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Poltransplant Recommendations on Organ Donation and Transplantation in the COVID-19 Era

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ABSTRACT

In this article, we present the standpoint and recommendations of Poltransplant on the use of organs, tissues, and cells other than hematopoietic cells for transplant in connection with SARS-CoV-2 infections (January 15, 2021).

POLTRANSPLANT'S STANDPOINT REGARDING THE USE OF ORGANS, TISSUES, AND CELLS OTHER THAN HEMATOPOIETIC CELLS FOR THE PURPOSE OF GRAFTING IN CONNECTION WITH SARS-COV-2 INFECTIONS (VERSION DATED JANUARY 15, 2021)

THE Poltransplant standpoint is based on the following:

- Epidemiologic reports concerning infections of SARS-CoV-2, which is responsible for the development of COVID-19, including prevention, treatment options, and mortality
- Articles on anti−COVID-19 vaccinations and vaccines
- Legal regulations regarding the issues of the COVID-19 pandemic
- Content-related compilations of works prepared by organizations associated with transplant medicine
- Knowledge on the risk of infection transmission from a graft donor to a recipient and the possibility of infection in a recipient
- Experience regarding the risks of and benefits from transplant therapies, including the fact that organ grafting is a life-saving procedure
- Assumption that in the case of using organs rather than tissues for transplants, a physician is entitled to take a greater risk

The Poltransplant standpoint is connected with the following:

- Recommendations of the national consultant in the field of clinical transplantation, for regional consultants in the field of clinical transplantation concerning the COVID-19 pandemic, dated March 17, 2020, June 15, 2020, and October 16, 2020
- The standpoint of the national consultant in the field of clinical transplantation on vaccinations in transplant recipients, which was expressed in a letter to the Ministry of Health dated January 8, 2020
- The Act of March 31, 2020, amending specific acts on the health care system related to the prevention of, counteracting, and combating COVID-19 (Journal of Laws of 2020, item 567)
- Regulation of the Ministry of Health of April 27, 2020, amending the regulation on the procedure for carrying out inspections in health care entities involved in the collection, storage, and transplant of cells, tissues, and organs (Journal of Laws 2020, item 766)
- Directive 2010/45/EU of the European Parliament and of the Council of July 7, 2010, on standards of quality and safety of human organs intended for transplantation
- Recommendations of the Polish National Transplant Council of June 30, 2020, for eye tissue banks and eye tissue transplant centers on the performance of tests for SARS-CoV-2 in cornea donors and recipients
- Regulation of the Minister of Health of April 28, 2020, on standards regarding restrictions on the provision of health care services to patients other than those suspected of or infected with SARS-CoV-2 by medical professionals who have had direct contact with patients suspected of or infected with SARS-CoV-2 (Journal of Laws of 2020, item 775) and the amending regulation of July 22, 2020 (Journal of Laws of 2020, item 1275)
- Regulation of the Council of Ministers of October 9, 2020, on the introduction of specific epidemic-related restrictions,

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prohibitions, and sanctions (Journal of Laws of 2020, item 1758) and the amending regulation of November 2, 2020 (Journal of Laws of 2020, item 1931)
- Regulation of the Council of Ministers of December 8, 2020, on the establishment of the Government Plenipotentiary for the National Immunization Programme against SARS-CoV-2 (Journal of Laws of 2020, item 2191)
- National Immunization Programme against COVID-19 (December 2020)[1]

The Poltransplant standpoint:

- It does not absolve medical doctors from their professional responsibilities under the Act of December 5, 1996, on the professions of medical doctor and dentist (Journal of Laws of 2020, item 514)
- It does not absolve medical doctors from their professional responsibilities in connection with the introduction of the state of epidemic announced by way of the Act of December 5, 2008, on the prevention and combating of infections and infectious diseases in humans (Journal of Laws of 2019 item 1239).

The following standpoint has been amended in comparison with the one from November 5, 2020, because:

- In December 2020, the National Vaccination Programme was initiated. It has covered persons above the age of 16 years. Issues connected with the efficacy and safety of vaccinations in immunosuppressed patients have been taken into account. [1]
- Diagnostic values of the SARS-CoV-2 gene and antigen positive tests results have been fixed.

The Standpoint of Poltransplant on Transplant-Associated Organizations and Coordination

1. Gene (reverse transcriptase polymerase chain reaction) or antigen test in all potential donors

All potential donors are advised to undergo reverse transcriptase polymerase chain reaction (RT-PCR) testing. Every deceased probable organ donor meets a clinical criterion of a person suspected of having a SARS-CoV-2 infection because they are the people in a condition of a sudden endangerment of life or health due to one of the following: trauma, stroke, a cardiologic reason or other reasons for a sudden health condition worsening.

In line with COVID-19 case definition, for the needs of epidemiologic supervision regarding SARS-CoV-2 infections in accordance with Main Sanitary Inspectorate (GIS) of October 31, 2020, and the standpoint of the national consultant from the area of medical microbiology of November 3, 2020:

- The detection of SARS-CoV-2 antigen(s) in a clinical material with an antigen test is sufficient for the confirmation of a COVID-19 case, and
- A negative result of an antigen test does not rule out the infection and requires a verification with an RT-PCR test.

2. A confirmed SARS-CoV-2 infection in a donor

The confirmation of a current infection in a potential donor (an infected person) rules out the donation of organs and tissues (an unacceptable risk).

3. Probable and possible infection in a deceased donor and graft recipient

A probable and possible infection (according to a definition by GIS) does not rule out donation and organ and tissue grafting. Under such circumstances, the decision is made by a transplant surgeon after carrying out a detailed analysis of other risk factors and possible benefits for the transplant recipient.

4. Potential donors recovered from COVID-19

Past infection in a potential deceased or live donor (convalescents) rules out organ and tissue donation for at least 28 days after having met the conditions and criteria for the cessation of isolation. The assumed 28 days has no objective medical grounds. The conditions and criteria for the termination of isolation originate from the Minister of Health's ordinance of September 1, 2020 (Journal of Laws, 2020 item 1506).

5. Coronavirus SARS-CoV-2 questionnaire in potential graft donors and recipients

Epidemiologic and clinical history data should be taken from every potential deceased or live organ and tissue donor and every potential organ and ocular tissue recipient. This procedure should be documented in the Coronavirus SARS-CoV-2 questionnaire. A copy of the completed questionnaire is deposited in the donor's or recipient's medical file and, in the case of deceased organ donors, in the rejestrytx.gov.pl website tool.

6. Chest computed tomography in all potential donors

A chest computed tomography (CT) scan is advised for all potential deceased donors with intact blood circulation, carried out as a "flag" examination in the disease diagnosing and classifying COVID-19 cases, similar to gene and antigen tests.

7. Test and chest CT result in a donor

A negative gene test result obtained no earlier than within the past 72 hours and a chest CT image with no lesions typically found in patients infected with SARS-CoV-2 allow organ and tissue donation and transplant.

In the case of a negative test result but a doubtful chest CT image, a decision on whether to procure and use organs and ocular tissues is made by a transplant surgeon or an ophthalmologist.

The evaluation of epidemiological risk factors related to COVID-19 and of laboratory test results (eg, C-reactive proteine or lymphopenia) is helpful in each case.

8. Procuring and grafting organs while no test result is accessible

Organ procurement and grafting are tolerated when a donor or a recipient has not been tested or when the test result is not known yet provided epidemiologic and clinical history data are negative and no CT-examined COVID-19−specific pulmonary lesions have been detected.

In these cases, the decision is up to a transplant surgeon and/or the head of a transplant center once the benefit-to-risk ratio has been assessed in a recipient.

9. COVID-19−free pathways in donor hospitals and transplant centers

Before organ and tissue procurement, storage, and transplant in the hospitals involved, a thorough risk assessment should be made, and internal procedures and quality systems should be adjusted to ongoing epidemics in order to reduce the risk for the donor, the recipient, and the staff, for example, by the designation of "clean green zones." This pertains to hospitals at the first and second levels of a system for hospital service provision for patients with COVID-19.

10. Limitations within organ and tissue procurement in multispecialist hospitals of the third-level system of hospital service provision for patients with COVID-19

An activity based on the enrollment of live and deceased donors and procurement of organs and tissues for grafting is suspended in multispecialist hospitals of the third-level system of hospital service provision for patients with COVID-19.

If a health care entity encompasses several medicinal establishments (hospitals) and only 1 of them is appointed as a multispecialist hospital of the third-level system of hospital service provision for patients with COVID-19, the remaining medicinal establishments of the entity may be involved in procurement of organs and tissues for transplants after making a detailed analysis of the epidemiologic risk for donors, recipients, and the staff.

If the donation refers to live donors, such an entity is obliged to make an immediate application to the Minister of Health for authorization to collect organs from live donors in a new location.

If in a multispecialist hospital of the third-level system of hospital service provision for patients with COVID-19 there is a zone designated for the treatment of patients who are not infected with SARS-CoV-2 (such hospitals may also provide services to these patients) that is strictly separated from the section of the hospital designated for patients infected with SARS-CoV-2 (separate entrance, corridors, lifts, staircases, hospital wards, operating rooms, recovery rooms, intensive care rooms, etc), this zone is entitled to serve for collecting organs and tissues for transplants provided that a detailed analysis of the epidemiologic risk has been undertaken.

A decision on the aforementioned issues is made by the hospital's managerial staff. The decision should take into account any limitations as to the provision of health care services to patients other than those suspected of or infected with SARS-CoV-2 by medical professionals having direct contact with patients suspected of or infected with SARS-CoV-2.

11. Prolongation of care for an eligible deceased donor

If possible, after confirming death and authorizing procurement, suspension of collection is required, leading to the proper care for the eligible donor, until a recipient has been chosen and gene test results have been obtained in both the donor and the recipient.

12. Team collaboration within organ collections

Some transplant teams are involved in collecting and transplanting a few organs of the abdominal cavity. If possible, it is recommended to introduce limitations as to the number of surgical teams concomitantly partaking in the collection of organs from a deceased donor. Multiprofile teams may procure organs for other centers for transplants. The organ collected is transported to a center that has approved a recipient for the transplant.

13. Not performing an autopsy in deceased organ and tissue donors and recipients

Owing to the danger of infection, performing a postmortem examination in graft donors and recipients is not indicated. In justified cases a decision on necropsy should be made together with a team for the control of hospital infections of a given hospital, and the examination itself should be carried out by an experienced and adequately protected staff. A potentially infectious section material collected for further tests should be properly packed and marked.

14. Complying with epidemiologic procedures in a donor's hospital

Teams collecting organs and tissues in the donor's hospital are obliged to the strict compliance with epidemiologic procedures in force in a given hospital. A hospital organ and tissue collection coordinator supervises the observation of procedures. Through Poltransplant, the coordinator at the donor's hospital must pass any information on the special rules of the sanitary regime in force at the donor's hospital (a COVID-19−free pathway) to collecting teams.

15. Limitations for storing and transplanting organs and grafting eye tissues at multispecialist hospitals of the third-level system of hospital service provision for patients with COVID-19

An activity based on the storage and transplant of organs and grafting of eye tissues is suspended in multispecialist hospitals of the third-level system of hospital service provision for patients with COVID-19.

Patients eligible for therapies by means of grafting extrarenal organs or ocular tissues enrolled in the national list of patients waiting for a graft in an entity where the transplant activity has been suspended should be transferred into another transplant center, stating the eligibility, in accordance with the procedure called "Management Rules for Centres Transplanting the Liver,

the Heart and the Lungs in the Case of Transplant Activity Suspension".[2] If several medicinal establishments (hospitals) are contained in the health care entity and only 1 of them is designated as a multispecialist hospital of the third-level system of hospital service provision for patients with COVID-19, storing and transplanting organs and eye tissues are allowed provided that a detailed analysis of the epidemiologic risk has been undertaken.

This entity is obliged to immediately apply for a new authorization for storing and transplanting organs in a new location to the Minister of Health.

If a multispecialist hospital of the third-level system of hospital service provision for patients with COVID-19 houses a zone for the treatment of patients without COVID-19 (these hospitals may also provide services to patients who are not infected with SARS-CoV-2), strictly separated from the section of the hospital designated for patients who are infected with SARS-CoV-2 (separate entrance, corridors, lifts, staircases, hospital wards, operating rooms, recovery rooms, intensive care rooms, etc), this zone is entitled to serve for transplant of organs and ocular tissues provided that a detailed analysis of the epidemiologic risk has been undertaken.

A decision on the aforementioned issues is made by the hospital's managerial staff. The decision should take into account the limitations as to the provision of health care services to patients other than those suspected of or infected with SARS-CoV-2 by medical professionals having direct contact with patients suspected of or infected with SARS-CoV-2.

16. Hospitals excluded from the collection and transplant activities owing to the suspended operation of key departments involved in the collection and transplant of organs and tissues

In hospitals where departments such as surgery, operating theaters, orthopedics, ophthalmology, neurology, anesthesiology and intensive care units, and/or postoperative departments have been temporarily closed because of SARS-CoV-2 infections, activities such as recruiting deceased donors, procuring organs and tissues, and transplanting organs and tissues (depending on the department's profile) are suspended.

Patients eligible for the transplant of nonrenal organs or eye tissues (enrolled in the national waiting list) in a health care entity in which the transplant activities have been suspended should be transferred to another transplant (qualification) center in accordance with the procedure of the "Operating Guidelines for Liver, Heart and Lung Transplant Centres in the Event That the Transplantation Activity Is Suspended" [2]

17. Transplant recipient's informed consent

Where possible, the recipient is informed in an impartial manner about the possible risk of transmission of SARS-CoV-2 infection and provides an explicit consent for the transplant as far as this risk is concerned.

18. Recipient's posttransplant isolation

The recipient should be subject to posttransplant isolation, to the extent possible (COVID-19−free pathways), for the sake of their own safety and for the safety of other patients and that of the medical staff.

19. Examination of recipients directly before the transplant

A clinical and epidemiologic examination of the potential organ or cornea recipient immediately prior to the transplant is mandatory.

It is also mandatory to perform gene or antigen testing in all potential recipients immediately prior to the transplant. In some cases, the test results may be available only after the transplant, but it will nevertheless allow the appropriate treatment and epidemiologic precautions to be applied.

For kidney recipients, the result of a test for coronavirus infection should preferably be available before the transplant procedure.

A chest CT scan is recommended in all recipients immediately prior to the transplant.

20. Kidney transfer to a transplant center where the recipient was found eligible for transplant

In order to limit the patient's transit, in the event that a recipient from a remote transplant center is selected for transplant, the kidney should be sent to this center as quickly as possible and after the appropriate arrangements have been made between the health care centers.

21. Activities of centers that qualify patients for transplant

Procedures for recipient eligibility assessment for an organ and cornea transplant involving recipient admission to the qualifying center or transfer to another center should be limited. The eligibility assessment process, whenever possible, should be carried out remotely with the use of informatic connection technology.

22. Patient information update in the national waiting list

On obtaining information from the attending physician of a potential recipient (eg, from dialysis centers or cardiology, hepatology, pulmonology centers) or directly from the patient concerning their health status, centers that qualify patients for a transplant will make an appropriate entry in the national waiting list register, including appropriate changes in the patient's transplant status, as applicable. Updating the patient information should not entail any additional hospitalization or patient transfer from one center to another.

23. Prior consent of the patient or lack thereof for an organ transplant

The mandatory explicit recipient's consent for a renal transplant as far as the risk of COVID-19 is concerned may be obtained in advance, that is, before a patient is called for a transplant, after being enrolled in the transplant waiting list. On

receiving the patient's consent, the qualifying centers should enter this information in the national waiting list register. If a patient refuses to grant their consent, the patient's status should be changed to "temporarily suspended."

24. Vaccinations against seasonal influenza in potential and actual graft recipients treated with immunosuppression

These vaccinations are recommended, bearing in mind any possible contraindications, that is, hypersensitivity to preparation ingredients (eg, an allergy to chicken, egg protein), an acute infection, or a fever-accompanied disease.

25. Vaccinations against COVID-19 in the potential recipients of organ grafts

In patients with organ insufficiency, the risk of a serious case of COVID-19 is high. Therefore, in the case of the mRNA Pfizer/BioNTech vaccine, vaccinations are advised for people enrolled in the national list of awaiting patients considering possible contraindications (a past serious allergic response to Comirnaty preparation ingredients).

If possible, potential recipients should be subjected to full vaccinations before transplant.

26. Vaccination against COVID-19 in potential and actual tissue transplant recipients who do not require any immunosuppressive treatment

It is recommended to fully vaccinate this patient population, taking into account the possible contraindications (a history of severe allergic reaction to the components of Comirnaty formulation).

27. Vaccination against COVID-19 in potential and actual living donors

It is recommended to fully vaccinate living donors, taking into account the possible contraindications (a history of severe allergic reaction to the components of Comirnaty formulation).

28. Vaccination against COVID-19 in actual organ or tissue transplant recipients who require immunosuppressive treatment

Immunocompromised persons are more likely to develop severe COVID-19. Currently there is insufficient evidence to assess the vaccine efficacy (mRNA, Pfizer/BioNTech) and the risks of vaccination in severely immunocompromised persons. The immune response to the vaccine may be altered, which could make the vaccine less effective. However, immunocompromised individuals can be vaccinated because the vaccine does not contain any live virus. Individual risk-benefit analysis when deciding whether to vaccinate should be based on the available information on vaccination safety and efficacy, according to the guidance of the World Health Organization of January 8, 2021:

It is recommended to delay vaccination against COVID-19 until approx. 1 month after organ or cell transplantation. Due to immunosuppression, a lower immune response can be expected after vaccination, especially after depletion-based immunosuppression (Thymoglobulin, ATG), in which case vaccination is recommended to be delayed until 3-6 months after the transplant. (According to recommendations of the national consultant in the field of clinical transplantation, dated 8 January 2021).[3]

29. Vaccination against COVID-19 in health care professionals involved in transplant activities

It is recommended that health care professionals be fully vaccinated, taking into account the possible contraindications (a history of severe allergic reaction to the components of Comirnaty formulation).

30. Preparation of transplant centers for long-term care of transplant recipients with COVID-19

Transplant recipients infected with SARS-CoV-2 often require in-patient treatment, including surgical treatment. It is impossible to predict the length of the COVID-19 pandemic. The emergency treatment of transplant recipients (eg, treatment at a department unrelated to transplant medicine) should be replaced with systemic solutions. Procedures should be introduced in transplant centers to be able to manage transplant recipients with COVID-19 in a manner that is safe for other patients and staff. The preparedness of transplant centers for the management of transplant recipients with COVID-19 will be assessed during inspections related to the granting of the Health Minister's authorization for transplant activities.

31. Transferring recipients to regional centers

In order to limit the transfer of actual organ recipients to distant transplant centers, it is recommended that the patient be transferred as soon as possible to a transplant center closer to the recipient's place of residence, after appropriate arrangements have been made, along with an entry to the online tool regitx.gov.pl. The transfer method of the recipient to another transplant center is described in the 2016 Poltransplant Information Bulletin "Procedure for Transferring Transplant Recipient to Another Transplant Center."[4]

32. Safety of health care personnel involved in transplant activities

Donor infection poses a risk to the recipient. The procurement teams, transplant teams, staff of tissue compliance laboratories, and staff of tissue banks will strictly follow the epidemiologic procedures adopted in a given unit to account for the risk of infection among health care personnel.

33. Suspicion of infection in recipients and the health care personnel

If a potential recipient, actual recipient, or member of the transplant team is suspected of being infected, the rules of epidemiologic management have to be strictly followed (depending on the circumstances: recusal of the staff member concerned from the procedure, isolation, quarantine, gene or antigen tests).

ADDITIONAL INFORMATION

Definitions of a COVID-19 Case[5]

GIS: Definitions of a COVID-19 case for the needs of epidemiologic supervision over SARS-COV-2 infections (definition from October 31, 2020, with Poltransplant comments).

Clinical Criteria

Every person who experiences at least 1 of the following symptoms:

- Cough
- Fever
- Dyspnea
- Anosmia of a sudden onset
- Ageusia or taste disorders of a sudden onset

Poltransplant's alternative criteria consists of the following: When patients are in a condition of a sudden life or health threat due to injury, stroke, a cardiologic cause, or other reasons for a sudden worsening of their health condition.

Imaging Diagnostics Criterion

- Changes in a radiologic image of the lungs indicating COVID−19
- Poltransplant: Specific symptoms of pneumonia in the infection with coronavirus are manifested by densities of a frosted glass type or mixed of a frosted glass type and vesicular (consolidated).

Laboratory Criteria

- The detection of SARS-CoV-2 nucleic acid in a clinical material
- The detection of SARS-CoV-2 antigen(s) in a clinical material

Samples of clinical material from the lower airways (bronchoalveolar lavage, bronchoaspirate, expectoration) have a greater diagnostic value than samples from the upper airways (eg, an epipharyngeal swab).

Epidemiologic Criteria

Every person who meets at least 1 of the following criteria within the 14 days before the development of symptoms:

1. A person who had close contact with an individual infected with SARS-CoV-2 (contact with a confirmed or probable case). The close contact should be understood as:
- Staying in a direct vicinity (face-to-face) with a sick person within a distance less than 2 m for more than 15 minutes
- Direct physical contact with a person infected with SARS-CoV-2
- Direct contact without protective measures taken against secretions of patients with COVID-19 (eg, touching a used tissue, exposure to a sick person's cough)
- Contact on board a plane or other means of public transport covering people occupying 2 seats (in every direction) counting from a seat occupied by a COVID-19−affected person, people accompanying the person infected with SARS-CoV-2, his or her caregivers, or crew members serving in a section where the person infected with SARS-CoV-2 stayed

2. Medical staff or another person directly involved in the care of a COVID−19−affected patient, or a person at a laboratory working directly with samples of patients with COVID−19 without adequate protection, in the case when damage occurred to personal protection measures in use, or in the case of their improper use.
3. Stayed as a guest or constituted a staff member of a social care center or a long-term care institution where the transmission of COVID-19 has been reported.

Classification of COVID-19 Cases

A. A possible case: every person meeting clinical criteria
B. A probable case:
- Every person meeting a clinical or epidemiologic criterion or
- Every person meeting a clinical criterion in the form of an olfaction loss of a sudden onset and/or of taste disorder of a sudden onset or
- Every person meeting a diagnostic imaging criterion

C. A confirmed case: every person meeting the laboratory criteria for confirmed cases

Conditions and Criteria for the Termination of Isolation (Recovery)

The Regulation of the Minister of Health of September 1, 2020, amending the regulation on infectious diseases resulting in mandatory hospitalization, isolation or self-isolation, and the mandatory quarantine or epidemiologic supervision (Journal of Laws of 2020, item 1506) applies.

Amendments to the Transplant Regulations Regarding the Carrying Out of Inspections and the Issuing of Authorizations for Transplant Activities by the Minister of Health

Amendments under the Act of March 31, 2020, amending specific acts on the health care system related to the prevention of, counteracting, and combating COVID-19 (Journal of Laws of March 31, 2020, item 567, Articles 6 and 17):

The minister competent for health may postpone the inspection (of a tissue and cell bank in connection with a suspicion of serious adverse reaction or a serious adverse event or periodic inspection carried out in accordance with the Transplant Act, every 2 years) on one occasion, for no longer than 6 months from the date on which 2 years have elapsed from the date of the last inspection. If the circumstances on the basis of which the inspection postponement was based persist, the minister

competent for health may further postpone the inspection for a period of up to 3 months.

If the proper operation of (tissue and cell banks, or as may otherwise apply) needs to be secured or in other urgent cases . . . the minister competent for health may order an inspection to be carried out via the ICT system or a connection system.

Authorizations to perform activities (collection of cells, tissues, and organs from living donors, organ storage, transplantation or use of cells, tissues, or organs to humans) which expire on 31 December 2020 following the five-year period of validity shall be extended by 6 months counting from the date of their expiry.

Changes Resulting From the Amendment to the Regulation on the Conduct of Inspections

Amendments resulting from the Regulation of the Ministry of Health of April 27, 2020, amending the regulation on the procedure for carrying out inspections in health care entities involved in the collection, storage, and transplant of cells, tissues, and organs (Journal of Laws 2020, item 766).

The amending regulation describes in detail the method of carrying out the inspections remotely, via an ICT system or a connection system.

Restrictions in the Provision of Health Services That Apply to the Health Care Personnel Working in Hospitals for Infectious Diseases

Regulation of the Minister of Health of April 28, 2020, on standards regarding restrictions on the provision of health care services to patients other than those suspected of or infected with SARS-CoV-2 by medical professionals who have had direct contact with patients suspected of or infected with SARS-CoV-2 (Journal of Laws of 2020, item 775) and the amending regulation of July 22, 2020 (Journal of Laws of 2020, item 1275):

Individuals involved in the provision of healthcare services who hold positions specified in the List of Job Positions may not participate in the provision of healthcare services to patients other than those suspected of or infected with SARS-CoV-2. . . . This restriction does not apply . . . where the head of the healthcare entity issues a written consent that the individuals involved in the provision of healthcare services who hold positions specified in the List of Job Positions are authorized to provide healthcare services to patients at the healthcare entity concerned other than patients suspected of or infected with SARS-CoV-2, after introducing the necessary precautions to prevent the transmission of SARS-CoV-2 during the provision of these services by persons covered by this restriction.

The List of Job Positions may only include job positions of healthcare professionals who are involved in . . . the provision of healthcare services in direct contact with patients suspected of or infected with SARS-CoV-2, and those associated with an increased risk of infection with SARS-CoV-2.

Excerpts From Literature Concerning Vaccination Against COVID-19 in Transplant Recipients

1. Recommendations of the National Advisory Committees on Immunization in the United Kingdom, Canada, and the United States, where the Pfizer/BioNTech mRNA vaccine has been approved for the COVID-19 vaccination program: vaccination is not recommended during immunosuppressive treatment as no clinical trials have been conducted in this group.[6]
2. World Health Organization: Interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use listing, January 8, 2021: Immunocompromised persons (ICPs) are at higher risk of severe COVID-19. Currently there is insufficient evidence to assess vaccine efficacy and the risks of vaccination in severely immunocompromised persons. The immune response to the vaccine may be altered, which could make the vaccine less effective. However, immunocompromised individuals can be vaccinated as the vaccine does not contain any live virus. Individual risk-benefit analysis when deciding whether or not to vaccinate should be based on the available information on vaccination safety and efficacy.[3]
3. The American Society of Transplantation COVID-19 Vaccine FAQ Sheet (released August 12, 2020): The effectiveness of COVID-19 vaccines will need to be further studied in the solid organ transplant recipient. Solid organ transplant recipients may have generally lower antibody responses than those without transplants. Patients vaccinated pre-transplant, may have reduced protection post-transplant, particularly if therapies that reduce B-cell function (eg, rituximab) are utilized.[7]
4. Summary of Product Characteristics and Package Leaflet for the COVID-19 mRNA vaccine (with modified nucleosides) Comirnaty from Pfizer/BioNTech: The efficacy and safety of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of Comirnaty may be lower in immunocompromised individuals.
5. COVID-19 vaccination for adult patients with kidney disease: a position statement from the UK renal community: Although initial clinical trials of COVID-19 vaccines did not include immunosuppressed patients, we would expect the vaccines to offer protection against COVID-19 infection in these extremely vulnerable patients.[8,9]

The standpoint of the national consultant in the field of clinical transplantation, on vaccinations in transplant recipients was expressed in a letter to the Ministry of Health dated January 8, 2021:

1. Vaccinations against SARS-CoV-2 are recommended in patients before a planned organ or cell transplant.
2. There was no difference identified between the available gene-based vaccines, including those from Pfizer and Moderna, for transplant patients.

3. It is recommended to delay vaccination against COVID-19 until approx. 1 month after an organ or cell transplant.
4. Due to immunosuppression, a lower immune response can be expected after vaccination, especially after depletion-based immunosuppression (Thymoglobulin, ATG), in which case vaccination is recommended to be delayed until 3-6 months after the transplant.
5. Vaccination against SARS-CoV-2 is deemed to be a better option in patients post organ and cell transplantation, despite the risk of a lower response to vaccination, as opposed to full blown COVID-19 disease.
6. Indications for vaccination against COVID-2 are examined individually by the attending physicians of transplant patients at transplant clinics.
7. Recommendations suggesting that patients on recipient lists and transplant recipients should be vaccinated against COVID-19 at the earliest opportunity are sent to the Ministry of Health.

Activity in the Area of Transplant Medicine During a 10-Month Period of the Pandemic in Poland (March 2020 to December 2020)

- The number of potential deceased donors reported to Poltransplant considerably decreased during the pandemic; an index of mean monthly activity from November 2018 until February 2020 was 31/54 = 0.57.
- The number of organ collections from deceased donors was considerably reduced during the pandemic; an index of mean monthly activity from November 2018 until February 2020 compared to monthly activity from November 2018 until February 2020 was 24/42 = 0.58.
- An index of medical exclusions from collections in the group of reported potential deceased donors increased during the pandemic up to 13% in comparison with 11% in the period before the pandemic.
- The number of all organ transplants from deceased donors considerably decreased during the pandemic; an index of mean monthly activity from March until December 2020 compared to mean monthly activity from November 2018 until February 2020 was 76/118 = 0.64.
- The number of renal transplants from deceased donors considerably decreased during the pandemic; an index of mean monthly activity from March until December 2020 compared to mean monthly activity from November 2018 until February 2020 was 45/75 = 0.60.
- The number of renal transplants from live donors considerably decreased during the pandemic; an index of mean monthly activity from March until December 2020 compared to mean monthly activity from November 2018 until February 2020 was 2.5/4 = 0.63.
- The number of hepatic transplants from deceased donors considerably decreased during the pandemic; an index of mean monthly activity from March until December 2020 compared to mean monthly activity from November 2018 until February 2020 was 17/27 = 0.63.
- The number of patients eligible for organ transplant de novo (all organs) considerably decreased during the pandemic; an index of mean monthly activity from March 2020 to December 2020 compared with mean monthly activity from November 2018 to February 2020 was 111/160 = 0.69: 55/91 = 0.60, 28/34 = 0.82, and 19/26 = 0.76 for the kidney, the liver, and the heart, respectively.

Ethics Statement

In Poland, organs are procured from a deceased person when all possibilities for treatment have been exhausted and the death has been diagnosed according to neurologic or circulatory criteria. Thus, Poland follows the Helsinki Congress and the Istanbul Declaration rules regarding donor recruitment.

DECLARATION OF COMPETING INTEREST

None.

REFERENCES

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