transplantation is necessary when the liver functions are damaged beyond the body's capacity to regenerate. Children and adults can suffer from liver failure due to long standing liver disease.
- In adults, the most frequent causes of liver disease that lead to the need for a liver transplant is chronic infection with hepatitis C or B, or Primary Biliary Cirrhosis. Cirrhosis is a chronic liver disease and a common cause of end-stage liver disease. It happens when healthy liver tissue is replaced with scar tissue. The end stage of scarring is termed cirrhosis. This in itself may not cause liver failure but due to long term liver disease and liver scarring, over time, the liver gradually loses its functions and may require to be replaced by transplantation.
- Other conditions in adults that commonly lead to a liver transplant include:
 - **Non-Alcoholic, Fatty Liver Disease:** a group of conditions where there is accumulation of excess fat deposits over the liver.
 - **Alcoholic Liver Disease:** liver failure due to excessive alcohol consumption.
 - **Primary Sclerosing Cholangitis:** a chronic inflammation of the liver. Many years of living with this condition usually results in liver failure. This condition affects people between ages 30 and 50.
 - **Acute liver failure** (Acute hepatic necrosis): occurs when a previously healthy liver suffers massive injury that causes tissue in the liver to die. Possible reasons include acute infections and reactions to drugs, or toxins, ingestion of a toxin such as poisonous mushrooms, or an idiosyncratic drug reaction.²¹
 - **Metabolic diseases:** disorders that change the chemical activity in cells affected by the liver.
 - **Primary liver cancers:** cancerous tumors that start in the liver.
 - **Autoimmune hepatitis:** a redness or swelling

(inflammation) of the liver. It happens when the body's immune system attacks the liver.

- In children hepatoblastoma (tumors) are the most common forms that necessitate a liver transplant. Among newborns, biliary atresia, a rare disease of the liver and bile ducts, might cause liver failure.

How can someone become a transplant patient?

- If a person suffers from end-stage liver failure, his/her doctor will make an initial decision as to whether he/she could become a transplant recipient. A patient will be referred to a transplant center or a specialized unit within a hospital for further evaluation and will be assigned a transplant team.
- The transplant team will perform a number of tests (medical and psychosocial) and decide whether to place the patient on a national transplant waiting list, unless there is a living donor. The transplant team often includes:
 - a transplant surgeon;
 - a hepatologist: a physician specialized in treating liver disease;
 - transplant nurses;
 - a social worker/patient advocate;
 - a psychiatrist or psychologist;
 - other team members such as a dietitian and anesthesiologist.
- After the medical and psychiatric evaluation, the patient's results are reviewed, and a decision is made as to whether the patient can safely undergo the transplant. A patient might not qualify for a liver transplant if he/she:
 - suffers from an existing or chronic infection that cannot be treated;
 - has metastatic cancer (cancer that has spread from its main location to 1 or more other parts of the body);
 - has severe heart problems or other health problems;
 - has a serious condition besides liver disease that would not improve after the transplant;
 - is not able to follow a post-transplant treatment plan;
 - drinks too much alcohol.
- If the patient is cleared for transplantation and if a living person is donating a part of his or her liver to the recipient, the organ removal will be planned in advance, after a positive evaluation of the organ donor. The transplant surgery will occur immediately afterwards.



If a transplant is performed in a third country, and if domestic law allows for unrelated organ donation, there might be additional procedures to verify the authenticity of identity documents presented by the donor and the recipient. When domestic law does not allow unrelated donation, documents might be falsified to show that the donor and the recipient are in a relationship that under domestic law is eligible for organ donation. In those instances, a number of countries require to contact the embassy or consulate of the (alleged) country of citizenship to verify that the donor and recipient are who they state to be, and that they are in fact related. Some transplant facilities might resort to performing a DNA test to confirm that the two are related, and this is not obviously available for spousal relations. However, this is not common practice.

C. Who is eligible to become a living donor?

- Only a small number of living transplants are performed using living donors due to the risks of the operation. Donors should be 18 to 60 years of age and not smoking for at least six weeks prior to surgery. Oftentimes genetically related donor, or unrelated (emotionally connected) donor provide the organ.
- The organ donor must undergo a comprehensive medical and psychological evaluation by the transplant team. The transplant team consists of specialists from a variety of fields, including a hepatologist, transplant surgeon, transplant coordinator, nurse, psychiatrist, social worker, nutritionist and financial coordinator.
- The evaluation is conducted to make sure that donors are healthy enough to donate, that they do not suffer from any major medical or psychiatric illnesses, that there are no significant health risks, and that donors understand and comply with instructions for surgery preparation and recovery.
- Importantly, the donation must be completely voluntary, informed and not involving any financial or other benefits. Donors should be free from any coercion, pressure or guilt associated with the donation a (for more information see Module 3).

D. What are the risks?²²

Organ donors

For living organ donors possible long-term risks associated with donating a lobe or segment of the liver may include wound infections, hernia, abdominal bleeding, bile leakage, narrowing of the bile duct, intestinal problems including blockages and tears and organ impairment or failure that leads to the need for transplantation.

Organ recipients

For organ recipients the transplanted liver may be rejected by the immune system, which is the body's normal reaction to a foreign object or tissue. To reduce the chances of rejection and help the new liver survive, recipients must take anti-rejection medicines (immunosuppressive medicines), which weaken the immune system's response. These medicines will have to be taken for the rest of the recipient's life, or the lifespan of the transplanted liver. According to the Mayo Clinic, it is difficult to compare long-term results between people who receive a liver from a living donor and those who receive it from a deceased-donor. Persons receiving a donor from a deceased-donor have lower short-term survival rates, but they also tend to be sicker so it is not possible to compare.²³

Complications associated with the surgery include:

- Clotting of the hepatic artery (hepatic artery thrombosis): clotting of the blood vessel that brings oxygenated blood from the heart to the liver occurs in 4-10% of all patients who receive a living donor transplant. The liver cells themselves typically do not suffer from losing blood flow from the hepatic artery because they are primarily nourished by blood from the portal blood flow. In contrast, the bile ducts depend strongly on the hepatic artery for nutrition and loss of that blood flow may lead to bile duct scarring and infection. If this occurs, another transplant may be necessary.
- Portal vein thrombosis or clotting of the large vein that brings blood from the abdominal organs (the intestines, the pancreas, and the spleen - the organs that belong to the portal circulation) to the liver occurs infrequently. This complication may or may not require a second liver transplant.
- Biliary complications: in general, there are two types of biliary problems: leak or stricture. Biliary complications affect up to 40% of all living donor transplants.
- Bleeding is a risk of any surgical procedure but a particular risk after liver transplantation because of the extensive nature of the surgery and because clotting requires factors made by

the liver. Most transplant patients suffer some blood loss and may get additional transfusions after the operation. If bleeding is substantial or brisk, return to the operating room for control of bleeding is often necessary. In general, approximately 10% of transplant recipients will require a second operation for bleeding.

- Infections can occur during the healing of the wound created by any operation. Liver transplant recipients are also at risk for infections deep within the abdomen, particularly if there is a collection of blood or bile (from a bile leak). The immunosuppressive medications along with the history of liver failure increase the liver transplant recipient’s risk for developing an infection after transplantation.

Some liver diseases can return after the transplant and can damage the new liver and eventually destroy it. Perhaps the best examples are hepatitis B and hepatitis C. Some transplant patients might develop Post-Transplant Lymphoproliferative Disorder (PTLD), an unusual type of cancer that arises exclusively in transplant recipients. It is almost always associated with Epstein-Barr virus (EBV), the same virus that causes infectious mononucleosis. Skin cancers are also the most common malignancy in the post-transplant population. The rate of skin cancer in patients who have undergone organ transplantation is 27% at 10 years, reflecting a 25-fold increase in risk relative to the normal population. In light of this substantial risk, it is strongly recommended that all transplant recipients minimize sun exposure.

EVALUATION PROCESS FOR LIVER DONATION AND TRANSPLANTATION²⁴

In a liver transplant only the blood group is crucial. It is possible to carry out “ABO-incompatible” transplants where there is no donor with the same blood group. Blood type and body size are critical factors in determining who is an appropriate donor. Below is the outline of the compatible blood groups.

		Donor							
		O-	O+	B-	B+	A-	A+	AB-	AB+
Recipient	AB+								
	AB-								
	A+								
	A-								
	B+								
	B-								
	O+								
	O-								

(Medix, Blood Group - What is it and does it matter, 15 October 2022. Available at <https://medix-global.com/blood-group-what-is-it-and-does-it-matter/>)

In living liver donation, a portion of the donor’s liver is used for transplantation. Usually, a full evaluation of the donor will be performed after the initial screening is completed, and there are no conditions that rules he/she out from donating. If after the evaluation the transplant team determines that liver donation can be performed, a surgery date is scheduled for both the donor and the recipient. This process usually takes up to 4 or 6 months unless there is an emergency.

When an organ recipient and an organ donor travel to a third country for a transplant, or if a paid donor joins an organ recipient in a third country, they might be admitted to a hospital at the same time. In this situation the evaluation process can be shorter. Blood test could be performed beforehand to check compatibility in their respective countries. They usually will be managed by brokers/traffickers.

NOTE: Organ recipients and organ donors should have separate transplant teams performing evaluation to ensure transparency, and to be able to advocate on behalf of their respective patients without any bias.

a. Recipients

As noted earlier, a patient in need of a liver transplant is referred to a transplant center to be evaluated by the transplant team. The transplant evaluation process can take up to 5 days and includes:

- **Psychological and social evaluation:** The patient will undergo a comprehensive evaluation to determine if he/she has any financial concerns, if the patient has support in recovery, whether it is from family or friends, after the surgery, and if there are any other issues/concerns that could impact the outcome of the operation (identification of any psychiatric disorders and substance abuses that could compromise the successful post-operative course).
- **Blood tests:** These tests are done to help to find a good donor match to improve the chances that the donor liver is not rejected. Test results can also assist in determining patient’s priority on the waiting list. If the recipient has a living donor, blood tests are performed to ensure that they are a good match.
- **Diagnostic tests:** Tests are done to check the

patient's liver and general health. These tests may include X-rays, ultrasounds, a liver biopsy, heart and lung tests, colonoscopy, kidney function tests and dental exams. Women may also have a pap test, gynecology exam and a mammogram.

Once the recipient completes all required testing, the ethics committee reviews the information. If the ethics committee determines that the person is a suitable candidate to receive a transplant, and that the living donor is a suitable donor, the transplant is approved. It is often assumed for living donation that the intended recipient will accept the procedure. The recipient should also have the option to refuse donation from one or more of the potential donors. In cases of paid donation refusal will of course not occur.

B. Organ donors

Living liver donation carries a higher risk for donors as compared to kidney donation. Medical professionals must be certain that the potential donor fully understands the implications of the donation and the donor must provide informed, free and specific consent to organ removal. Due to the seriousness of the procedure the potential donor must undergo an exhaustive health check (some examinations can be carried out in the country of origin) and psychosocial evaluation. The process of organ donor evaluation might differ from country to country but generally could be divided into 3 stages.

i. FIRST STAGE – Initial Screening

Upon the first visit, the organ donor must provide basic information regarding his/her health and agree to basic medical examination. The lab work and diagnostic tests are done. For example, in this stage blood type might be tested to confirm compatibility between the recipient and the donor, in addition to a urine test and pap smear. The screening can take place in a medical facility where the transplant is to be performed, or in another medical facility, for example in the donor's country of residence. If upon reviewing the result, a transplant coordinator, or other authorized medical professional considers the person to be a potential donor, he/she will proceed to the evaluation stage.

ii. SECOND STAGE – Evaluation

Evaluation might take between 2 to 3 days and will be usually performed in a medical facility where the transplant will occur. If the organ donor has been referred to this hospital/clinic a medical test from the initial screening might be repeated. Commonly, during this stage donation-specific examinations are carried out by the transplant team. The volume and

anatomical characteristics of the donor's liver are studied in detail. The evaluation test includes:

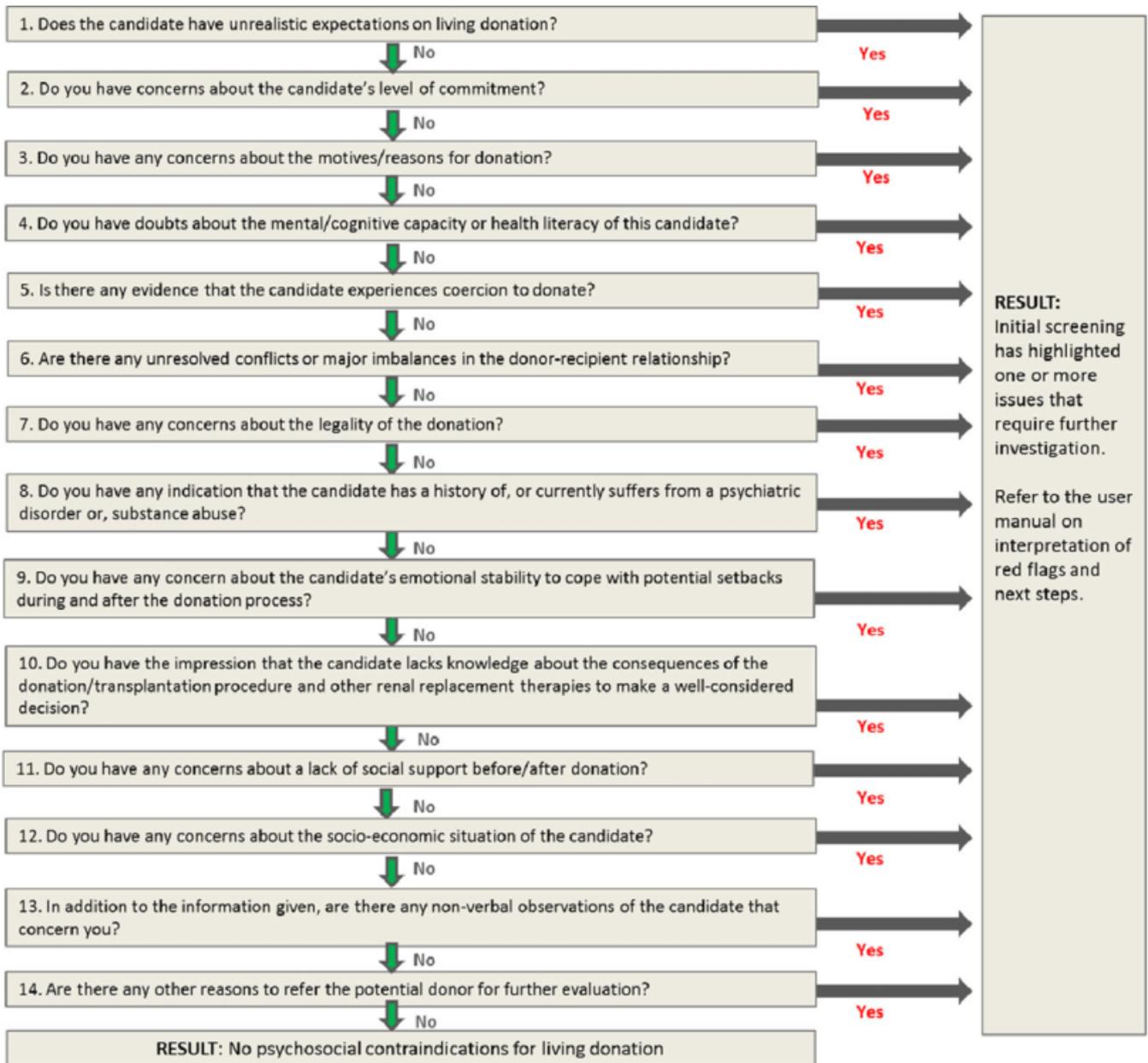
- chest X-ray;
- electrocardiogram (EKG or ECG);
- abdominal ultrasound.

A physician who is not a member of the transplant team (or other appointed person for this role) should serve as the donor advocate throughout the evaluation process, the surgery and recovery. In addition, during the evaluation stage a hepatologist and a surgeon should hold separate meetings with the organ donor to discuss the medical risks, the procedure, and the consequences.

In addition to the medical evaluation, a psychosocial evaluation should be conducted by a professional mental health expert with experience in transplantation, more specifically a psychologist, transplant coordination, donor advocate, or a social worker. The assessment is sometimes performed by a hepatologist or a surgeon, but this is not recommended practice. The donor will meet in person with the living donor advocate, or the psychologist to undergo the psychosocial screening to determine that:

- the donation is voluntary, free from any coercion;
- no monetary or other benefits have been offered in exchange for organ donation;
- the donor is not suffering from any mental health issues that would increase the risks of post-operative care;
- the donor is capable of making an autonomous decision; and
- the donor has a sufficiently large support network to undergo the surgery and the recovery.

Below is a Figure 1 which entails questions for professionals after conducting the psychosocial assessment to identify red flags regarding vulnerability, non-suitability or increased risk for psychosocial complications.



When a living donor knows the recipient (or pretends to be a relative) the psychosocial evaluation could help to determine whether their relationship is genuine (for instance by examining what they know about each other), whether possible pressure or coercion is being issued, and whether a monetary incentive was offered. In the case of a direct donation from an unrelated donor, the psychosocial evaluation could provide insights into the donor's background and social and financial situation so as to determine whether there are any pre-existing vulnerabilities that could be exploited and would change the character of the altruistic donation to paid donation.

NOTE: In some countries, an organ donor might meet twice with a psychologist or a social worker, with a break (several days) between those meetings to allow for a proper reflection period. If upon a first evaluation there are doubts as to the organ donor's intention and capacity to make a decision, another meeting might be scheduled before the decision/opinion is made. Occasionally, one additional meeting could be conducted where both the organ recipient and the donor are invited for the assessment, especially if it involves donation between relatives.

iii. THIRD STAGE – Result and approval

Once all required tests are completed it might take up to a week for all the results to come through. Then the transplant team will meet to discuss the medical result and psychosocial evaluation and clear the donor for the surgery. The donor's case, with all the evaluation results, will be presented to the ethics committee (or transplant authority). This committee will decide if the donor is indeed a good candidate for transplantation. The practice might differ across the states, but in case of unrelated living donors, the ethics committee might conduct an additional evaluation of the organ donor in person to ensure that the donation is voluntary and no payment has been offered in exchange for his/her consent. When the donor does not speak the language of the country where the transplant is to take place, an independent translator should be provided so that he/she can communicate freely and to exclude any coercion from the donor's family, recipient's family or brokers posing as friends or relatives. Upon approval from the ethics committee, a date for surgery will be set in preparation for the transplant. In most circumstances, the transplant is scheduled four to six weeks in advance. If the organ donors and recipients travelled from another state, this time might be shortened even to a week or less.

NOTE: At any time during the evaluation process up until the very moment of removal, the organ donor is entitled to change his or her mind about the donation. This decision is made with physicians, or the donor's advocate, and should be kept completely confidential.

B. TRANSPLANT SURGERY ²⁵

Liver transplantation is an orthotopic transplantation in which the diseased organ is removed and the transplanted organ is placed in the same location. The surgical strategy (i.e. whether to remove the left or right side of the donor's liver) is determined on a case-by-case basis. The segmental anatomy of a liver allows surgeons to create grafts of varying size, depending upon the recipient's requirement for a new liver. The aim of this approach is to ensure that the transplant can be carried out with the least possible risk to both donor and recipient. On average, for a living donor it takes about four to six hours to remove the part of the liver, then another six to 12 hours to implant it into the recipient. Generally, a liver transplant follows this process:

a. Donor Operation²⁶

1. The donor is taken to the operating room and goes under general anesthesia.
2. Large intravenous (IV's) are placed to give fluids and medicines during surgery.

3. The type and size of incision made depends on the type of liver graft to be removed, and the surgical expertise of the surgical team. A laparoscopic surgery also called 'keyhole' surgery is possible now.
4. The proper anatomy is identified, and the liver is split in preparation for transplant into the recipient.
5. The liver graft is fully removed from the donor after splitting, prepared for transplantation and transported to the recipient's operating room.
6. The donor is transported to the intensive care unit (ICU) for recovery and monitoring.

b. Recipient operation²⁷

1. When the recipient arrives at the hospital, he/she will be taken to a ward where a doctor will go through the medical history. A chest X-ray and an electrocardiogram (ECG) test will be done again.
2. In the operating theatre, an IV (intravenous) line will be started. Other tubes (catheters) will be put in the neck and the wrist. Or they may be put under the patient's collarbone or in the area between the belly and the thigh (the groin). These are used to check heart and blood pressure, and to get blood samples.
3. The patient will be placed on his/her back on the operating table.
4. A catheter will be put into the bladder to drain urine.
5. After the patient is sedated, the anesthesiologist will insert a tube into the lungs. This is so that breathing can be helped with a machine (a ventilator). The anesthesiologists will keep checking the heart rate, blood pressure, breathing, and blood oxygen level during the surgery.
6. The skin over the surgical site will be cleaned with a sterile (antiseptic) solution.
7. The doctor will make a cut (incision) just under the ribs on both sides of the belly. The incision will extend straight up for a short distance over the breastbone.
8. The doctor will carefully separate the diseased liver from the nearby organs and structures.
9. The attached arteries and veins will be clamped to stop blood flow into the diseased liver.
10. Different surgery methods may be used to remove the diseased liver and implant the donor liver. The method used will depend on a specific case.

11. The diseased liver will be removed after it has been cut off from the blood vessels.
12. The surgeon will check the donor liver before implanting it into the patient's body.
13. The donor liver will be attached to the patient's blood vessels. Blood flow to the new liver will be started. The surgeon will check for any bleeding.
14. The new liver will be attached to the patient's bile ducts.
15. The incision will be closed with stitches or surgical staples.
16. A drain may be placed in the incision site to reduce swelling.
17. A sterile bandage or dressing will be applied.

medicines are prescribed and are closely monitored to ensure the recipient is getting the right dose and the right mix of medicines.

- Follow-up of the recipients continues throughout their life (particularly their antirejection therapy) jointly with a hepatologist, including the annual health check (e.g. liver biopsy).

If an organ donor received a transplant abroad, upon returning home, he or she would have to report to a physician for a medical checkup and to receive the required medications. If the patient is coming from a country known as being at high risk of illicit transplants or transplant tourism, the physician could suspect that the transplant might not be legitimate. When a donor suffers from an infection, or other post-operative complications, further inquiry might reveal that the transplant was indeed carried out illegally. In these situations, it is recommended that physicians alert appropriate authorities regarding the patient's situation. When the organ donor returns home and is taken off the national transplant list for reasons not known to the transplant coordinators, such scenarios could also be of interest for law enforcement.

Prior to a live liver lobe donation to a potential recipient (between relatives or in case of unrelated donation) the transplant assessment process should be conducted to ensure safe, voluntary and legal organ donation. This process includes several stages that require specific medical and psychosocial (when applicable) assessment, and fulfillment of a number of administrative, and legal requirements. They are described below. Each stage highlights areas vulnerable to manipulation.

Living Liver Donor Transplant Evaluation Process

Prior to a live liver lobe donation to a potential recipient (between relatives or in case of unrelated donation) the transplant assessment process should be conducted to ensure safe, voluntary and legal organ donation. This process includes several stages that require specific medical and psychosocial (when applicable) assessment, and fulfillment of a number of administrative, and legal requirements. They are described below. Each stage highlights areas vulnerable to manipulation.

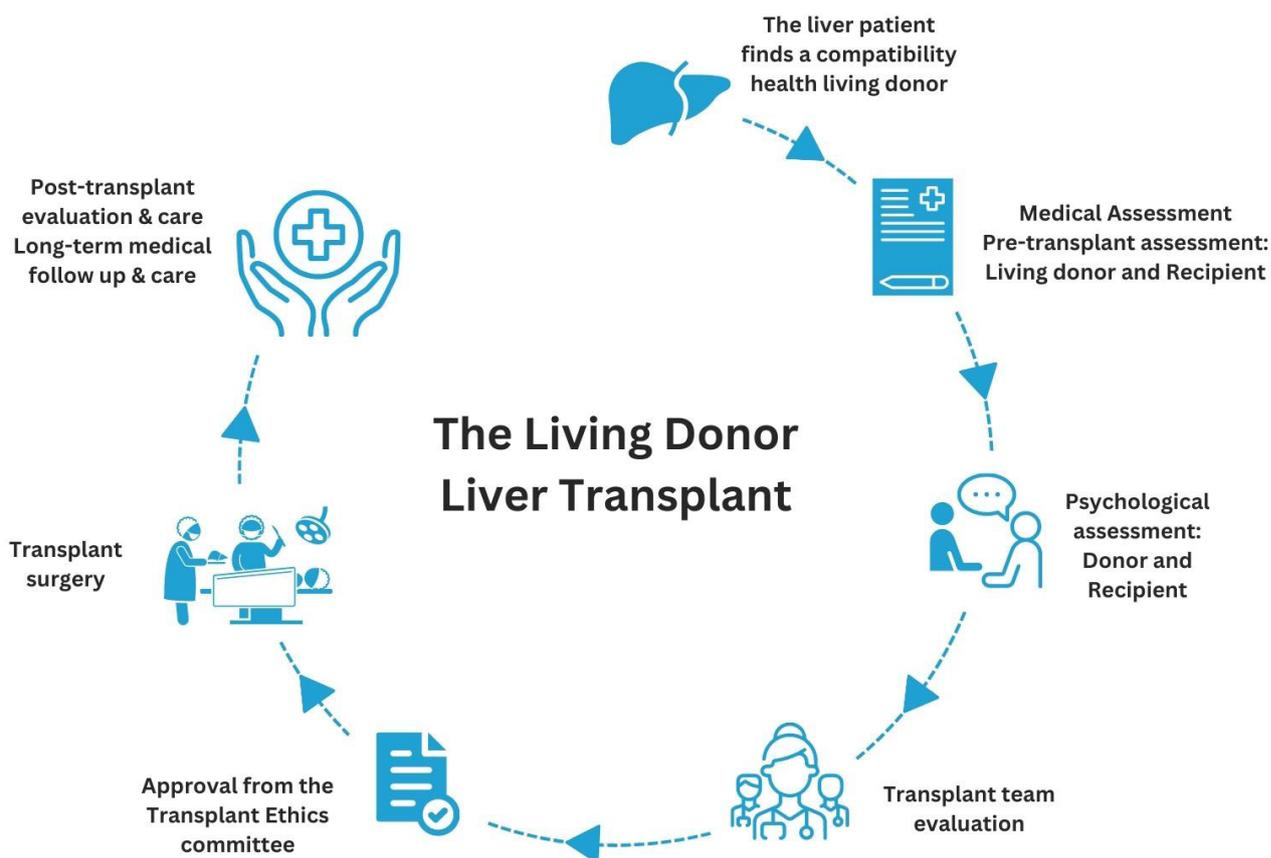
C. POST-TRANSPLANT CARE²⁸

a. Organ donors

- If there are no complications, the donor remains hospitalized for approximately ten days. Painkillers will be provided for pain management. After being discharged, donors should not lift anything heavier than 10 kilograms for at least six weeks and abstain from drinking alcohol for about a year.
- On average, most donors are fully recovered after three to six weeks. However, every donor's recovery time is different. During this period, donors should return to the hospital for routine visits so that their recovery can be monitored. Lab tests will be carried out and the donor will be examined for any signs or worrying symptoms. Physicians will assess the donor's health and together with the donor will determine when the donor can resume normal activities and return to work.
- Additionally, a liver MRI (magnetic resonance imaging) scan is done six months after the procedure. The purpose is to evaluate regeneration of the remaining liver and exclude any complications.
- Generally, medical follow-up is performed for up to two years after the donation.

b. Organ recipients

- For the recipient, the period in hospital is longer, 3 weeks on average.
- Regular monitoring of the recipient is required to ensure a good postsurgical outcome. Blood tests are carried out for several months. Anti-rejection



5. GLOSSARY²⁹

Transplant team: The transplant team is a group of medical professionals who conduct the evaluation to decide if a patient qualifies for a transplant. They are also responsible for managing the recipient’s medical care before and after the transplant. The composition of the transplant team might vary from country to country but usually includes: transplant coordinator, transplant physicians, transplant surgeons, transplant nurses, transplant dietitians, psychologist, and/or social workers. A living organ donor should have a separate transplant team, specifically assigned to evaluate the donor’s health condition and psychological state, to obtain informed consent and to advocate on his or her behalf.

Transplant coordinators organize the patient’s evaluation, prepare patients for the transplant, and organize the treatment and follow-up care after the surgery.

Transplant physicians are physicians who handle patient medical care and prescriptions. The transplant physician does not perform the surgery but provides the medical care for the patient leading up to, and after the surgery.

Transplant surgeons are the physicians who perform the actual transplant surgery and work closely with the rest of the transplant team right before and right after the surgery.

Financial coordinators work with the transplant coordinators and insurance companies to ensure that the patient has adequate public health coverage or the financial means to cover the transplant costs.

Transplant nurses are responsible for patient care before and after the transplant surgery. They play a major role in the transplant patients’ recovery.

Transplant dietitians provide information to the transplant recipient regarding the best food options before and after the transplant surgery.

Donor advocate is in some transplantation centers persons that, represent the donor and his/her rights/ interests and can be a sign of quality and possibly assist in the identification of abuse.

Psychologist, psychiatrist: Mental health experts who are specifically involved in conducting the psychosocial evaluation of the organ donor and recipient. In some states or medical centers such a screening can also be conducted by a social worker.

Social workers help transplant patients to develop healthy coping skills to deal with challenges they may have before or after the transplant surgery, such as emotional problems, fear and physical side effects.

Ethics Committee: an ethics committee, or a hospital transplant committee, is an official body created in accordance with domestic legislation on transplantation to ensure that donations are

altruistic, voluntary and free of coercion. Depending on the legal framework and transplant capacities, an ethics committee might need to be established in every medical facility offering organ transplants. The ethics committee should participate in the process of living organ donation in all cases, specifically to assess the process and assess the donor's consent. The person responsible of the living transplant program (transplant coordinator) should provide the ethics committee with the necessary documentation. An interview with the potential donor can be required in some cases.

ENDNOTES

- 1) In 1988, I.R. of Iran legalized living non-related donation (LNRD) of kidneys and established an associated transplantation system.
- 2) Amit X. Garg and others, "Application of the 2017 KDIGO Guideline for the Evaluation and Care of Living Kidney Donors to Clinical Practice", *Clinical Journal of the American Society of Nephrology*, vol. 15, No. 6 (June 2020).
- 3) For more information see: Iain A. M. MacPhee and Jiří Froněk, eds., *Handbook of Renal and Pancreatic Transplantation* (Wiley-Blackwell, 2012); Bernard M. Dickens, "Ethics Committees, Organ Transplantation and Public Policy", *Law, Medicine and Health Care*, vol. 20, No. 4 (Winter 1992); Mary Ann Abacan, "Profile of hospital transplant ethics committees in the Philippines", *Developing World Bioethics*, vol. 00 (August 2020); Miguel Casares, "Ethical aspects of living-donor kidney transplantation", *Nefrología*, vol. 30, (S2 2010).
- 4) Email to author from a leading transplant expert based in Costa Rica, 23 December 2020.
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