












**BRIEF COMMUNICATION**

# Liver transplantation from active COVID-19 donors: Is it ethically justifiable?

Alessandra Agnese Grossi<sup>1,2</sup>  | Federico Nicolì<sup>1,3</sup>  | Massimo Cardillo<sup>4</sup>  |  
Salvatore Gruttadauria<sup>5,6</sup>  | Giuseppe Tisone<sup>7</sup>  | Giuseppe Maria Ettore<sup>8</sup>  |  
Luciano De Carlis<sup>9</sup>  | Renato Romagnoli<sup>10</sup>  | Carlo Petrini<sup>11</sup>  |  
Paolo Antonio Grossi<sup>4,12</sup>  | Mario Picozzi<sup>1</sup> 

<sup>1</sup>Center for Clinical Ethics, Department of Biotechnologies and Life Sciences, University of Insubria, Varese, Italy

<sup>2</sup>Department of Human Sciences, Innovation and Territory, University of Insubria, Varese, Italy

<sup>3</sup>Clinical Ethics Service, Domus Salutis Clinic, Teresa Camplani Foundation, Brescia, Italy

<sup>4</sup>Italian National Transplantation Center (CNT), Italian National Institute of Health, Rome, Italy

<sup>5</sup>Department for the Treatment and Study of Abdominal Diseases and Abdominal Transplantation, IRCCS-ISMETT, UPMC (University of Pittsburgh Medical Center), Palermo, Italy

<sup>6</sup>Department of Surgery and Medical and Surgical Specialties, University of Catania, Catania, Italy

<sup>7</sup>Department of Surgical Sciences, University of Rome - Tor Vergata, Rome, Italy

<sup>8</sup>Department of General and HBP Surgery, Liver Transplantation Service, San Camillo Forlanini Hospital, Rome, Italy

<sup>9</sup>General Surgery and Abdominal Transplantation Unit, University of Milano-Bicocca and Niguarda-Cà Granda Hospital, Milan, Italy

<sup>10</sup>General Surgery 2U and Liver Transplantation Center, AOU Città della Salute e della Scienza di Torino, University of Turin, Turin, Italy

<sup>11</sup>Bioethics Unit, Italian National Institute of Health (ISS), Rome, Italy

<sup>12</sup>Department of Medicine and Surgery, Infectious and Tropical Diseases Unit, University of Insubria, ASST Sette Laghi, Varese, Italy

**Correspondence**

Paolo Antonio Grossi, Department of Medicine and Surgery, Infectious and Tropical Diseases Unit, University of Insubria, ASST Sette Laghi, Varese, Italy.

Email: [paolo.grossi@uninsubria.it](mailto:paolo.grossi@uninsubria.it)

**Abstract**

The debate on the opportunity to use organs from donors testing positive for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in recipients with naïve resolved or active COVID-19 is ongoing. We aim to present the ethical analyses underlying the decision to perform liver transplantation (LT) in selected patients with resolved or active COVID-19 in Italy. We used Jonsen, Siegler, and Winslade's Four-Boxes casuistic method, addressing the four topics considered as constitutive of the essential structure of single clinical cases for their ethical analysis (medical indications, patient preferences, quality of life, and contextual features) to enable decision-making on a case-by-case basis. Based on these topics, we elucidate the meaning and balance among the principles of biomedical ethics. Clinical ethics judgment based on the relation between the risk of acquiring SARS-CoV-2 along with its potentially negative effects and the expected benefits of transplant lead to consider LT as clinically appropriate. Shared decision-making allows the integration of clinical options with the patient's subjective preferences and considerations, enabling a valid informed consent specifically tailored to the patients' individual circumstances. The inclusion of carefully selected SARS-CoV-2 positive donors represents an opportunity to offer lifesaving LT



to patients who might otherwise have limited opportunities to receive one. COVID-19 positive donor livers are fairly allocated among equals, and respect for fundamental rights of the individual and the broader community in a context of healthcare rationing is guaranteed. The ethical analysis of the decision to perform LT in selected patients shows that the decision is ethically justifiable.

#### KEYWORDS

COVID-19 donors, ethics, liver transplantation

## 1 | INTRODUCTION

The coronavirus disease (COVID)-19 public health emergency has affected healthcare systems with an unprecedented impact on hospital settings and standards of care, including organ donation and transplantation activities.<sup>1</sup> Italy was the first Western country to be severely hit by the pandemic. Yet, it reported a lower decrease (less than 10%) in organ donation and transplantation relative to other European countries (United Kingdom –27%, France –25%, Spain –19%), being second only to Germany (–7%).<sup>2</sup> Multiple efforts were made by the Italian National Transplantation Center (CNT) to mitigate the disruptive effect of COVID-19 on the transplant activity.<sup>3,4</sup> Although it was initially recommended to exclude the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection in both potential deceased donors and transplant recipients,<sup>5</sup> the debate on the opportunity to use organs from donors testing positive for SARS-CoV-2 in naïve recipients<sup>6</sup> or with resolved or active COVID-19 is ongoing.<sup>7</sup> In November 2020, for the first time in Europe, the CNT developed protocolled indications (from here onwards “protocol”) to enable the use of carefully selected deceased donors testing positive for SARS-CoV-2 for a selected group of patients wait-listed for liver transplantation

**TABLE 1** Italian protocol on the use of organs from SARS-CoV-2 positive donors (1951/CNT 2020 1-Dec-2020)

Organs from donors with active SARS-Cov-2 infection may be considered exclusively from donors with **asymptomatic infection** who **died for causes unrelated to COVID-19**.

Organs may be offered to:

**Patients wait-listed for liver transplantation with severe clinical conditions**

- (a) With asymptomatic SARS-CoV-2 infection
- (b) With a history of resolved COVID-19
- (c) Fully vaccinated with a mRNA vaccine (three doses) and documented seroconversion (update January 2022)

*Note:* The protocol includes also patients wait-listed for heart and kidney transplantation. The same criteria of liver transplant candidates apply to patients wait-listed for heart transplant. In contrast, the criteria for patients wait-listed for kidney transplant exclude criterion (a).

Abbreviations: COVID-19, coronavirus disease 19; SARS-CoV-2, Severe Acute Respiratory Syndrome Coronavirus 2.

(LT) with resolved or active COVID-19 (in January 2022, the protocol was extended also to fully vaccinated recipients) (Table 1),<sup>8,9</sup> in line with prior reports providing arguments on the opportunity to do so.<sup>10</sup> A selected number of donors/recipients meeting well-defined criteria were approved for the transplant procedure following a case-by-case analysis.<sup>7</sup> Case analysis was performed by single transplant teams, the CNT, and the national infectious disease second opinion. Besides, specifically tailored patient and family informed consent (IC) were developed along with a request for the patient’s agreement to post-transplant monitoring.<sup>9</sup> This contribution aims to present the ethical analyses underlying the decision to perform the 10 consecutive LTs in selected patients between November 20, 2020 and February 8, 2021 across five transplant centers in Italy<sup>7</sup> (as of March 31st 2022, a total of 45 whole LTs and five split LTs have been performed from SARS-CoV-2 positive donors).<sup>11</sup>

## 2 | METHODS

We used the Four-Boxes casuistic method by Jonsen, Siegler, and Winslade<sup>12</sup> to enable decision-making on a case-by-case basis. There are numerous models of moral reasoning. Deductive theories begin with abstract theories that are then applied to particular moral problems. Inductive theories begin with particular cases and draw general rules from them. The Four-Boxes method (i.e., inductive) is easier for use in transplant clinical practice, where the involvement of various specialists requires a common language. Consideration of Beauchamp and Childress’s<sup>13</sup> principles of biomedical ethics (autonomy, beneficence, nonmaleficence, justice) is critical to resolve the difficult ethical conundrums posed by clinical cases. The Four-Boxes method relates the principles of biomedical ethics with particular contexts and guides action in specific circumstances.<sup>12</sup> The Four-Boxes method does not provide answers directly; it is a method for organizing data and ethical reasoning into four topics, namely medical indications, patient preferences, quality of life, and contextual features and allows to draw conclusions. The Four-Boxes ability to enable the analysis of single clinical cases and to grasp their unique features, as recommended by the CNT protocol, justifies the choice of this method.



## 3 | RESULTS

### 3.1 | Medical indications

Recommendations against the use of SARS-CoV-2 positive donors and exclusion of transplant eligibility in SARS-CoV-2 positive recipients are aimed at preventing the potential for SARS-CoV-2 transmission through organ transplant with the potential for serious clinical manifestations with posttransplant immunosuppression and in the absence of effective targeted treatments in the event of transmission.<sup>10</sup> While evidence of transplants from SARS-CoV-2 positive donors remains limited,<sup>6,14–18</sup> studies suggest that transmission of SARS-CoV-2 has been reported only in lung transplant recipients.<sup>17,19</sup> In the analyzed cases, liver donors were all either asymptomatic or paucisymptomatic, with a donor risk index ranging between 1.11 and 2.41 and with a cause of brain death considered unrelated to COVID-19 (two trauma, seven cerebrovascular, one meningitis). Recipients were all active candidates for LT and presented serious clinical conditions (half had alcohol cirrhosis, and 40% had hepatocellular carcinoma; the model for end stage liver disease score at LT ranged between 7 and 35, and one patient had a pediatric end stage liver disease score of 2). Most had a recent history of COVID-19 ( $n = 8$ ) or tested positive for SARS-CoV-2 ( $n = 2$ ). Therefore, in line with prior evidence,<sup>20</sup> the majority of them (five of seven) had sufficiently high titers of neutralizing antibodies to protect them against the SARS-CoV-2 infection. Further, testing for SARS-CoV-2 RNA on donors' liver biopsy at the time of transplant was negative in all cases except one which was not tested, suggesting a very low risk of transmission by LT.<sup>7</sup> Additionally, an analogy exists with transplants from Human Immunodeficiency Virus (HIV)- and Hepatitis C Virus (HCV)-positive donors for HIV- and HCV-positive recipients in that the recipients are not exposed to the potential risk of acquiring the infection through transplantation.<sup>21,22</sup> Clinical ethics judgment is based on the relation between the risk of acquiring SARS-CoV-2 along with its potentially negative effects (clinical factors) and the expected benefits of transplant (the patient's quality and quantity of life).<sup>23</sup> The patients in this protocol needed an LT, they had recently recovered from COVID-19 so the risk of transmission was low, and there was evidence from small case series of good outcomes from SARS-CoV-2 positive liver donors. Because Medical indications are based on the balance between the principles of beneficence—expected benefits of transplantation - and nonmaleficence - risk of acquiring SARS-CoV-2 for transplant recipients—these considerations have led multidisciplinary teams to consider transplantation as clinically appropriate.

### 3.2 | Patient preferences

The patient consent to receive LT from a SARS-CoV-2 positive donor is based on the balance between the scientifically calculated low risk to acquire COVID-19 through transplantation and the opportunity to receive a life-saving organ (i.e., medical indications).<sup>13</sup>

Patients gave IC after receiving information of the risks associated with the acuity of their clinical condition and an assessment of the possible consequences of every clinically viable option, including refusal of the procedure and remaining on the waiting list (WL). Besides, patients were informed about areas of absent or emerging data and the anticipated risks and potential benefits of transplantation at that time according to the physicians' opinion related to each patient's individual features (the IC form used at transplant centers in Italy is reported in the [Supplementary Appendix](#)). Patient autonomy should also be considered in relation to the principles of beneficence and nonmaleficence. Yet, patient preferences relate primarily with the principle of respect for autonomy,<sup>12</sup> which finds its practical application (at the micro-level) in the IC process.<sup>24</sup> When faced with high risk procedures, with low levels of certainty, and when multiple treatment options exist, shared decision-making and IC should coincide so as to allow the integration of clinical options with the patient's subjective preferences and considerations, enabling a valid IC tailored to the patients' individual circumstances.<sup>24,25</sup>

Respect for the principle of autonomy is particularly tenuous in an exceptional pandemic context characterized by uncertainty and fear. Patient preferences may include the preference to receive transplant or not at a given point in time, but also more abstract preferences like risk-aversion or boldness, or a desire to advance science. In the Italian context, patients are informed about the risks and benefits of accepting nonstandard risk donor organs. Therefore, although evidence of the outcomes of LT by use of COVID-19 positive donors remains limited, it is likely that patients had been previously informed that acceptance of a nonstandard risk donor liver would be more beneficial than remaining on the WL in the event of a decline of their clinical condition.<sup>24</sup>

Based on these considerations, we contend that, despite uncertainty, IC was ethically appropriate. Yet, because we did not formally assess whether IC was subjectively meaningful to recipients in this study, this accounts as a study limitation. Studies are needed to determine the recipients' understanding and satisfaction with IC about COVID-19 positive donors.

### 3.3 | Quality of life

The Quality of life section primarily addresses the question of what the prospects are, “with or without treatment, for return to normal life and what physical, mental, and social deficits might the patient experience even if treatment succeeds.”<sup>12</sup> Based on the protocol criteria, the ability to procure donor livers from COVID-19 positive donors allowed to offer a chance to subjects with a high risk of mortality, and/or who were likely to drop out from the WL because of worsening clinical conditions compromising the potential benefit of transplantation.<sup>7</sup> For instance, delayed transplant might still lead to unfavorable outcomes due to deteriorating clinical conditions. Further, frequent healthcare contacts may increase the patient's exposure to the potential risk of acquiring the SARS-CoV-2 infection. Therefore, the inclusion of carefully selected SARS-CoV-2 positive donors represented an opportunity

**TABLE 2** Prescribed conditions and measures to enable balance among the principles of biomedical ethics

Prescribed conditions	Specific measures adopted to enable the balance among principles
(a) The moral objective justifying the action is realistically attainable.	<ul style="list-style-type: none"> <li>The ability to offer survival opportunity is justified provided the scientifically calculated risks and the expected benefits of transplantation.</li> </ul>
(b) No morally preferable alternative actions are available.	<ul style="list-style-type: none"> <li>Postponement of transplantation may lead to unfavorable outcomes such as wait-list withdrawal or death due to deteriorating clinical conditions.</li> <li>Frequent healthcare contacts may increase the patient's exposure to the potential risk of acquiring the SARS-CoV-2 infection.</li> </ul>
(c) Any negative effects of the action have been minimized.	<ul style="list-style-type: none"> <li>Liver donors were either asymptomatic or paucisymptomatic.</li> <li>The cause of donor's brain death was unrelated to COVID-19.</li> <li>Recipients had sufficiently high titers of neutralizing antibodies to protect them against the SARS-CoV-2 infection.</li> <li>Testing for SARS-CoV-2 RNA on donors' liver biopsy at the time of transplant was negative, suggesting a very low risk of transmission by liver transplantation.</li> <li>Despite uncertainty, by reviewing anticipated risks and potential benefits and by acknowledging areas of absent or emerging data, along with patient involvement in decision-making, it was possible to obtain an ethically appropriate IC.</li> </ul>
(d) All patients have been treated impartially.	<ul style="list-style-type: none"> <li>COVID-19 positive donor livers are fairly allocated among equals (i.e., clinically eligible recipients with resolved or active COVID-19 or—since January 2022—fully vaccinated with a mRNA vaccine).</li> <li>Because an analogy exists between COVID-19 patients and patients in need of an urgent transplant requiring ICU, both are assigned the same priority in accordance with the principle of equity.</li> </ul>

Note: This table summarizes some of the prescribed conditions to balance the principles as presented by Beauchamp and Childress, and their application to the specific issue of performing liver transplants from donors with active COVID-19 in recipients with resolved or active COVID-19.

Abbreviations: COVID-19, coronavirus disease 19; IC, informed consent; ICU, intensive care unit; SARS-CoV-2, Severe Acute Respiratory Syndrome Coronavirus 2.

to offer lifesaving transplant to patients who might otherwise have limited opportunities to receive one for a variety of reasons (limited time due to disease acuity and severity, and/or limited matches related to blood type and/or sensitization status).<sup>10</sup> Besides, it is likely that the recipients' quality and quantity of life would be improved after LT relative to remaining on the WL and wait for a different donor offer.<sup>26,27</sup> Therefore, the protocol appears to be ethically sound in its ability to promote the patient's good. However, we did not explore the recipients' quality of life following LT. While this stands as a potential limitation of this study, research on these aspects is warranted.

### 3.4 | Contextual features

Studies have stressed that contextual features (geographical area along with its cultural values, available resources, and local epidemiological data) are key factors to balance the COVID-19 burden and the ability to respond effectively to the needs of individual patients waiting for transplant.<sup>28</sup> From this perspective, contextual features require consideration of the macro and meso levels, (the national healthcare systems and individual transplant centers, respectively) relative to the need to allocate resources to the process of transplantation in a context of healthcare rationing. At the macro-level, the Italian constitution promotes the cultural values of solidarity, equity, and health protection as fundamental rights of the individual and collective interest. As such, the resource needs of patients in need of transplant such as COVID-19 free intensive care unit (ICU) pathways after surgery must be balanced with the competing needs of COVID-19 patients requiring mechanical

ventilation in ICUs. COVID-19 patients may be in a life-threatening condition requiring ICU hospitalization, and, in the absence of comorbidities, they have a generally good prognosis. Similarly, patients waiting for LT have a serious, life-threatening condition, require ICU hospitalization following surgery, and have a very good prognosis in the event of transplantation. Therefore, given the analogy between COVID-19 patients and patients in need of an urgent transplant, both should be assigned the same priority in accordance with the principle of equity.<sup>29</sup>

At the meso-level, the potential for higher WL mortality associated with the COVID-19 burden requires consideration of WL mortality rates at single transplant centers and the need to ensure life-saving transplants even during the peaks of the pandemic.<sup>29,30</sup>

The principles at stake are those of *fairness* (moral characteristic relevant to transactions and relationships between individuals) and *justice* (equitable distribution of benefits for individual patients and additional resources requested of the healthcare systems),<sup>12</sup> which are inherent and critical to the field of organ transplantation. In regard to this, the protocol respects the principle of justice in that COVID-19 positive donor organs are fairly allocated among equals (i.e., clinically eligible recipients with resolved or active COVID-19), as previously noted for transplants from HIV- and HCV-positive donors for HIV- and HCV-positive recipients.<sup>21,22</sup> Further, while reviewing the distribution among different transplant centers depending on pandemic-related burdens (local resource availability, community rate of infection, competing needs for ICU and operating room beds, staff, etc.), the continuity of organ donation and transplantation activity was ensured.

## 4 | CONCLUSIONS

The analysis by the Four-Boxes method allowed examination of the balance among the principles of biomedical ethics (i.e., the process of finding reasons to support beliefs about which moral norms should prevail) as applied to the issue of performing LTs from donors with active COVID-19. As prescribed by Beauchamp and Childress,<sup>13</sup> the judgment about these specific cases shows the protocol's ability to balance between the weights (pandemic situation, risk of SARS-CoV-2 transmission, communication of uncertainty, imminent risk of death, local resource availability) and the strengths of norms (enhancing the patient's quantity and quality of life in a pandemic context, specifically tailored IC). Further, the balance among principles must be as rigorous as possible, requiring that specific conditions must be met. These imply that (a) the moral objective justifying the action is realistically attainable; (b) no morally preferable alternative actions are available, (c) any negative effects of the action have been minimized and, and (d) all patients have been treated impartially<sup>13</sup> (the measures to enable the balance among the principles of biomedical ethics as applied to the specific issue of performing LT from donors with active COVID-19 in recipients with resolved or active COVID-19 are summarized in Table 2).

Based on these considerations, the CNT protocol meets all conditions. Therefore, provided that studies are needed to determine the recipients' understanding and satisfaction with IC about COVID-19 positive donors and their quality-of-life following LT, the protocol may be considered ethically justifiable.

### CONFLICT OF INTEREST

The authors have no conflict of interest to disclose as described by *Transplant Infectious Disease*.

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### AUTHOR CONTRIBUTIONS

Alessandra Agnese Grossi and Federico Nicoli developed the conceptual framework, performed ethics analyses, and wrote the article. Massimo Cardillo, Salvatore Gruttadauria, Giuseppe Tisone, Giuseppe Maria Ettore, Luciano De Carlis, Renato Romagnoli, and Paolo Antonio Grossi provided data and insights of the protocol and clinical cases, critically revised, and approved the article. Mario Picozzi and Carlo Petrini contributed to ethics analyses, critically revised, and approved the article.

### ORCID

Alessandra Agnese Grossi  <https://orcid.org/0000-0002-2352-6756>

Federico Nicoli  <https://orcid.org/0000-0002-5590-6702>

Massimo Cardillo  <https://orcid.org/0000-0002-2776-2297>

Salvatore Gruttadauria  <https://orcid.org/0000-0002-9684-8035>

Giuseppe Tisone  <https://orcid.org/0000-0001-8860-5909>

Giuseppe Maria Ettore  <https://orcid.org/0000-0002-7501-5472>

Luciano De Carlis  <https://orcid.org/0000-0002-9133-8220>

Renato Romagnoli  <https://orcid.org/0000-0001-8340-8885>

Carlo Petrini  <https://orcid.org/0000-0002-7895-4440>

Paolo Antonio Grossi  <https://orcid.org/0000-0003-2883-5061>

Mario Picozzi  <https://orcid.org/0000-0001-5327-4441>

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#### SUPPORTING INFORMATION

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