






## BRIEF COMMUNICATION

# Expedited SARS-CoV-2 screening of donors and recipients supports continued solid organ transplantation

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Universal screening of potential organ donors and recipients for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is now recommended prior to transplantation in the United States during the coronavirus disease 19 (COVID-19) pandemic. Challenges have included limited testing capacity, short windows of organ viability, brief lead time for notification of potential organ recipients, and the need to test lower respiratory donor specimens to optimize sensitivity. In an early U.S. epicenter of the outbreak, we designed and implemented a system to expedite this testing and the results here from the first 3 weeks. The process included a Laboratory Medicine designee for communication with organ recovery and transplant clinical staff, specialized sample labeling and handoff, and priority processing. Thirty-two organs recovered from 14 of 17 screened donors were transplanted vs 70 recovered from 23 donors during the same period in 2019. No pretransplant or organ donors tested positive for SARS-CoV-2. Median turnaround time from specimen receipt was 6.8 hours (donors), 6.5 hours (recipients): 4.5 hours faster than daily inpatient median. No organ recoveries or transplantations were disrupted by a lack of SARS-CoV-2 testing. Waitlist inactivations for COVID-19 precautions were reduced in our region. Systems that include specialized ordering pathways and adequate testing capacity can support continued organ transplantation, even in a SARS-CoV-2 hyperendemic area.

## KEYWORDS

COVID-19, organ transplant, rapid testing, SARS-CoV-2, turnaround time

## 1 | INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) epidemic in the United States has led to the intentional reduction or suspension of many nonurgent medical procedures in order to reserve hospital capacity for surge capacity to meet the coronavirus disease

19 (COVID-19) threat, conserve personal protective equipment (PPE), and prevent nosocomial SARS-CoV-2 transmission.<sup>1,2</sup> The COVID-19 pandemic has also threatened solid organ transplantation due to multiple factors, including increased demand for intensive care resources, PPE shortages, and concerns for donor-transmitted SARS-CoV-2 and/or increased morbidity and mortality in solid organ transplant (SOT) recipients.<sup>3-6</sup> Although the Center for Medicare & Medicaid Services has designated organ transplantation within its highest priority (Tier 3b) “do not delay” category,<sup>7</sup> early reports from Italy suggested a

**Abbreviations:** OPO, Organ Procurement Organization; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SOT, solid organ transplant; TAT, turnaround time; UNOS, United Network for Organ Sharing.

25% reduction in organ procurement during the first 4 weeks of the COVID-19 outbreak there.<sup>8</sup> Starting March 2020, patients awaiting transplantation in the United States could temporarily be assigned to inactive status out of concern for COVID-19; such patients would not receive organ offers until reactivated. During March 2020, thousands of patients were deferred nationwide (<https://unos.org/COVID>, accessed April 16, 2020). Global guidelines consider proven or suspected SARS-CoV-2 infection as a contraindication to donation and require negative donor testing prior to transplantation.<sup>9,10</sup> In the region of the United States first hit by the pandemic, the Pacific Northwest, similar guidelines were adopted by local transplant programs, and donations from living donors were temporarily suspended. The University of Washington hospital system expanded this requirement to include testing of transplant candidates. In order for solid organ transplantation to continue, laboratory capacity for SARS-CoV-2 testing must be sufficient to return results within the window of organ viability. Some of the challenges have included limited in vitro testing capacity for SARS-CoV-2 in the United States, shortages in key supply chains, and, until recently, absence of rapid testing platforms approved by the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA).<sup>11</sup>

The University of Washington Medical Center (UWMC) is a large academic multiorgan transplant center in Washington State. The clinical laboratory went live with SARS-CoV-2 testing on March 2, 2020.<sup>12</sup> The laboratory sought to support organ donation by rapidly developing and implementing a system to expedite SARS-CoV-2 testing for organ donors and potential transplant recipients identified by the Transplant Surgery clinical services. The local organ procurement organization (OPO), LifeCenter Northwest, serves the largest geographic region of all 58 OPOs in the United States, including most of Washington, Alaska, Montana, and northern Idaho, thereby exacerbating the challenge of predonation testing due to significant prelaboratory specimen transport times. In addition, UWMC's location in Seattle/King County was at the center of the rapidly expanding outbreak in Washington, complicating transplant screening due to high demand for SARS-CoV-2 testing for hospital system patients and from other local and regional systems seeking reference laboratory testing services.

Here we describe key components of the system designed to expedite screening for donors and potential recipients while maintaining and without disrupting the flow of the large volume of non-transplant-related specimens handled by our laboratory. We describe the first 3 weeks of universal COVID-19 screening in the organ donor and recipient populations and highlight important pitfalls that could result in missed transplant opportunities.

## 2 | METHODS

### 2.1 | Ethical approval

This study was approved by the UWMC Institutional Review Board (STUDY00009957). Informed consent was not required.

### 2.2 | Study populations and specimens

The study period was March 15, through April 5, 2020, and included the following: all potential donors screened for SARS-CoV-2 infection by local OPO clinical staff; all potential transplant recipients screened for SARS-CoV-2 prior to transplant at UWMC; and UWMC patients who were posttransplant with an urgent need for another procedure (eg, washout of intra-abdominal abscess, endoscopic retrograde cholangio-pancreatography). Donor specimens (N = 27) included nasopharyngeal (NP), combined oropharyngeal (OP)/NP swabs, endotracheal tube (ETT) sputum aspirates, or bronchoalveolar lavage fluid (BAL). Specimens were not frozen prior to testing. Potential recipient specimens (N = 16) were exclusively NP swabs. Testing was performed every day, around-the-clock, at the UW Clinical Virology laboratory (Data S1).<sup>12,13</sup>

### 2.3 | COVID-19 risk assessment

Potential donors and recipients were screened for epidemiologic risk, clinical features, and radiographic findings (Data S1).

### 2.4 | Data analysis

Data accessed from the UW Department of Laboratory Medicine's Data Warehouse included sample type, test result, date/time stamps for specimen order, receipt in the laboratory, and final result time. Two turnaround time (TAT) parameters were calculated: collected TAT = result date/time - collection date/time; and laboratory TAT = result date/time - receipt date/time. Overall and in-laboratory, TAT were compared to the daily median TAT from specimen receipt for inpatient specimens, which were continuously monitored by the Department of Laboratory Medicine throughout. Aggregate data for patients were temporarily assigned to inactive transplant waitlist status by week and region (Pacific Northwest, including Alaska, Montana, and Hawaii), and were nationally retrieved from the United Network for Organ Sharing (UNOS) COVID website (<http://unos.org/COVID/> and accessed on April 16, 2020) and used to calculate percent of total inactivations due to COVID-19 precautions. Temporary inactivation indicated that a transplant program decided that the candidate was unavailable or unsuitable for transplantation and would not receive organ offers; such patients could be reactivated at any time (<http://unos.org/COVID/>). Regions used here were defined by UNOS (<http://unos.org/COVID/>) and do not correspond to the 11 transplant regions defined by the U.S. Department of Health and Human Services. Statistical analysis was performed by two-tailed Fisher's exact test in GraphPad Prism v7.0d. based on data from the Organ Procurement and Transplantation Network. Wilcoxon signed-rank test performed in R version 3.5.0 was used to compare patient/donor TATs paired with the median TAT for inpatient samples on that day.

### 3 | RESULTS

#### 3.1 | Expedited pathway design

UW Laboratory Faculty and Staff designed a pathway for expedited screening of potential SOT donors and recipients in collaboration with the SOT Infectious Diseases Service and LifeCenter Northwest (Figure 1A). Key goals were to make specimens highly visible, quickly traceable, and processed immediately. Prior to specimen submission, the laboratory medicine physician on call for SOT was paged and provided with identifying patient information, including the UNOS number and the estimated time of arrival at the specimen receiving area of the laboratory. To clearly distinguish SOT-related specimens requiring expedited testing from the large volume of other specimens, a printed “flag” (Figure 1B) was attached to each specimen to identify SOT specimens, which were hand delivered to the laboratory with a verbal handoff to a lead technologist in Specimen Processing. Specimens were immediately logged for rapid transport to the Clinical Virology Laboratory for SARS-CoV-2 testing. Donor specimens were transported by an OPO-designated courier service. Potential recipients’ specimens were placed in individual specimen batches and transported by hospital couriers who transported specimens to the Clinical Virology laboratory every 2 hours. Testing staff recognized specimens by virtue of the “flag” and ensured that SOT-related specimens were unbatched and processed immediately upon receipt. Job aids were created for Specimen Processing and Virology staff and couriers. SOT specimens were thus processed first, even within the highest priority testing tier previously established by hospital policy, which included specimens from inpatients and health-care workers.

During the study period (starting on March 31, 2020), rapid assays (75-90 minute runtime) were verified at each of the three hospital study sites for on-site testing of preoperative patients. Five of 17 specimens from transplant patients had NP swabs tested on this

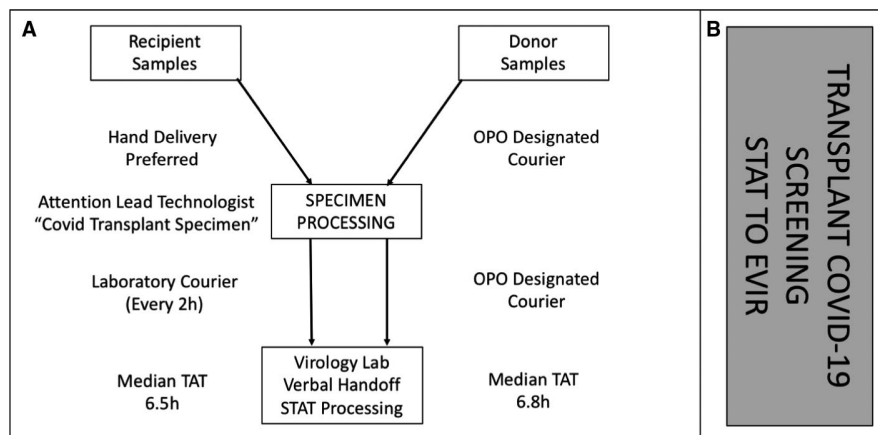
platform, including 3 of 4 posttransplant patients who required additional surgical procedures. Because only NP swabs could be run on the DiaSorin assays at the time,<sup>14</sup> donor specimens were not included because BAL and sputum specimens were an important component of preorgan recovery screening, particularly for potential lung donation.

#### 3.2 | Total tests, donations, and transplants performed

During the 3-week study period, our laboratory performed expedited screening for 17 organ donors, 13 transplant candidates, and 4 post-transplant patients who required nontransplant procedures (Table 1), accounting for 46 unique specimens. Recipients were screened with a single NP swab and, once this protocol was established, donors were screened with both upper and lower respiratory specimens collected in parallel. Seven of 17 donors had a single NP swab and two had three specimens submitted (NP, sputum, and BAL). Thirty-eight organs were recovered from 14 donors, resulting in 32 transplantations performed at transplant centers in Washington or extra-regionally (Figure S1). Other tissues (eg, heart for valves, bone, skin) were collected from 7 donors (Table 2). As a comparison, during the same time frame in 2019, a total of 70 organs were recovered and transplanted from 23 donors (Figure S2). Although specimens from OPO clinical staff were eligible for expedited testing, the pathway was not automatically deployed and did not need to be activated for them during the study period.

#### 3.3 | SARS-CoV-2 results and impacts on organ transplantation procedures

None of the donors tested positive for SARS-CoV-2. All donor tests resulted in time for organ or tissue recovery to proceed without



**FIGURE 1** Overview of Expedited Workflow and Specimen Identifiers. Specimens for both potential organ donors and recipients were collected and transported to the laboratory, where specimens were immediately accessioned and logged by a lead technologist. A, From there, specimens were transported to the virology laboratory, where they became the next specimens processed. OPO-designated couriers maintained custody of donor specimens throughout. Median TAT from specimen receipt are displayed. Verbal handoffs played an important role in identifying these to laboratory personnel for proper handling, as did a flag that was attached to each specimen requisition (B). “EVIR” indicates the Clinical Virology laboratory

**TABLE 1** Study population and calculated turnaround times for SARS-CoV-2 screening

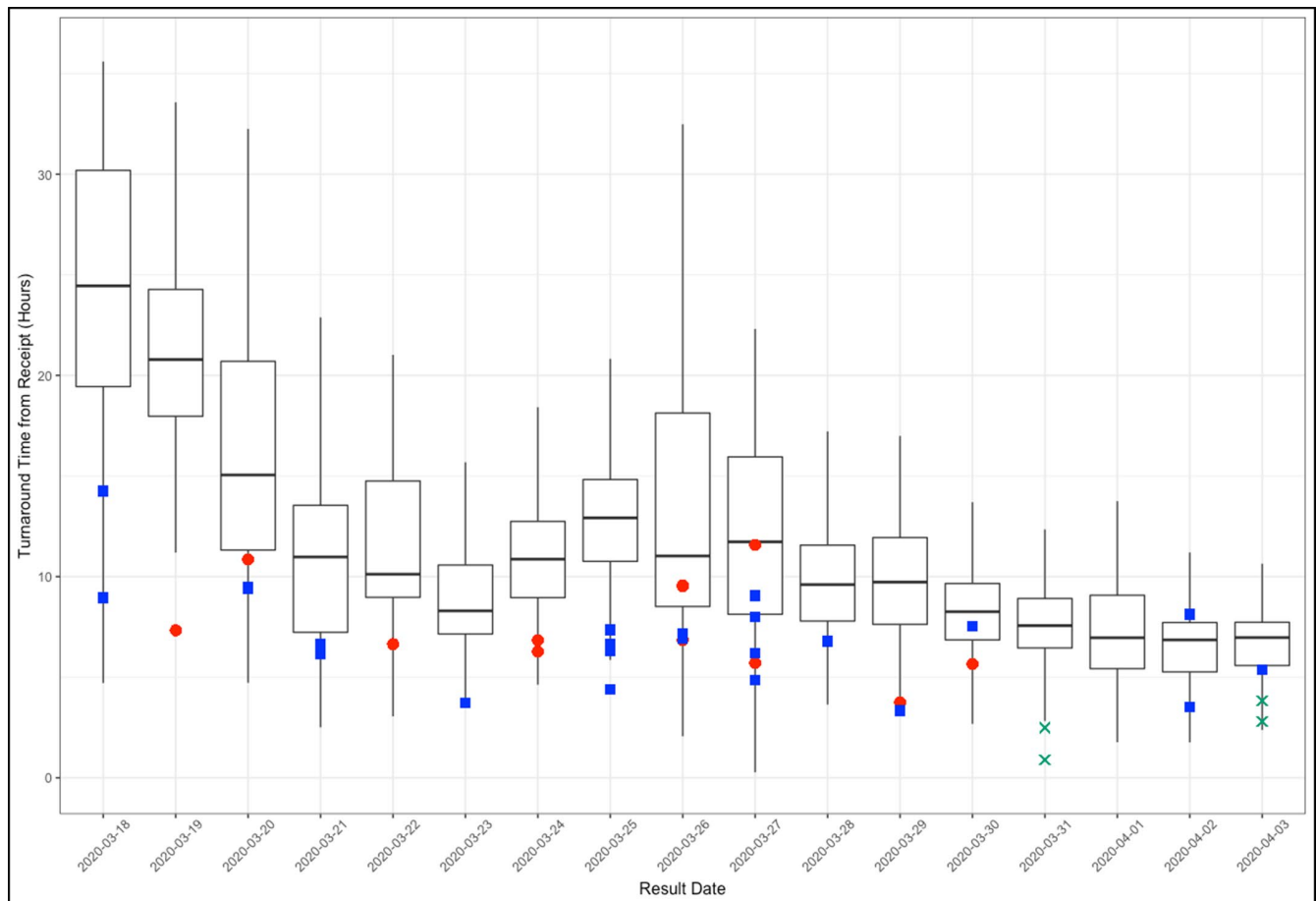
	Total patients	Total specimens	Positive test results	TAT, collected Median (IQR)	TAT, received Median (IQR)
Donors	17	29	0	10.2 (8.1-12.5)	6.8 (6.2-8.0)
Potential recipients	13 <sup>a</sup>	13	0	7.8 (7.0-9.9)	6.5 (3.8-7.9)
Posttransplant patients	4	4	1	N = 14 <sup>b</sup>	N = 16 <sup>b</sup>

<sup>a</sup>An additional potential transplant recipient was not screened because their case was cancelled for non-COVID-19 related reasons.

<sup>b</sup>Specimens with ambiguous collection or laboratory receipt times were censored.

**TABLE 2** Impact of SARS-CoV-2 test results on procedures

	Potential cases	Cases discontinued for SARS-CoV-2	Cases with organs recovered or transplanted	Cases with tissue recovered
Donors	17	0	14	7
Potential recipients	13	0	8	n/a
Posttransplant patients	4	0	n/a	n/a



**FIGURE 2** Donor and Recipient SARS-CoV-2 Turnaround Times Compared to Routine Inpatient Result Times. Box and whisker plots show the calculated median inpatient TAT by day. Individual TATs for transplant patients, red circles. Individual TATs for transplant patients performed on rapid tests, green exes. Individual TATs for donor specimens, blue squares. Two-tailed Wilcoxon signed-rank test indicates a significant difference ( $P = 6.557 \times 10^{-9}$ ) between the expedited sample TAT vs daily median TAT for routine samples [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.com)]

delays. Three donor cases were discontinued for non-COVID-19 reasons. None of the potential transplant recipients tested positive for SARS-CoV-2. One renal transplantation was briefly delayed waiting

for SARS-CoV-2 results (Table S1). One patient did not receive a transplantation for reasons not related to COVID-19 infection and was not screened. A second case was not delayed, but the result was

reported within an hour of scheduled start time. No procedures for posttransplant patients were delayed while awaiting SARS-CoV-2 results.

### 3.4 | Comparison of turnaround time with concurrent daily averages

Median TATs calculated from specimen receipt were similar for both donors (median 6.8 hours, interquartile range [IQR] 6.2-8.0 hours) and candidates/recipients (median 6.5 hours, IQR 3.8-7.9) and slightly longer for donors when calculated from time of collection (Table 1), reflecting the broad geographic range served by the OPO. Donor and recipient TATs were faster than median inpatient TAT (median -4.5 hours, IQR -3.3 to -6.2,  $P = 6.6 \times 10^{-9}$ ), which varied over the course of the study period with a trend toward faster result time (Figure 2). Weekly median TAT for donors and recipients also decreased during the study period, with a marked decrease in recipient TAT in week 3 following the implementation of the rapid assay (Table S2).

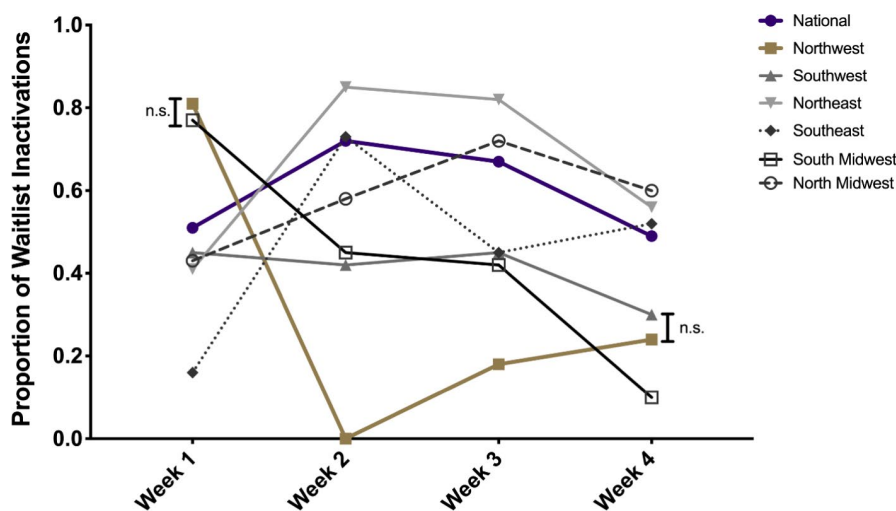
### 3.5 | Temporary waitlist inactivations for SARS-CoV-2 precautions by week in the pacific North West

Weekly changes to the organ transplant waitlist were reported by UNOS, including number of patients temporarily listed as inactive, grouped by region (NW, SW, NE, SE, N Midwest, and S Midwest) and nationally (<http://unos.org/>, accessed on April 13, 2020). Starting in week 1 (March 15) of this study period, temporary inactivations due to COVID-19 precautions were reported. In the first week, 81% of

waitlisted patients inactivated in the NW region were due to COVID-19 (Figure 3; Table S3): a significantly higher proportion ( $P < .0001$ ) than all other regions except the South Midwest ( $P = .2651$ , Table S4). Throughout the remainder of the study period and in the week after (week 4), the percentage of waitlisted patients inactivated due to COVID-19 precautions was less than 25%, including 0 patients during week 2 (Figure 3; Table S3). The proportion of COVID-19-related inactivations in the NW was significantly less than in all other regions throughout weeks 2, 3, and 4, except during Week 4 when the SW region was not different ( $P = .4050$ ) and the S Midwest had fewer COVID-19-related inactivations ( $P = .002$ , Figure 3; Table S3). This occurred despite high to very high COVID-19 activity tracked by the Centers for Disease Control and Prevention (CDC) in the Pacific NW throughout the study period.<sup>15</sup>

### 3.6 | Near misses and unanticipated challenges

Although no opportunities for transplantation or organ recovery were missed due to a delay or lack of access to COVID-19 screening during the study period, several near misses occurred: 2 donor and 4 transplant patient specimen submissions. The second donor specimen submitted was transported from Alaska and arrived during a specimen backlog. The samples were not identified by the laboratory as potential donor specimens but were retrieved by the on-call laboratory medicine provider after being re-contacted by the responsible OPO clinical staff member. The donor tested negative and organ recovery proceeded as planned. This event prompted the use of SOT flags (Figure 1B). In a second case, a donor ETT sputum trap was separated from the SOT flag and UNOS identifier; brief phone conversations between the on-call laboratory medicine provider for



**FIGURE 3** Temporary Transplant Waitlist Inactivation for COVID-19 Precautions by Region. The proportion of transplant waitlist patients temporarily inactivated nationwide and regionally due to COVID-19 precautions for the study period (week 1, starting March 15) and for the subsequent week (week 4, starting April 5). Purple line and circles, National; gold line and squares, Northwest; dark gray line and triangles, Southwest; light gray line and inverted triangles, Northeast; dotted line and diamonds, Southeast; dashed line and open circles, North Midwest; dash-dot line and open squares, South Midwest. Two-tailed Fisher's exact, n.s. indicates not a significant difference ( $P > .05$ ); all other comparisons  $P < .05$  [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

SOT and the laboratory personnel involved quickly resolved this issue.

Challenges arose when testing recipients due to evolving hospital procedures for outpatient COVID-19 screening and transition to the rapid DiaSorin Simplexa FDA-EUA cleared assay. In one case early in the study period, an SOT flag was missed, although the result was reported in time to proceed with transplantation. In another case, 2 patient specimens were collected at a drive-through clinic without first contacting laboratory medicine personnel on-call for SOT patients/specimens. These were identified and expedited, but one caused a brief delay (<2 hours) to the surgical start time. This occurred prior to rapid assay implementation. A fourth patient's result was delayed due to unexpected instrument downtime (failed positive control, followed by successful trouble shooting), but was still reported in time for patient care needs.

## 4 | DISCUSSION

During an escalating phase of the SARS-CoV-2 outbreak in one of the early U.S. COVID-19 epicenters, we developed, implemented, and refined a system that facilitated rapid testing to support our center's SOT program and organ recovery from donors across a wide geographic area. The system was designed to expedite SARS-CoV-2 testing to screen donors, potential recipients, and posttransplant patients needing follow-up procedures or surgeries. The key components of the system included: (a) consolidated specimen transport by OPO-designated couriers from collection to delivery at the Clinical Virology laboratory (Figure 1A); (b) verbal handoffs and expedited logging by a specimen processing lead; (c) unique, highly visible identifier attached to the patient specimen (Figure 1B); (d) priority processing of these specimens; and (e) an on-call Laboratory Medicine provider to track specimens.

During the first 3 weeks of this process, no transplantation or organ recovery opportunities were missed due to delays or lack of access to SARS-CoV-2 test results. This resulted in 14 organ recovery procedures, permitting transplantation of 32 organs (Figure S1). Our hospital was able to provide transplants for 8 of 13 candidates during the study period (Table 2); 3 of 5 remaining patients subsequently received transplants. Within the laboratory, TAT for both donors (median 6.8 hours) and recipients (6.5 hours) was faster than other specimens, including other inpatients (Figure 2). Recipient specimen TAT was accelerated in week 3 by implementation of an FDA-EUA cleared rapid assay.

The first week of the study period coincided with UNOS instituting and tracking a new waitlist inactivation status due to precautions for COVID-19. Although the proportion of waitlisted patients in our region (NW) inactivated for COVID-19 precautions was significantly higher during week 1 than either the national average or reported from most other regions, that proportion dropped significantly and was less than or equal to all other regions for the remainder of the study period (weeks 2 and 3) and for all but the South Midwest during the week following the study period (Figure 3; Table S3). It is

unclear to what extent our expedited testing pathway contributed to this reduction, although we note that our local OPO recovers organs for much of the Northwest Region. Although it is possible that the expedited COVID-19 screening pathway described here helped to reduce the number of temporary waitlist inactivations due to COVID-19 precautions, the differences may reflect regional variation in the progression of the outbreak in the United States or the significant testing capacity available through our hospital laboratory.

The expedited testing pathway continues to successfully support organ recovery and transplant during the COVID-19 outbreak in our area. However, the system we designed was feasible due to several key factors. First, the UW Clinical Virology laboratory developed an assay, received EUA early (go-live March 2, 2020), rapidly expanded capacity, and is part of a robust reference laboratory. Second, a small group of laboratory medicine personnel were able to devote significant attention to managing these specimens and adapt the pathway in real-time to avoid system failures. Third, we were able to rapidly build relationships and lines of communication between laboratory medicine faculty, infectious diseases physicians, OPO clinical leadership and staff, and transplant surgery clinical teams. Finally, and perhaps most important, widespread social distancing and outbreak mitigation strategies may have limited the potential for surge and other catastrophic trajectories of the outbreak in our region.

COVID-19 screening of potential organ donors and transplant recipients may remain important for a prolonged period, depending upon the trajectory of the epidemic. We hope that our experience suggests best practices for transplant centers that aim to continue or restart organ transplantation. The success of other programs will depend upon local outbreak factors and testing capacity. We note that multiple vendors offer rapid, FDA-EUA cleared systems, at least one of which is approved for BAL specimens.<sup>14</sup> We nonetheless recommend that laboratories and clinical teams work collaboratively to evaluate local testing capacity, identify SOT patients, track specimens, and prioritize testing as needed.

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## DISCLOSURE

The authors have no financial disclosures to report.

## DATA AVAILABILITY STATEMENT

Data used in this study are available in the supplemental materials and by accessing either the UNOS COVID-19 (<https://unos.org/COVID/>) dashboard or the Organ Procurement and Transplant Network Database (<https://optn.transplant.hrsa.gov/data/>). Deidentified turnaround time data may be shared upon request.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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