# LETTER TO THE EDITOR



# COVID-19 test result reporting for deceased donors: Emergent policies, logistical challenges, and future directions

## Abstract

The coronavirus disease 2019 (COVID-19) pandemic poses unprecedented challenges to the transplant community, including organ procurement organizations (OPOs), transplant centers, regulatory agencies, and recipient candidates. Access to timely, accurate information on the status of deceased donor viral infection is essential in determining organ acceptance. The Organ Procurement and Transplantation Network expeditiously added fields to collect these data; however, use of the data collection fields was not uniform nationally. Standardized, field-defined data capture and reporting are vital to ensure optimal organ utilization during this pandemic, and to prepare the community for subsequent challenges.

The coronavirus disease 2019 (COVID-19) pandemic poses unprecedented challenges to the transplant community, including organ procurement organizations (OPOs), transplant centers, regulatory agencies, and recipient candidates. The profound decline in transplant activity at the start of the pandemic was driven by the fear of disease transmission, limited access to testing for SARS-CoV-2, constraints on healthcare facilities resources, and the lack of a standardized, consistent method to document and communicate deceased donor testing results.<sup>1</sup> Safe reopening of transplantation required access to accurate and timely information on clinical status. In response, the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) expeditiously enacted emergency policies (4/2/2020) that included addition of a new field to capture COVID-19 testing in the electronic organ offer system (DonorNet<sup>®</sup>).<sup>2</sup> These fields allow accepting clinicians to rapidly confirm that donors have been tested and are currently negative. Initially, the use of this data field was optional, with some OPOs choosing to attach PDF documents of testing results or communicate with text entries in "Donor Highlights." Our review of national data shows the OPO community progressively increased field-defined documentation of COVID-19 testing (Figure 1A). While OPTN review including natural language processing of free-text information and uploaded attachments confirms that all OPOs are now testing for COVID-19, the use of the data collection fields was not uniform

nationally. At its December 2020 meeting, the OPTN Board adopted a policy for mandatory reporting of donor testing.<sup>3</sup>

As the pandemic continues to surge, the number of potential donors being identified with prior or current COVID-19 infection is rapidly rising. Because DonorNet<sup>®</sup> only captures information after a decedent is deemed appropriate for donation, the proportion of donor referrals that are closed due to active infection is unknown. Anecdotally, it has been estimated that ≥50% of ventilated in-hospital deaths are being ruled out for donation based on COVID-19. In addition, as nearly 7% of the US population has been exposed to COVID-19, a growing number of patients dying from non-COVID-19 causes but with evidence of current or past infection is anticipated.<sup>4</sup> To date, the transplant community has favored caution with regard to organ acceptance from deceased donors with prior COVID-19 infection, but safe acceptance of organs from recovered individuals has been documented. A recent case series of six previously infected deceased donors reported successful transplant of 13 organs with no transmission of SARS-CoV-2 to recipients, procurement teams, or hospital personnel.<sup>5</sup> Transplantation from living donors with recovered COVID-19 has been also reported.<sup>6</sup>

We applaud the OPTN's responsiveness to the pandemic with rapid implementation of tools to collect and disseminate infection status, and the decision to mandate the use of field-defined information in DonorNet<sup>®</sup>. While the new programming required resources, it overcame important limitations of communication through free text or attachments (Figure 1B). We advocate not only for continued data reporting on potential donors, but also improved collection and monitoring of decedent referrals excluded from donation on the basis of COVID-19. These data are vital to assess the ongoing impact of the pandemic on donor potential. Future decisions regarding organ utilization from donors with prior COVID-19 infection will need to balance donor organ scarcity, exposure prevalence, time from infection (if known), and the latest science on transmission risk, patient education, and transparency. Accurate data reporting and communication are essential in these considerations. As illustrated by the addition and policy related to the COVID-19 testing field, we believe that standardized, field-defined data capture and reporting are vital to ensure optimal organ utilization during this pandemic and to prepare the community for subsequent challenges.

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# (A) Deceased Donor COVID-19 Field-Defined Test Reporting, by Month and Geography





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# Considerations for Rapid Implementation & Evolution of Emergent Donor Reporting Requirements

#### FREE-TEXT FIELD OR ATTACHMENT

#### PROS

- Quickly and easily implemented without additional programming
- Easily removed once the need is over
- Allows for nuanced explanation prior to standardization of testing or comprehensive disease process understanding

#### CONS

- Easy to overlook missing data during organ offer, potentially complicating placement or safety
- Not always easily findable during organ donor evaluation, particularly for non-local offers
- Takes additional time to find during an offer, particularly if information is in an attachment
- Not readily utilizable for quality improvement or research, particularly if information is in an attachment
- Not as easy to find if assessing the offer on a mobile device such as a cell phone

#### DEFINED DATA FIELD

#### PROS

- Easier to find, particularly for those evaluating organs from OPOs from which they do not commonly receive offers, potentially expediting national or higher-risk offers
- Easier to tell if data are missing or pending and requiring follow-up
- Readily utilizable for quality improvement or research

#### CONS

- Requires additional programming, making implementation more complicated and less timely
- May require additional training or administrative enforcement
- When testing is no longer necessarily, de-implementation requires additional programming, takes time, and may require significant administrative effort to discontinue (e.g. HTLV-1)

## GOALS

L. Rapid and reliable

- communication of test results
- Protect patient safety
- Facilitate organ placement and
- logistics
- 2. Rapid and effective response to national emergencies that can be efficiently escalated
- and de-escalated as needed

FIGURE 1 A, Field-defined US deceased donor COVID-19 test reporting, by month and geography. Geographic areas are based on current UNOS COVID-19 reporting, defined as<sup>7</sup>: Northwest (WA, OR, ID, MT, AK, HI), Southwest (CA, NV, UT, AZ, NM), North Midwest (ND, MN, SD, WY, NE, IA, CO, KS, MO), South Midwest (OK, TX), Great Lakes (WI, IL, IN, MI, OH), Southeast (KY, AR, TN, NC, MS, AL, GA, SC, LA, FL, PR), Mid-Atlantic (WV, VA, PA, DC, MD, DE), and Northeast (NJ, NY, CT, RI, MA, VT, NH, ME). B, The balance of considerations during rapid implementation and evolution of emergent donor reporting requirements

#### ACKNOWLEDGMENTS

The data reported here have been supplied by the Hennepin Healthcare Research Institute (HHRI) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy of or interpretation by the SRTR or the US Government. SRTR registry data can be obtained from the SRTR.

#### CONFLICT OF INTEREST

The authors have no relevant conflicts of interest or other relevant financial disclosures. All authors approve and agree to be accountable for ensuring the accuracy and integrity of the final manuscript.

#### AUTHOR CONTRIBUTIONS

KLL, NS, and DA were responsible for drafting the manuscript. KLL, RL, and MAS were responsible for data collection and analysis. All authors were responsible for data interpretation and critical revision of the manuscript

#### **IRB/ETHICS STATEMENT**

The publicly available data analyzed in this letter are IRB exempt.

#### DATA AVAILAIBLITY STATEMENT

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> Krista L. Lentine<sup>1</sup> Neeraj Singh<sup>2</sup> Kenneth J. Woodside<sup>3</sup> Mark A. Schnitzler<sup>1</sup> Ruixin Li<sup>1</sup> Tarek Alhamad<sup>4</sup> Richard Rothweiler<sup>5</sup> Ronald F. Parsons<sup>6</sup> Roslyn B. Mannon<sup>7</sup> Jon Snyder<sup>8</sup> Matthew Cooper<sup>9</sup> David A. Axelrod<sup>10</sup>

<sup>1</sup>Saint Louis University, St. Louis, MO, USA

<sup>2</sup> John C. McDonald Regional Transplant Center, Shreveport, LA, USA

<sup>3</sup>University of Michigan, Ann Arbor, MI, USA

<sup>4</sup>Washington University, St. Louis, MO, USA

<sup>5</sup>Mid-America Transplant, St. Louis, MO, USA

<sup>6</sup>Emory University, Atlanta, GA, USA

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<sup>7</sup>University of Nebraska Medical Center, Omaha, NE, USA <sup>8</sup>Scientific Registry of Transplant Recipients, Minneapolis, MN, USA <sup>9</sup>Medstar Georgetown Transplant Institute, Washington, DC, USA <sup>10</sup>University of Iowa, Iowa City, IA, USA

### Correspondence

Krista L. Lentine, Saint Louis University Center for Abdominal Transplantation, 1402 S. Grand Blvd., St. Louis, MO, 63104. Email: krista.lentine@health.slu.edu

Krista L. Lentine and Neeraj Singh Co-first authors.

## ORCID

Krista L. Lentine b https://orcid.org/0000-0002-9423-4849 Neeraj Singh b https://orcid.org/0000-0002-3814-1920 Kenneth J. Woodside b https://orcid.org/0000-0002-7495-3758 Ronald F. Parsons b https://orcid.org/0000-0002-9243-1582 Roslyn B. Mannon b https://orcid.org/0000-0003-1776-3680 David A. Axelrod b https://orcid.org/0000-0001-5684-0613

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