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COVID-19 Test Reporting for Deceased Donors: Emergent Policies, Logistical Challenges and Future Directions

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CONTRIBUTIONS STATEMENT

K.L.L, N.S, D.A. were responsible for drafting the manuscript. K.L.L. R.L and M.A.S. were responsible for data collection and analysis. All authors were responsible for study design, data interpretation, and critical revision of the manuscript.

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IRB/ETHICS STATEMENT

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

COI STATEMENT

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.

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To the Editor:

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 health care facilities resources, and the lack of a standardized, consistent method to document and communicate deceased donor testing results.¹ 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®).² These fields allow accepting clinicians to rapidly confirm that donors have been tested and are currently negative. Initially, 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 58 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.³

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® only captures information after a decedent is deemed appropriate for donation, the proportion of donor referrals which are closed due to active infection is unknown. Anecdotally, it has been estimated that $\geq 50\%$ of ventilated in-hospital deaths are being ruled out for 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.⁴ 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.⁵ Transplantation from living donors with recovered COVID-19 has been also reported.⁶

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 use of field-defined information in DonorNet®. 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.

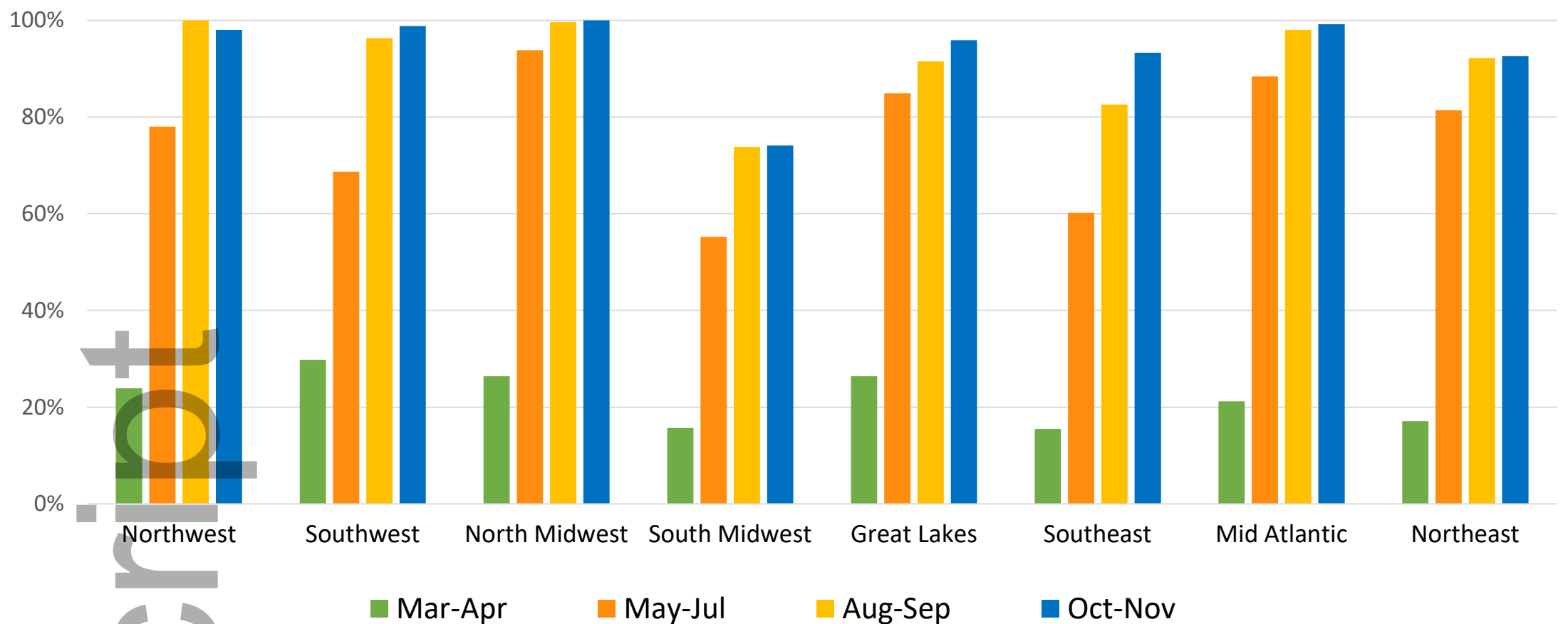
Figure Legend

- A. Field-defined U.S. deceased donor COVID-19 test reporting, by month and geography. Geographic areas are based on current UNOS COVID-19 reporting, defined as:⁷
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 reporting requirements.

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A. Deceased Donor COVID-19 Field-Defined Test Reporting, by Month and Geography



B.

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 necessary, de-implementation requires additional programming, takes time, and may require significant administrative effort to discontinue (e.g. HTLV-1)

GOALS

1. 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