

Intent of COP.09.06

Organ, tissue, and cell transplants carry unique risks; to make an informed decision about whether to proceed with a transplant, the potential recipient must be informed of these risks and challenges. To consent, a patient must be informed of those factors related to the planned care required for an informed decision. Patients are informed about factors that could affect the success of the graft or the candidate's health as a recipient.

In addition, there may be psychological, ethical, financial, and other factors that are unique to the transplant patient, such as the need for immunosuppressive medications and the projected survival rate. The patient needs to be informed of all special considerations as part of the consent process. The transplant program also follows the hospital's policy for informed consent and local and regional laws and regulations.

Measurable Elements of COP.09.06

1. ☐ The transplant program follows the hospital's written policy when obtaining informed consent from solid organ, tissue, and/or cell transplant candidates. (*See also* PCC.03.00, MEs 1 and 2)
2. The transplant program informs the prospective transplant candidate of organ donor risk factors that could affect the success of the graft or the candidate's health as a recipient, including but not limited to the following:
 - Donor's history, as appropriate to the laws and regulations of the country/region
 - Condition of the organ(s) used
 - Age of the organ(s)
 - Potential risk of contracting infectious disease(s) if disease(s) cannot be detected in an infected donor
 - Potential psychosocial risks
3. The transplant program informs the prospective transplant candidate of the transplant center's observed and expected one-year survival rate following solid-organ transplant; or, when the transplant program has been in operation less than 18 months, the one-year survival rate as documented in the literature.
4. The transplant program informs the prospective solid organ, tissue, and/or cell transplant candidate about potential rejection rates, immunosuppressive drugs, and possible associated costs, as applicable to the type of transplant.
5. The transplant program informs the prospective organ, tissue, and/or cell transplant candidate of alternative treatments.

Standard COP.09.07

The transplant program has documented protocols, clinical practice guidelines, or procedures for organ recovery and organ receipt to ensure the compatibility, safety, efficacy, and quality of human cells, tissues, and organs for transplantation.

Intent of COP.09.07

To reduce the risk of organ, tissue, or cell rejection, the transplant surgeon must ensure the compatibility of the donor organ(s), tissue, and/or cells to the recipient. Transmission of infectious diseases and malignancies is a potential risk for recipients of donor cells, tissues, and organs.

Therefore, the level of safety, efficacy, and quality of human cells, tissues, and organs for transplantation must be ensured. Evaluation of organ and tissue donors may identify those donors who have a higher risk for infection with a potentially harmful pathogen. Donor screening of clinical history and donor testing for communicable diseases can significantly reduce the incidence of donor transmission of disease. Donor screening should include evaluation of medical history, behavioral risk factors, and a physical examination. Donor testing should include tests for HIV, hepatitis B, hepatitis C, and other recommended tests.

The most frequently used tests for compatibility include blood typing and crossmatching and tissue typing. The transplant surgeon ensures that testing for compatibility occurs before organ recovery and organ transplantation take place. For any transplantation of human material, traceability should be ensured for the anticipated lifetime of the donor and the recipient. Internationally agreed-on means of coding to identify tissues and cells used in transplantation are essential for full traceability.

Measurable Elements of COP.09.07

1. ⑩ The transplant team follows written organ recovery protocols, clinical practice guidelines, or procedures, which include reviewing the essential donor data and recipient data to ensure compatibility before organ, tissue, or cell recovery takes place.
2. The transplant surgeon is responsible for confirming, in writing, the medical suitability of donor organs, tissues, and cells for transplantation into the recipient.
3. When an organ or tissue arrives at the transplant center, the transplanting surgeon and at least one other health care practitioner at the transplant center verify and document that the donor's blood type and other essential data are compatible with the recipient prior to transplantation.
4. The transplant surgeon is responsible for confirming that donor evaluation and donor testing for infectious diseases and malignancy have been completed, and are documented in the medical record, before organ, tissue, or cell recovery and transplantation occur.
5. When an organ arrives at the transplant center, the transplanting surgeon and at least one other health care practitioner at the transplant center verify and document that evaluation and testing of the donor organ shows no evidence of disease and the condition of the organ is suitable for transplant.

Standard COP.09.08

Clinical practice guidelines and clinical criteria guide the selection and care of organ, tissue, and cell transplant patients.

Intent of COP.09.08

Individualized care plans are developed and guide the care of transplant patients in conjunction with clinical practice guidelines, as the care of the patient donating or receiving a cell, organ, or tissue transplant is based on the type of transplant and individual needs. The patient's health history has an impact on their recovery. In addition, the patient's psychological status may impact the transplant's success. A psychological evaluation will be conducted by a psychiatrist, psychologist, social worker, or other qualified health care professional with experience in transplantation to determine the decision-making capacity of the patient and screen for any preexisting psychiatric illness.

Measurable Elements of COP.09.08

1. ⑩ The transplant program has documented cell-, tissue-, and/or organ-specific clinical practice guidelines for the pre-transplant, transplant, and discharge phases of transplantation.
2. Each transplant patient is under the care of a multidisciplinary patient care team coordinated by the patient's primary transplant physician throughout the pre-transplant, transplant, and discharge phases of transplantation.
3. Transplant recipient candidates are evaluated for the suitability of other medical and surgical therapies that may yield short- and long-term survival rates comparable to transplantation.
4. Transplant recipient candidates receive a psychological evaluation by a psychiatrist, psychologist, social worker, or other qualified health care professional with experience in transplantation to determine the decision-making capacity of the patient and screen for any preexisting psychiatric illness.
5. The transplant program updates clinical information in the transplant donor's and/or recipient's medical record on an ongoing basis.
6. The transplant program documents organ compatibility confirmation in the living donor's medical record.