

BRIEF COMMUNICATION

There are no best practices in a pandemic: Organ donation within the COVID-19 epicenter

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LiveOnNY, the organ procurement organization (OPO) for the greater New York metropolitan area, suspended several best practices to manage the rising referrals of deaths from hospitals during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. On April 2, 2020 hospitals in the donor service area were notified that coronavirus disease 2019 (COVID-19) referrals should be deferred. Still, only 2% of referred patients to the OPO in April 2020 were on ventilators and considered possible organ donors, versus a baseline of 11% in 2019. Few of these deaths were unrelated to COVID-19. Accordingly, organ donors declined to 10 in April (from 26 in March). Despite the exclusion of marginal donors and organs, the implementation of COVID-19 donor testing, and the availability of local procurement surgeons, only 1 organ (a liver) was accepted by a transplant center outside of New York State and 8 organs (5 livers, 4 kidneys) were transplanted in state; 11 organs (1 liver, 10 kidneys) were discarded. Allocation was unsuccessful for 11 additional organs (1 liver, 4 kidneys, 4 hearts, 2 lungs). Despite the obstacles, organ donation remained an important model of collaboration and satisfaction for the health care community in the pandemic's US epicenter. Declining COVID-19 deaths led to the resumption of the comprehensive referral policy on May 6, 2020, with improvement to 18 donors in May.

KEYWORDS

clinical research/ practice, donors and donation: deceased, infection and infectious agents - viral, organ procurement and allocation, organ procurement organization, social sciences

Deceased organ donation requires coordinated efforts, alignment of priorities across multiple organizations, and management of a spectrum of human issues. Best practices in donation have emerged from organized national efforts to leverage locally successful experiences.¹ Evidence of the effectiveness of best practices in increasing organ donation in the United States by nearly 50% over the past decade² has led to their entrenchment within the culture and

regulation of donation. As the primary action that initiates the donation process, hospital staff referral of every potential organ, eye, and tissue donor to the Organ Procurement Organization (OPO), early and without exception, had been considered an inviolable, fundamental, best practice. Every state, including New York, has legislation that obligates hospitals to make these referrals.

As the OPO covering the greater metropolitan New York area, LiveOnNY serves 98 hospitals, a population of 13.6 million, and 10 transplant centers. Best practices in donation have been purposefully deployed throughout the LiveOnNY donor service area (DSA).

Abbreviations: CMS, Centers for Medicare & Medicaid Services; COVID-19, coronavirus disease 2019; DSA, donor service area; NSICU, neurosurgical intensive care unit; OPO, Organ Procurement Organization; OPTN, Organ Procurement and Transplantation Network; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; USS, United States Ship.

But when New York State confirmed its first coronavirus disease 2019 (COVID-19) patient on March 1, 2020 we could not fully anticipate how much overall change would ensue and the extent to which our operations, and, indeed the entire local health care environment, would be affected. Governor Cuomo put our state "on pause" effective March 22, 2020; halting all nonessential services with residents ordered into isolation. By then, the Centers for Medicare & Medicaid Services (CMS) had already clarified that transplantation is a tier 3B essential service not to be postponed.³ This high acuity surgery, and the unhealthy conditions of transplant candidates in need of transplants, were determined to merit the use of critical resources. Correspondingly, the essential nature of organ donation itself and the particular importance of adherence to established best practices was unchallenged.

As the pandemic unfolded in New York City, death referrals from 98 hospitals to LiveOnNY rose sharply, beginning in the third week of March 2020, correlating with COVID-related deaths reported by the New York State Department of Health. At first, every death referral was triaged, including the surge of coronavirus infected patients. Although consensus was rapid that active infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is inconsistent with safe organ donation, altering this best practice seemed inappropriate. Ultimately, the pandemic dictated otherwise.

On March 31, 2020, LiveOnNY, deferred the referrals of COVID-19 patients because of 3 concerns:

1. Direct requests from front-line providers in hospitals throughout the DSA to be released from the obligation to refer COVID-19 patients were logical, data driven, and compelling; "We are only admitting COVID patients, and given that no organs or tissue can be harvested (*) from these patients, and the incredible increase in workload our staff is experiencing, they can't always safely take the time to make these calls. I am heavily inclined to suspend calls to LiveOn from our NSICU [neurosurgical intensive care unit] until the COVID crisis begins to subside. I strongly suggest that you make this a blanket policy for NY. It's the right thing to do. I understand what you say about CMS regulations, but these are extreme circumstances. What do you think?" Critical Care Physician on March 31, 2020
2. The critical resource shortage meant that prolonged ventilator support of the deceased COVID-19 victim solely for evaluation and exclusion would translate directly into the denial of care for another, living patient.
3. LiveOnNY staff were emotionally and physically overwhelmed by the sheer volume of deaths. Established, self-determined requirements for a prompt, thorough response to each referral could not be satisfied. The backup service provider was similarly inundated.

Reluctance to change the best practice for referral by excluding only 1 specific patient subset had been based on concern that the hardwired referral process might be destabilized by the introduction of hospital staff judgment into a pathway specifically designed to

accomplish the opposite objective. To forestall such interpretations, hospital partners were simultaneously advised of the temporary nature of this change. Standard educational trainings about the urgent need for organs were reinforced remotely.

The OPO began notification of all 98 hospitals in the DSA on April 1, 2020 that referral of positive COVID-19 cases was being deferred. Another deviation from best practice that was implemented at this time related to makeshift hospitals that were being rapidly built (a total of 8,000 new hospital beds ranging from the USS Comfort to a tented facility in Central Park).⁴ The development of new memoranda of agreement was not pursued, despite regulatory requirements for both the hospitals and the OPO to establish them. Additionally, donation cases were actively expedited by omission of repeat laboratory and imaging tests and decisive allocation (eg, heart not allocated from 29-year-old with low ejection fraction, Table 1). Marginal organs were not pursued to minimize the need for hospital resources.

Prior experience with the shift of HIV infection in potential donors from an absolute to a relative contraindication informed the manner of rolling out the COVID-19 change. Dissemination of the HIV Organ Policy Equity (HOPE) Act passage had not been fully reflected in incoming referrals to LiveOnNY for 3 years (8 in 2015, 38 in 2016, 45 in 2017, 150 in 2018) despite targeted, multidisciplinary educational activities about this legislation.⁵ Thankfully, the response to our "no-COVID-19 referrals" request became apparent within days.

Figure 1 demonstrates that referrals to the OPO from the hospitals in our DSA began to decline on April 3, 2020 whereas COVID deaths in the DSA did not peak until approximately 10 days later.

Available aggregate data from the New York State Department of Health demonstrated (as of June 9, 2020) that 94% of reported, confirmed COVID-19 decedents within all of New York State (62 counties) lived within the 12 counties comprising our DSA.^{6,7} We also know from the same data that approximately 70% of COVID-19 deaths from within our DSA are from the 5 New York City boroughs (Brooklyn, Bronx, Manhattan, Queens, Staten Island) versus Long Island (Nassau, Suffolk counties) or the North (Westchester, Putnam, Rockland, Dutchess, Orange counties). To capture overall COVID-related deaths occurring in the entire DSA following this practice change, we started with data representing only NYC daily deaths⁸ because equivalent data from the other 7 counties were not available to us. Daily deaths in the total DSA were imputed by applying the representative percentage of 29% from the other 7 counties based on aggregate state data. We also assumed that the death peaks in the counties included within the geographically small, but population dense DSA were on or about the same day. It should be noted that the COVID-19 confirmed deaths are identified by the decedent's residence, whereas hospital referrals are identified by hospital location. Also, these data include a small proportion of deaths that would not typically be referred to the OPO (in nursing homes and adult care facilities).

Among total referrals received in April 2020, ventilated patients (eg, organ donation candidates) fell to 2% from a proportion of 11%

TABLE 1 Donation outcomes for donors within the LiveOnNY donor service area from April 1, 2020 to April 30, 2020 during the COVID-19 pandemic

LiveOnNY Organ Donors + Outcomes April 1, 2020 - April 30, 2020						
Donor age (years)	Donor type	KDPI (%)	Liver disposition	Kidney disposition	Heart disposition	Lung disposition
37	Brain dead	34	Transplant	Transplant, Transplant	Declined in OR	Declined in OR
21	Brain dead	30	Transplant	Transplant, Transplant	List exhausted	List exhausted
37	DCD	49	Not recovered, procurement preserologies	Discard, Discard	Not recovered, procurement preserologies	Not recovered, procurement preserologies
29	Brain dead	57	Transplant	Discard, Discard	Poor function, not allocated	Poor function, not allocated
26	Brain dead	40	List exhausted	Discard, Discard	List exhausted	Declined in OR
72	Brain dead	94	Transplant	Poor function, not allocated	Not allocated	Not allocated
21	Brain dead	48	Transplant	List exhausted, List exhausted	List exhausted	Poor function, not allocated
52	Brain dead	90	Discard	Discard, Discard	List exhausted	Poor function, not allocated
20	DCD	15	Declined in OR	Discard, Discard	Poor function, not allocated	Poor function, not allocated
56	Brain dead	95	Transplant	List exhausted, List exhausted	Poor function, not allocated	Poor function, not allocated

COVID-19, coronavirus disease 2019; DCD, donation after cardiac death; OR, operating room.

LiveOnNY Referrals versus Imputed, Confirmed COVID-19 Deaths in the LiveOnNY Donor Service Area 3/13/2020 -5/31/2020

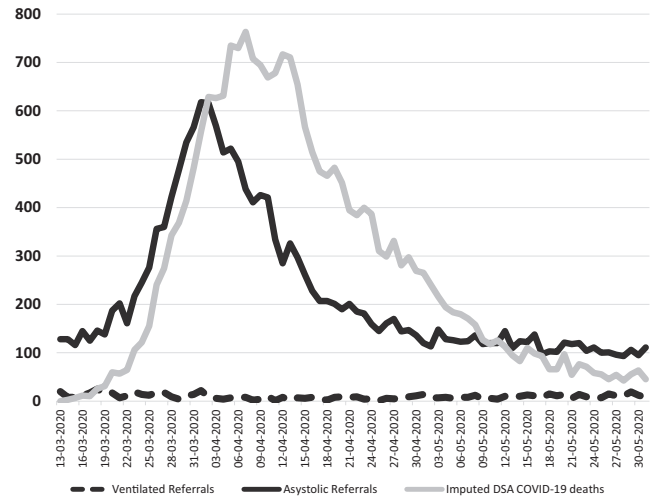


FIGURE 1 Deaths within the LiveOnNY donor service area from March 13, 2020 to May 31, 2020, as of June 9, 2020. Deaths reported from 98 hospitals in the 12 counties to LiveOnNY include patients on ventilators and those with asystole, as required by New York state (NYS) law. NYS coronavirus disease (COVID) deaths in 12 counties imputed to provide daily counts based on NYS aggregate data. The 2 populations do not completely overlap

in 2019. Among the 2% who were potential organ donors, few were not COVID-19 related (Figure 2).

Donation cases dropped precipitously, from 20 in January, 23 in February, and 26 in March to 10 in April. The mean age of the 10 donors was 37 years (range 20-72 years). Transplant center behavior had significant impact with teams outside of New York State declining organs due to COVID-19 risk even with a negative COVID-19 polymerase chain reaction from the nasopharynx (every donor was tested after March 14, 2020), and when offered the use of a local procurement surgeon. Organs transplanted dropped even more sharply, as seen in Figure 3. Allocation was unsuccessful for multiple organs that were, therefore, not recovered Table 1. Only 1 of 10 transplanted organs was exported from New York State (this was a locally procured liver procured on April 2, 2020), and 11 procured organs were discarded (1 liver, 10 kidneys) (Figure 4). No organs were transplanted from 4 donors (mean age 33.8 years, 2 were donations after cardiac death).

Organizational agility and reassessment of objectives were paramount. Management of the OPO during the early pandemic phase included other shifts in the culture of donation. All on-site educational activities were aborted, including grand rounds, donor councils, and visibility rounds in the critical care units. They were replaced with virtual rounds and conversations with individual donation champions (health care providers who support and assist with organ and tissue donation).⁹ Often, the message received from hospital providers was that organ donation should not be proceeding at all during the height of the pandemic. The chief executive officer and chief medical officer advocated for active donation efforts directly with their

COVID-19 ventilated related deaths versus non-COVID-19 ventilated related deaths reported to LiveOnNY

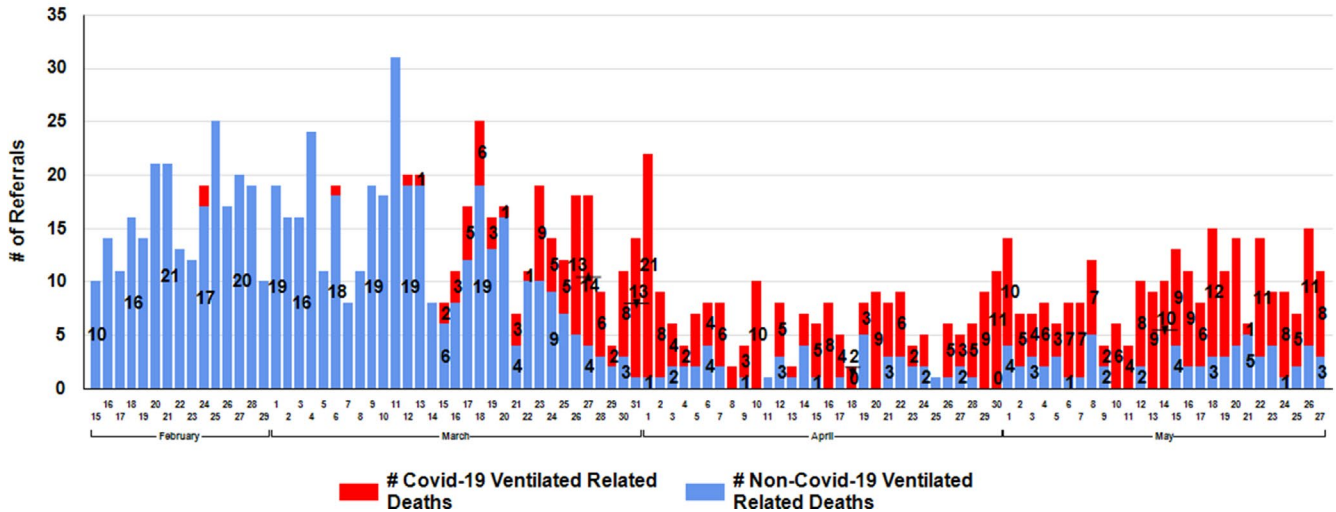


FIGURE 2 Referrals of ventilator-dependent patient deaths to LiveOnNY from February 15, 2020 to May 27, 2020. Coronavirus disease 2019 (COVID-19) patient status was reported by the callers making the referrals

**Organs Transplanted From LiveOnNY Donors
January 1, 2020 - May 31, 2020**

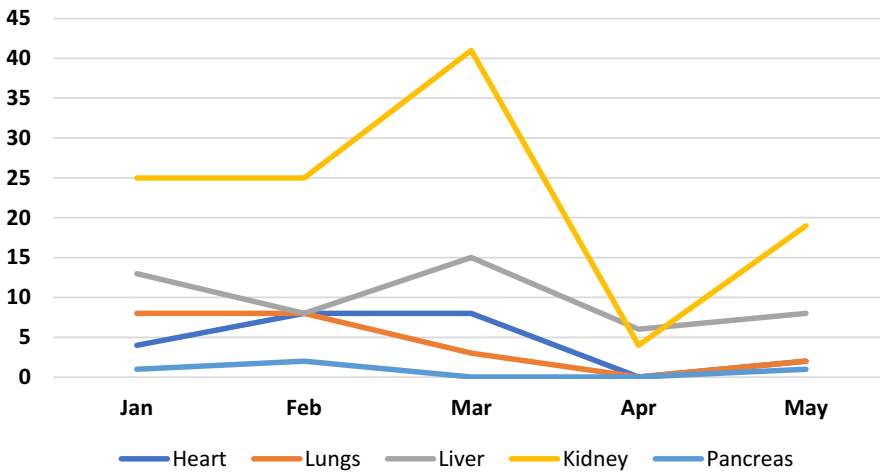


FIGURE 3 Organs transplanted from deceased donors recovered in the LiveOnNY donor service area from January 1, 2020 to May 31, 2020

hospital peers by emphasizing the sustained and immediate need for organs. Without exception, top hospital leaders supported these requests and intervened to facilitate donation, when necessary.

Finally, family interactions were revised. When, and how, conversations about donation opportunities were conducted with families changed. Many were conducted by phone or video conference because many hospitals did not allow any visitation. In 1 case, the coordinator went to a family's home to speak masked face to masked face with a next of kin. The modern best practice of lining the hallway to honor the donor on his/her way to the operating room (an honor walk) was also avoided, although in 1 case, hospital staff did manage to accomplish 1 honor walk on May 3, 2020.¹⁰ An intense approach to allocation that requires exhausting the waitlist for every organ that is offered was preserved. Our team's pride and satisfaction

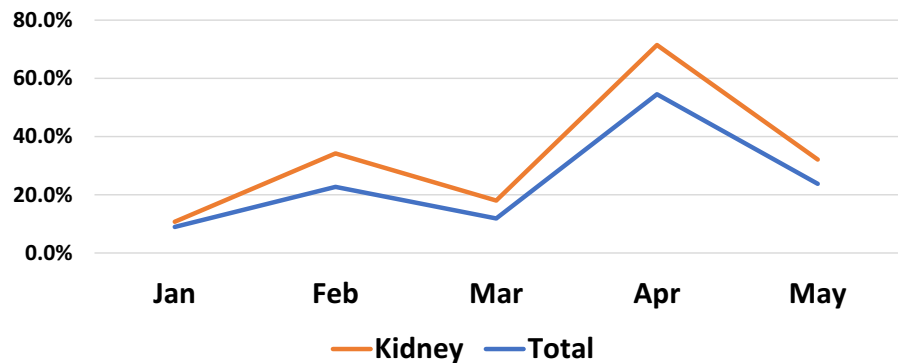
with each organ that has been transplanted are indescribable. Our gratitude for the privilege of representing the needs of the 112 000 awaiting organs was best summarized by our colleague,

“You are lucky enough to have the ability to save lives at this time, when we are just losing them.”

The pandemic induced changes exceeding our emergency preparedness plans. We have described the key responses required to preserve working relationships with our collaborators on the frontlines. As a result of these modifications, donation has persisted. On May 6, 2020 with COVID-19 deaths steadily declining in the DSA, hospitals were asked to resume routine referral of all patients, including those with positive COVID-19. OPO operations remained principally

FIGURE 4 Organs recovered for transplantation and discarded from LiveOnNY deceased donors from January 1, 2020 to May 31, 2020

**Organs Recovered and Discarded from LiveOnNY Donors
January 1, 2020 - May 31, 2020**



virtual throughout May 2020, with plans to slowly phase in greater physical presence in hospitals, as they permit. Total donors increased to 18 in May.

Managing best practices in a pandemic required bold decisions and frequent reassessment of rationales, not business as usual. Our processes are clearer, relationships are stronger, and our streamlined approach has spurred greater efficiency. We remain prepared to share organs per Organ Procurement and Transplantation Network policy. New York City and Long Island entered phase 1 of the state's regional phased reopening plan on June 8, 2020.¹¹ It will take time to reimagine our new best practices as normal life resumes, whenever that may be.

* The term "harvest" used by the physician in our DSA is reported accurately but is not consistent with the currently supported lexicon of transplant terminology.

DISCLOSURE

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

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