

Measurable Elements of COP.09.04

1. The individual responsible for the coordination of the live donor's and transplant recipient's care is identified and available through all phases of transplant care.
2. The hospital ensures that continuity of care for transplant patients (candidates and recipients) is facilitated through the pre-transplant, transplant, and discharge phases of transplantation.
3. Continuity of care is facilitated for living donors during the evaluation, donation, and discharge phases of donation.
4. The coordination of all transplant activities is communicated to all staff involved in the transplant program activities.

Standard COP.09.05

The hospital complies with organ, tissue, and cell transplant responsibilities.

Intent of COP.09.05

Organs, tissues, and cells are a limited resource. The hospital ensures that organs, tissues, and cells are managed in a way that protects these resources and ensures their integrity. Organ, tissue, and cell donation, procurement, and transplantation are highly regulated. The hospital complies with all rules and regulations set by the local, regional, or national procurement and transplantation network(s). These networks often require various data regarding transplant services to monitor the quality of these services and to allocate organs, tissues, and cells only to hospitals with successful, compliant programs.

The hospital implements procedures for the handling of all organs, tissues, and cells to ensure their safe handling and to ensure that patients receive the correct organ, tissue, or cells in a condition that increases the likelihood of a successful transplantation. Organs, tissues, and cells have specific requirements for their transportation and storage until transplantation. The hospital fully implements these conditions to maintain the viability of the organ, tissue, and cells. In addition, the hospital has a process to track transplanted organs, tissues, and cells for data collection purposes, including outcomes of the transplant and ability to recall any transplants.

Measurable Elements of COP.09.05

1. The hospital performing solid organ, tissue, and/or cell transplants complies with all rules set by the local, regional, or national procurement and transplantation network.
2. The hospital performing solid organ transplants shares all data related to transplant processes required by the local, regional, or national procurement and transplantation network.
3. ☉ The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of organs, tissues, and/or cells.
4. ☉ The hospital verifies at the time of receipt of the organ that package integrity is met, and transport temperature range was controlled and acceptable for the organ(s), tissues, and/or cells. This verification is documented.
5. ☉ The hospital follows the tissue suppliers' or manufacturers' written directions for transporting, handling, storing, and using tissue.
6. The hospital follows a process to track transplanted tissues.
7. ☉ Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store organs, tissues, and cells at a controlled temperature have functional alarms and an emergency backup plan.

Standard COP.09.06

The transplant program obtains informed consent specific to organ, tissue, and/or cell transplant from the transplant recipient candidate.

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. 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.