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CONSENSUS STATEMENT

Ethical considerations regarding heart and lung transplantation and mechanical circulatory support during the COVID-19 pandemic: an ISHLT COVID-19 Task Force statement



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To understand the challenges for thoracic transplantation and mechanical circulatory support during the current coronavirus disease 2019 pandemic, we propose separating the effects of the pandemic into 5 distinct stages from a healthcare system perspective. We discuss how the classical ethical principles of utility, justice, and efficiency may need to be adapted, and we give specific recommendations for thoracic transplantation and mechanical circulatory support centers to balance their clinical decisions and strategies for advanced heart and lung disease during the current pandemic.

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The coronavirus disease 2019 (COVID-19) pandemic has disrupted healthcare services, requiring rationing of people and resources.^{1,2} Resource intensive therapy for advanced heart and lung failure will need to adapt to this new reality. We outline the classical ethical framework that

guides heart and lung transplantation and mechanical circulatory support (MCS) and discuss adaptations to this construct during different stages of the ongoing pandemic.

Thoracic transplantation and MCS before the COVID-19 pandemic

Generally, heart and lung transplantation centers face unique challenges. These include safe management of the waitlisted patient including bridging strategies, assessment

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and recovery of deceased organ donors, the need for long-distance travel, complex surgery, multidisciplinary post-operative care with uncertain rates of complications, and transitional care to a rehabilitation facility or home management. Ensuing are frequent clinic visits and surveillance testing, especially in the first few months. Similarly complicated care pathways and team engagement are required for MCS implantation.

Ethical considerations in thoracic transplantation and MCS

General ethical principles that govern the field include non-maleficence (do no harm), beneficence (do good), and respect for persons (autonomy). Some additional principles such as utility, justice, and efficiency need to be addressed before the circumstances of the crisis standards of care during the different stages of the pandemic are discussed.

Utility

Utility is defined as maximizing the expected overall good based on considerations of patient survival, graft survival, quality of life (QoL), availability of alternative treatments, and age.³ Because heart and lungs are vital organs and retransplantation is often not available, patient and graft survival are often coincident. QoL is an important consideration, but because of scarcity of organs for transplant and challenges in standardization of QoL assessments, improvement in QoL plays a lesser role in utility estimation for thoracic transplantation.⁴ When considering utility in terms of survival benefit, the recipient's age may also be relevant (although not determinative) as older age may be a risk marker for poor outcome.

Justice

Justice is a commitment to equitable access and fair allocation of donated organs. This includes considerations of medical urgency, the likelihood of finding a suitable organ in the future, waiting list time, first vs repeat transplants, age, and geographic fairness. Medical urgency means that those who are most severely ill should be given the highest priority, even if this may reduce overall utility. In addition, a commitment to justice may require prioritization of candidates who have reduced access to the donor pool because of factors such as immunologic sensitization. In contrast, waiting list time plays a lesser role when survival is the main determinant of priority. Age in the context of a just distribution of a life-saving treatment is interpreted as giving priority to those who have passed through fewer life cycles (childhood, young adulthood, middle age, and old age).^{5,6} Few thoracic transplant centers have operationalized this by defining an upper age limit for transplantation, but in some organ allocation systems, children are given priority. Geographic fairness in thoracic transplantation and MCS is problematic, as organ exchange may be limited by geographic distance (USA) or by regional or national borders.

Efficiency

Efficiency is the moral commitment to make the most out of scarce resources and avoid waste.⁷ Care for patients with advanced heart and lung disease may be resource intensive and more so in some than others. In thoracic transplant, efficiency consideration is used to avoid futile transplants of scarce organs. However, apart from that, most official allocation rules for heart or lung transplantation do not reduce the priority of patients that are expected to consume greater resources.

In summary, the estimation of survival benefit, with categorical emphasis on saving imminently threatened lives (Rule of Rescue), and the utilitarian estimation of expected survival are the dominating factors for organ allocation in thoracic transplantation or MCS. Generally, efficiency and other aspects of distributive justice play a lesser role.

Pandemic stages: A healthcare system perspective

To analyze how to adjust treatment strategies for advanced heart and lung disease, we propose separating the effects of the COVID-19 pandemic from a healthcare system perspective into different stages. Not all programs, centers, or health systems will go through all stages, but the challenges and ethical dilemmas faced in a particular stage may be similar (Figure 1).

The Anticipation stage

During this stage, the number of patients with COVID-19 admitted to the hospital is low (or zero) but expected to

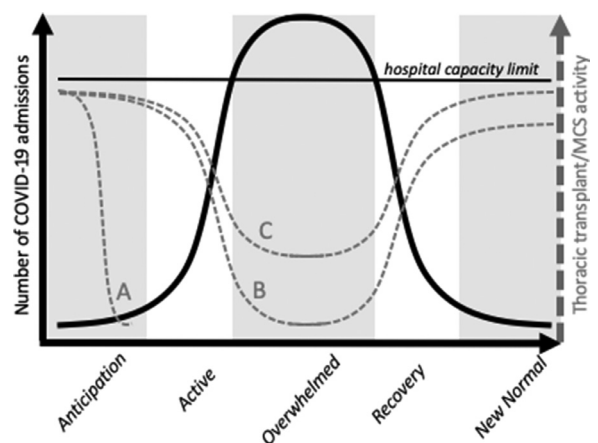


Figure 1 Adjustment of transplant activity during various stages of the COVID-19 pandemic. The black curve illustrates the admission rate of patients with COVID-19. The thin horizontal black line illustrates the capacity of the healthcare system. The gray dotted line marked A illustrates an exaggerated reduction of transplant and MCS in the Anticipation stage, and the gray dotted line marked B illustrates a total cessation of transplant and MCS activity during the Overwhelmed stage of the pandemic and a reduced volume after the pandemic. The gray dotted line marked C illustrates a measured reduction, balancing resource allocation to patients with COVID-19 and those without. COVID-19, coronavirus disease 2019; MCS, mechanical circulatory support.

increase. There are sufficient resources, but elective activities at the hospital may be pre-emptively reduced. Some travel restrictions and social distancing within the community may have been introduced, affecting scheduled care of patients. Risks from a health system perspective include underutilization of available resources and incomplete preparation for upcoming stages.

The Active stage

In this stage, an increasing number of patients with COVID-19 are hospitalized. The operations of the healthcare system remain functional, including adequate hospital capacity, medication availability, and staffing. Although there is no scarcity, resources need to be reallocated. Organ donation may decline. Risks include underutilization of available resources and transmission of infection to patients or healthcare workers (HCWs).

The Overwhelmed stage

In this stage, the number of patients with COVID-19 exceeds hospital capacity, with a large proportion of critically ill patients. Rationing of medical resources such as critical care capacity, staff, or personal protective equipment is necessary. Organ donation is severely reduced. The number of HCWs absent owing to infection, quarantine, or burn-out is substantial. Risks include inadequate care for infected patients and inefficient allocation of scarce resources between patients with COVID-19 and other patients, with high morbidity and mortality in both groups. There is a substantial risk of infection, exhaustion, and psychological trauma to HCW.

The Recovery stage

In this stage, the number of admissions for COVID-19 is decreasing, but secondary waves may occur. Normal activity may gradually resume. Resource availability is unpredictable. Augmented measures to prevent disease transmission are still needed. Risks include inefficient use of available resources and increased infection risks to patients and HCW due to pre-mature loosening of infection control practices.

The new normal stage

This is after the pandemic. Many hospital and outpatient clinic routines may have changed. Episodic bursts of local epidemics may still occur, resulting in a periodic need to reduce elective procedures and patient or HCW travel activity or in other intermittent resource restrictions. Overall hospital resource availability may be permanently changed as a result of the pandemic. Lessons learned during the pandemic may alter the healthcare workflow measurably and permanently in many cases.

Considering how the various stages of the pandemic might look from the healthcare institution perspective and

weighing the practical and ethical factors that characterize thoracic transplant and MCS, we have created a table that outlines the risks and opportunities in each stage (Table 1).

Rationing of medical resources during the COVID-19 pandemic

Rationing in medicine is the allocation of insufficient resources and withholding a potentially beneficial treatment because of scarcity.^{7,8} A recent publication suggests several points to consider in the current pandemic as detailed below.⁵

Maximizing treatment benefit: Utility during the pandemic

The primary goal of resource allocation under crisis standards of care is to maximize the total number of lives saved. During the COVID-19 pandemic, even in the absence of restrictions on resources, it is not clear how individual patients will be affected. For instance, the effects of COVID-19 on the overall survival of waitlisted or post-transplanted patients is unclear.^{9,10} Risk differences may be mediated by COVID-19 itself, changes in access to medical treatment, or reduction in risk of acquiring other infections as a result of stringent social distancing. Therefore, it is not certain that criteria determining transplant urgency before the pandemic still apply during the current pandemic.

Data from Europe demonstrate a reduction in organ donation rates during the pandemic.¹¹ This may increase the expected benefit of durable MCS and conservative treatment modalities (such as inotropic therapy) compared with listing for transplant.

Recommendation: a commitment to maximizing overall utility while preserving fair allocation of donor organs requires reconsideration of existing prioritization calculations among patients with advanced heart and lung disease. This reconsideration should be continuously adjusted to the changing conditions during the pandemic.

Consideration of age during the pandemic

Guidance documents for resource prioritization during a pandemic recommend a commitment to maximizing the number of life-years saved as a secondary goal beyond simply saving the most lives.^{5,12,13} This justice-related consideration, characterized as the fair innings principle,¹⁴ has been operationalized as a tiebreaker when considering 2 people who are equally likely to survive if given access to critical care resources. Thus, age (and life-years saved) may become an additional factor when rationing scarce critical care resources (such as ventilators) during the current pandemic.¹⁵ Although this has not been the usual practice at most transplant centers, preference to younger patients might be one principle that transplant or MCS clinicians must consider during the severe rationing of resources in the Overwhelmed stage.

Table 1 Risk and Opportunities for Thoracic Transplant and MCS Through Different Stages of the COVID-19 Pandemic

Stage of pandemic	Characteristics	Risk for heart and lung transplant activity and MCS	Opportunities	Guiding ethical principles
Anticipation	High awareness in society, travel restrictions, and social distancing. Few cases of COVID-19 hospitalized. Elective hospital activity reduced. Resource situation: Free capacity.	Premature reduction of transplant and MCS activity; increased death on waitlist. Insufficient planning for the following stages.	Maintain transplant and MCS activity, adjusted to present capacity. Plan for replacements of key personnel. Re-evaluate patient prioritization for transplant and MCS, including estimated resource needs and other factors. Create written strategies for next phases of the pandemic, including rules for prioritization between patients with COVID-19 and other patients. Ensure collaborating donor centers are prepared for next stages. Prepare collaborative research studies. Clear communication of strategies and goals with staff and patients.	Allocate donor organs and MCS according to usual standards of care principles, including balancing utility, justice, and efficiency.
Active	A high but manageable influx of patients with COVID-19. Resource situation: There are resources, but reallocation occurs.	Unintended over or underactivity of transplant and MCS. Infection of transplant and patients with MCS or HCW. Reduced staff (repurposing or quarantine, etc.).	Planned reduction of transplant activity to higher-status patients based on continual assessment of OR and ICU capacity. Adjust plans as outlined above. Adjust transplant activity according to local circumstances. Rehearse plans for next stage. Be aware of underutilization of health care among transplanted patients and patients with MCS fear. Share experiences with others and participate in studies.	Allocate donor organs according to utility, justice, and efficiency informed by new information about the impact of COVID-19 on waitlist survival, individual patient after transplantation resource needs, and local capacity.
Overwhelmed	The demand for ICU is higher than the available capacity. High number of HCWs are absent. Unpredictability and high levels of stress among HCWs. Resource situation: Rationing is necessary.	Possibly unjustified cessation of transplant activity. Insufficient follow-up of transplanted patients. Infectious and/or psychologic harm for HCWs. Low number of organ donors. Geographic sharing of organs may be limited or impossible.	Maintain clean zones for organ donation, if possible. Use a prepared plan if there is a need to strongly reduce the transplant and MCS program until space and staff availability allows for resuming activity. Use the prepared list of prioritized patients. Shield and protect HCWs.	Allocate resources to patients without COVID-19 (including transplant and MCS) and those with COVID-19 efficiently to maximize the overall numbers of lives saved and secondarily, the number of life-years preserved.
Recovery	The influx of patients with COVID-19 declines. Resource situation: Unpredictable.	Delayed restart and/or escalation of transplant activity. Accumulated need for follow-up of neglected non-COVID-19-related issues.	Increase transplant activity according to local capacity. Re-evaluate waitlist and criteria for allocation on the basis of local and international evidence. Be prepared for second epidemic waves.	Allocate donor organs and/or MCS according to usual standards of care principles, including balancing utility, justice, and efficiency, informed by local capacity.
New Normal	Pandemic over. Sporadic local epidemics and risk of recurrence occur. Resource situation: May be reduced because of macroeconomic conditions.	As above Fewer resources than before.	As above Evaluate experiences broadly and redesign workflow and strategies.	Allocate donor organs and/or MCS as above, incorporating experiences acquired during the pandemic.

Abbreviations: COVID-19, coronavirus disease 2019; HCW, healthcare workers; ICU, intensive care unit; MCS, mechanical circulatory support; OR, operating room.

Recommendation: to ensure a just distribution of scarce resources and to avoid additional burden on front-line clinicians during the Overwhelmed stage, the controversial issue of patient's age and life-years saved as criteria for prioritization should be discussed in advance, and local guidelines should be specified and communicated.

Efficiency of thoracic transplantation and MCS during the pandemic

The expected resource needs of individual patients have not traditionally been given weight in the selection or allocation for transplantation or MCS—at least not explicitly—although some variation between centers may occur. An example of such variation is the varying tendency to give priority to transplant candidates who are treated with Extra Corporeal Membrane Oxygenation (ECMO).¹⁶ However, during the pandemic, considerations of efficiency may carry considerable weight, depending on local resources during the various stages of the pandemic. For instance, if critical care capacity is scarce, a patient considered in urgent need for transplant or MCS but will likely have a complicated post-transplantation course may not be given priority. Similarly, whereas MCS implants in ambulatory, non-inotrope-dependent patients and even stable patients dependent on inotrope may be safely deferred, the resource need of patients with unstable disease severity should be considered in the interest of overall efficient use of limited resources.¹⁷ Thus, patients who may be predicted to have a lesser likelihood of requiring limited resources (such as ECMO or dialysis) may be given priority. Conversely, if a patient in critical care is transplanted or receives MCS, it may liberate resources and be counted as a benefit.

Recommendation: estimating the resource need for each individual patient is necessary to devise a plan for a balanced allocation or a reduction of transplant or MCS activity during resource scarcity.

Effect of reduced donor volume on resource allocation

Another principle that may gain increased importance in organ allocation for transplant is the chance that a specific candidate may be offered a suitable organ in a timely manner. During the pandemic, it is expected that the number of organs available for transplant will decrease. Some transplant candidates have a limited donor pool, such as sensitized patients. When the expected time to wait between available organs is long, the rare occurrence of a matching organ may be given more weight in the allocation than it would in times of usual organ availability. In other words, a good match may count more than urgency.

The expected reduction in transplant or MCS volume may have additional effects. For strategies to bridge a critically ill patient to transplantation, the expected bridging time may become too long to justify priority in times of resource scarcity. Conversely, the reduced availability of organs may justify increased use of durable MCS or

alternative treatment strategies that previously may have been considered inferior to transplant.

Recommendation: a reassessment of waitlist priority for transplant or MCS should include considerations about the effects of reduced transplant volumes and longer wait times. These may require engagement with regulatory agencies.

Prioritization of HCWs

Recently published data indicate considerable COVID-19 infection rates in HCWs, ranging from 3.8% to 9% in different countries.^{1,18} As the pandemic progresses, all travel between healthcare institutions carries a risk of acquiring or spreading infection for the HCW, especially if the supply of personal protective equipment is limited. Strategies to minimize exposure should be implemented, but depending on the stage of the pandemic, organ procurement may still involve risk of contagion, especially because lung retrieval and transplant are considered an aerosol-generating procedure. It is important to consider this when considering a donor offer. Furthermore, the highly specialized nature of thoracic transplant and MCS means that some HCWs are difficult to replace in case of infection or quarantine. This may have significant collateral consequences for other patients and should be considered under a commitment to maximizing the overall benefit of resource expenditure. In particular, many transplant surgeons are also responsible for ECMO and other advanced life-sustaining therapies required to support patients with COVID-19 and should be protected from non-essential disease exposures.

Another risk to HCWs is the emotional stress in the Overwhelmed stage. To unburden HCWs, the establishment of triage officers and triage teams has been suggested,⁵ but this may not always be feasible.

Recommendation: strategies for prioritization of organs for transplant and other resources should consider the effects on HCWs, including the risk of infection and emotional stress. Such strategies should be developed before the Overwhelmed stage, ideally in the Anticipation stage, and then continuously adapted to the evolving situation. The support of an ethics committee should be considered.

Response to evidence and research participation

Current evidence to guide treatment for COVID-19 is anecdotal and difficult to interpret; thus, there is a moral imperative to gain evidence regarding efficacy and/or toxicity of various investigative clinical approaches.

In addition, China has been accused of tolerating organ procurement from executed prisoners.¹⁹ Whereas suspicion of such unethical standards has hitherto barred publications, exceptions have been made during the COVID-19 pandemic in order to gain early evidence regarding the disease.²⁰

Recommendation: it is a moral obligation for the transplant and MCS community to participate in COVID-19-related research protocols, where possible, and to encourage

patients to consent in order to gain evidence-based treatment recommendations in this patient population.²¹ Global collaboration is absolutely essential during a pandemic. Scientifically unproven practices should be used with great caution, if at all, because of the risk of doing harm.

Similar rationing principles for all kinds of treatment

In the Overwhelmed stage of the pandemic, thoracic transplant candidates and recipients must compete for intensive care unit resources with COVID-19 and non-COVID-19 critically ill patients. Importantly, the prognosis of a patient following thoracic transplant or MCS may be better than that of some patients with COVID-19. In fact, the collateral damage caused by withheld treatment may be a substantial part of the cumulative total losses caused by the pandemic.^{5,22} Although it is important to prepare for a significant reduction in transplant activity in the worst stages of the pandemic, it is also important that this reduction be balanced. How to prioritize for such balance should be discussed early. In the Overwhelmed stage of the pandemic, the ability to design plans for optimal resource reallocation may be reduced (Figure 2).

Recommendation: when rationing scarce resources, a commitment to maximizing the total number of lives saved does not support entirely suspending transplant activity.

This should also be remembered when considering repurposing of HCWs. Although there are some large dedicated centers, thoracic transplantation or MCS is often done at units where many of the transplant or MCS professionals are not uniquely dedicated to this particular task. At such centers, activity may be outcompeted and is vulnerable to a pre-emptive shutdown both in the Anticipation stage and during the Active and Overwhelmed stages. In a few

countries, if a transplant center is shut down, transplant candidates may be referred to other centers that are in different stages of the pandemic or are larger. Whether it is justified for the other center to prioritize its patients would require a different set of ethical considerations because there may be contracts with the existing patients that should be respected. However, the imperative to save lives would suggest acceptance of such referrals. On the basis of the current allocation rules and geographic limitations, such referrals are possible only in some countries.

Organ donation during the COVID-19 pandemic

Data from Spain and Italy show a dramatic reduction (up to 60%) in the number of organs recovered, and US data show a similar trend.^{11,23} A major cause of this reduction is the lack of availability of critical care beds in the Overwhelmed stage, during which access is restricted to patients with the highest chance of survival. However, the concept of utility in allowing and managing potential organ donors should be seen as the utility of saving many lives through organ donation not as scarce capacity wasted on a futile effort to achieve an unlikely survival.

Recommendation: similar rationing for all kinds of treatment and a commitment to maximizing the number of lives saved suggest the development of an appropriate process to allocate critical care resources to patients who may become organ donors.

Simultaneously, it must be acknowledged that the organ procurement process involves several risks during the pandemic,²² and mitigation strategies are warranted.²⁴

Recommendation: the risk of harm to the HCWs and the recipient should be included in the consideration of benefit or maleficence in performing a transplant.

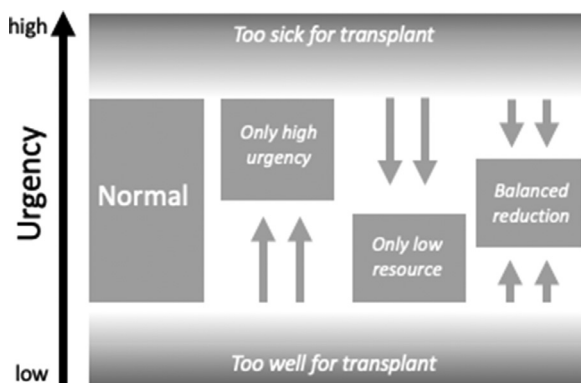


Figure 2 Recipient selection for the adjustment of transplant activity during the COVID-19 pandemic. The left rectangle illustrates the spectrum of patients accepted for transplant in normal times. During the pandemic, only highly urgent patients may be prioritized (middle left rectangle) or only those expected to require little resources after the transplant, that is, no ECMO, short ICU stay, etc. (middle right rectangle). The right rectangle illustrates an activity reduction balancing both urgency and resource allocation. COVID-19, coronavirus disease 2019; ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit.

Pediatric thoracic transplant during the pandemic

Children appear to be at lower risk for COVID-19-related morbidity and mortality than adults.²⁵ The prioritization of healthcare resources to adults over children must be done with caution to preserve resources needed for pediatric patients, particularly keeping in mind that pediatric transplant programs are typically smaller than their adult counterparts. For transplant, survival benefit algorithms are not well-established in pediatric patients, particularly infants and children under 12 years of age.²⁶ Moreover, illness severity score prediction models that may be used to allocate resources to critically ill patients with COVID-19 are not validated for children. Thus, there is a lack of data regarding both benefits and urgency measures in pediatric transplantation. However, neither the risks to the HCWs nor the challenges in resource use are changed in this circumstance.

Recommendation: reallocation of resources to serve the increased needs of the adult population needs to be done carefully to ensure that resources and staff that are critical

for the provision of pediatric transplant or MCS services remain available.

The new normal

The pandemic in its various stages and variable penetrance across different regions will challenge the way we manage patients with advanced heart and lung disease. Grim as the situation may be today, a few benefits may ensue. The current pandemic will force healthcare systems to be better prepared for the next pandemic, for a local epidemic, or even for the next influenza season. Our abilities to communicate digitally with our patients and with each other will improve and may be valuable in the future. Importantly, allocation rules and follow-up strategies may change as a result of the pandemic and the decisions made during this time. Finally, we may have increased our ability to collaborate nationally and internationally through scientific societies, scholarly journals, and other channels.

The ongoing pandemic is an unprecedented event since the advent of solid organ transplantation and certainly involves many challenges including a reframing of ethical principles.²⁷ We have developed a staged approach to ensure efficient life-saving thoracic transplant and MCS activity during the COVID-19 pandemic by incorporating ethical principles within a healthcare system perspective on the basis of changing availability of resources.

Disclosure statement

Mandeep R. Mehra has consulting relationships with Abbott, Medtronic, Janssen, Mesoblast, Portola, Bayer, NupulseCV, FineHeart, Leviticus, Triple Gene, Riovant, and Baim Institute for Clinical Research. He has no direct conflict with this work. Jeffrey Teuteberg received personal fees from Medtronic, Abbott, Abiomed, CareDx, and Paragonix, outside of the current work. Stuart Sweet is a Board President for the International Society for Heart and Lung Transplantation (ISHLT). Luciano Potena received personal fees from Novartis, Abbott, Thermo Fisher, and Sandoz and grants from Qiagen, outside of the current work. Saima Aslam is a consultant for Merck, unrelated to current work. The remaining authors have no conflicts of interest to declare.

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19 Task Force who did not participate in the writing, provided reviews. In addition, the document was reviewed and approved by the ISHLT Executive committee, including 2 members who served as independent reviewers and were not part of the COVID-19 Task Force.

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