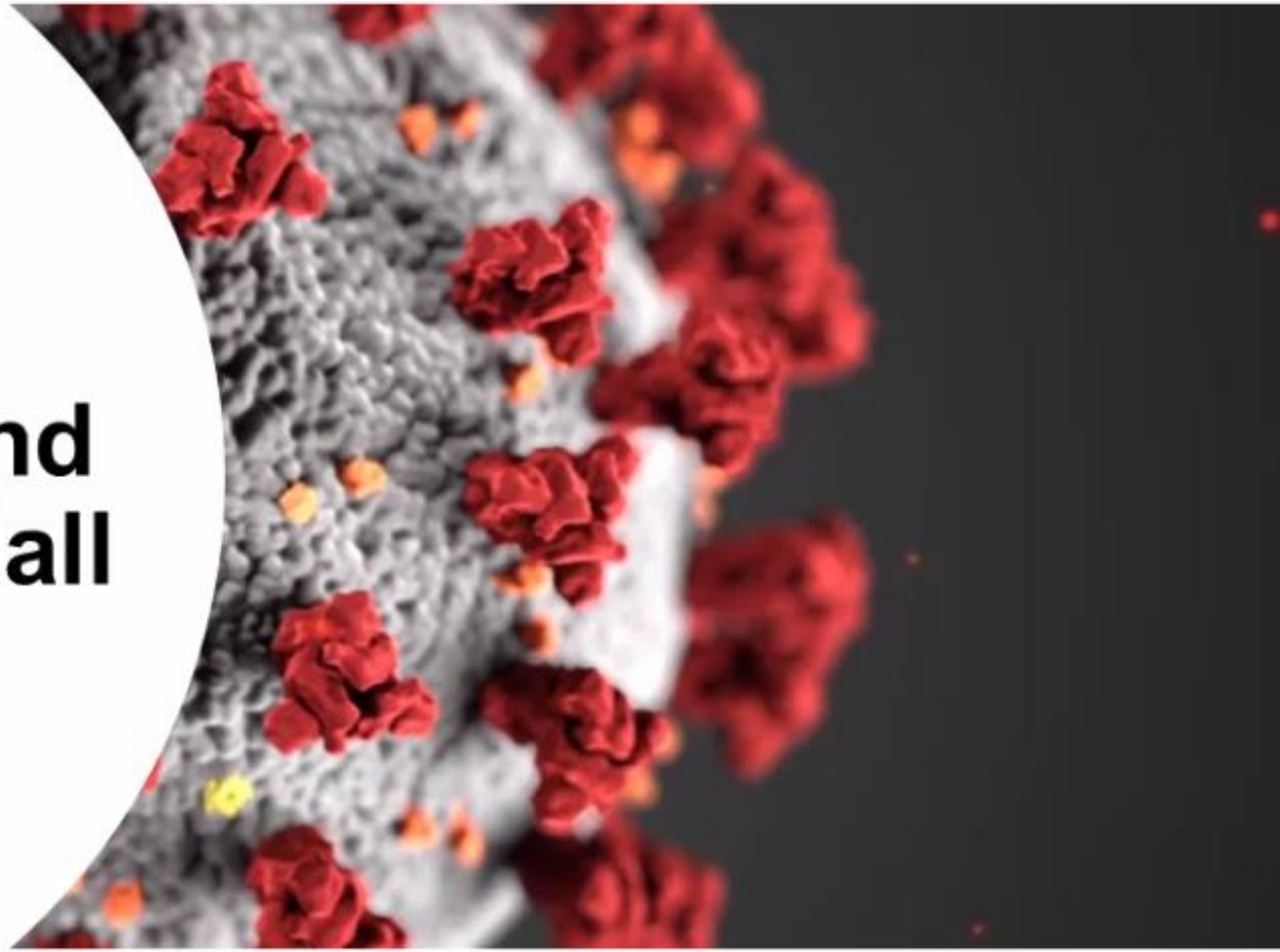
COVID-19:
Organ Donation and Transplant Town Hall

International Webinar #3

May 11, 2020



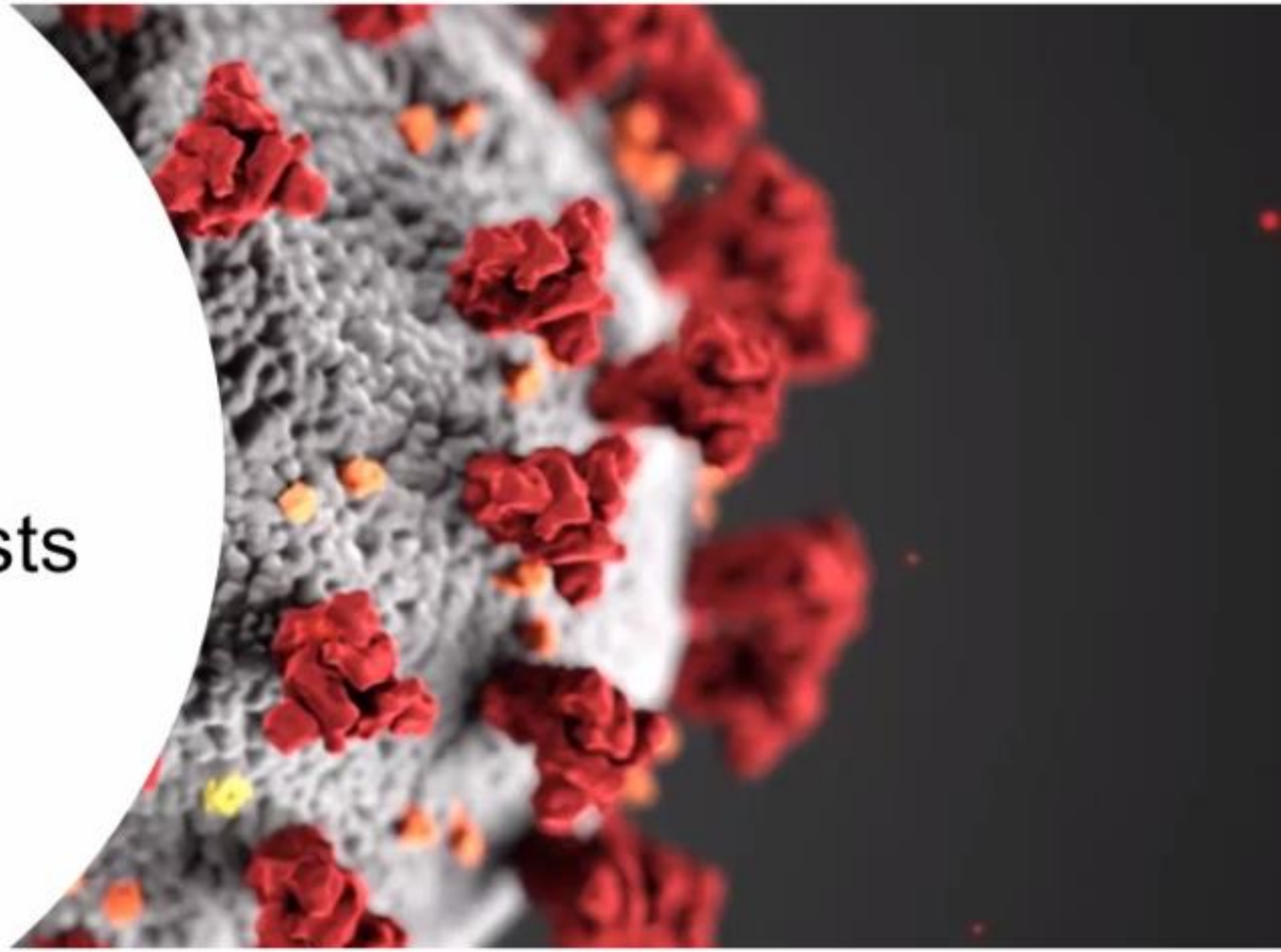
Special thanks to:

Planning Committee

- **AOPO:** Kelly Ranum, Steve Miller*
- **AST:** Emily Blumberg, Deepali Kumar, Shandie Covington,* Brian Valeria,* Izabella D'Onofrio*
- **ASTS:** Lloyd Ratner, Tim Pruett, Lew Teperman, Dan Garrett*
- **CST:** Atul Humar
- **ESOT:** Luciano Potena, Luca Segantini*
- **ISHLT:** Stuart Sweet, Greg Schultz*
- **NATCO:** Donna Dickt,* Stacee Lerret
- **TTS:** Mike Ison, John Fung, Jean-Pierre Mongeau,* and Robert Colarusso*
- **UNOS:** Brian Shepard, David Klassen, Maryl Johnson, Erica Inge, Daryl Chesley

** Organization Staff*

COVID-19:
Making Sense of the Tests



Moderated by:
Erika Demars, RN, BSN
Treasurer, NATCO
CCTC Advanced Heart Failure, Cardiac Transplant Coordinator at Henry Ford Hospital, Detroit, MI

Making Sense of COVID-19 Testing: Interpreting PCR testing results

Marwan Mikhael Azar, M.D.

Assistant Professor of Internal Medicine, Infectious Diseases

Department of Internal Medicine

Yale University, School of Medicine

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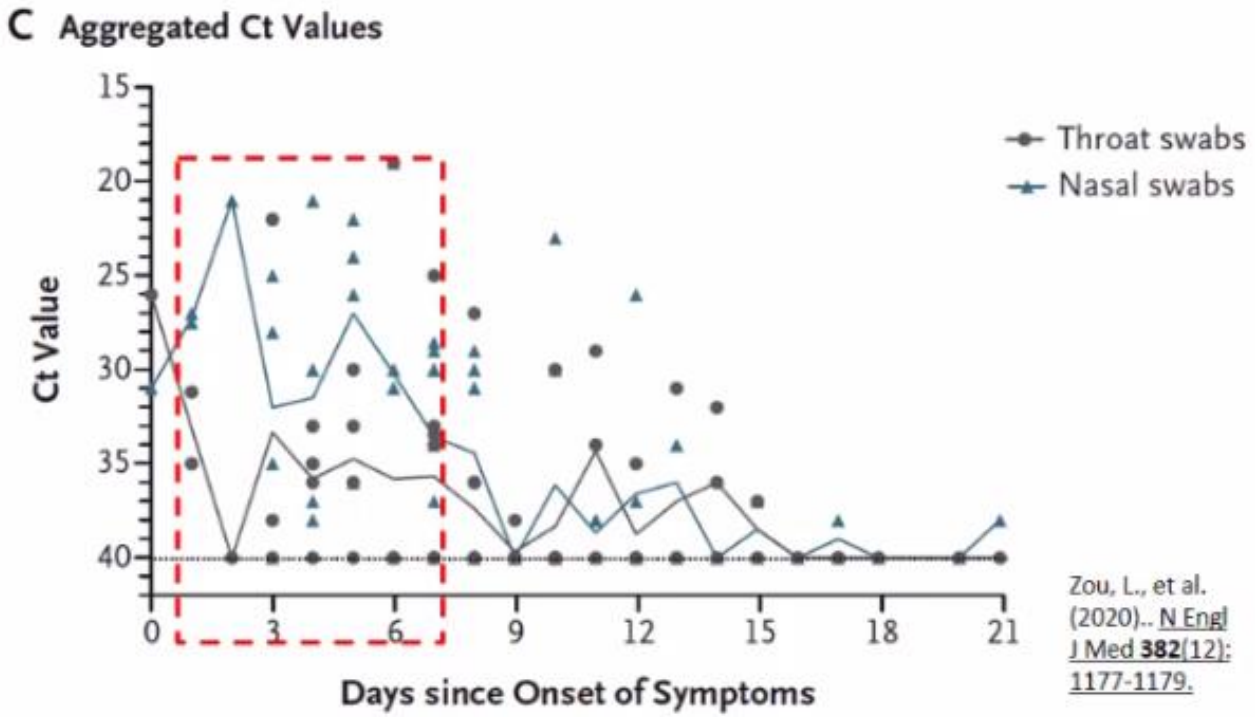
SARS-CoV 2 PCR Testing

- In COVID-19, viral replication **begins 24-48 hours** prior to symptoms and **peaks at 3-5 days** after symptom onset



Zou, L., et al. (2020).. N Engl J Med **382**(12): 1177-1179.

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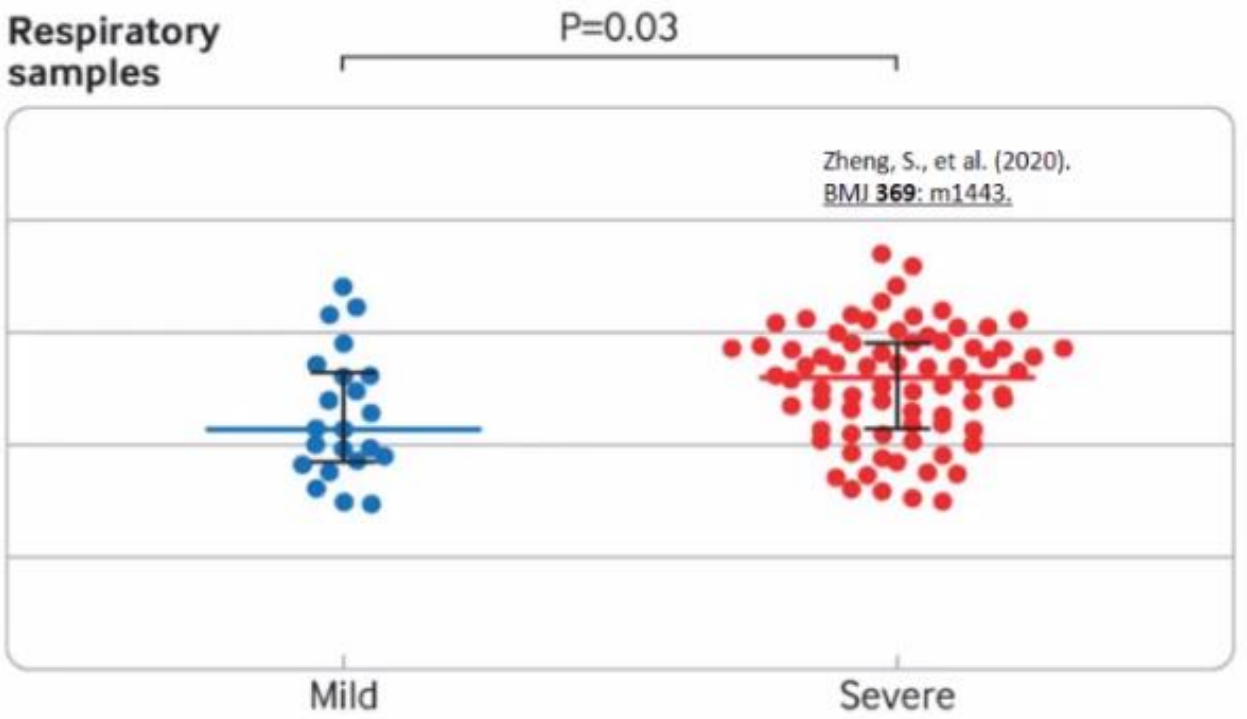
SARS-CoV 2 PCR Testing

- In COVID-19, viral replication **begins 24-48 hours** prior to symptoms and **peaks at 3-5 days** after symptom onset

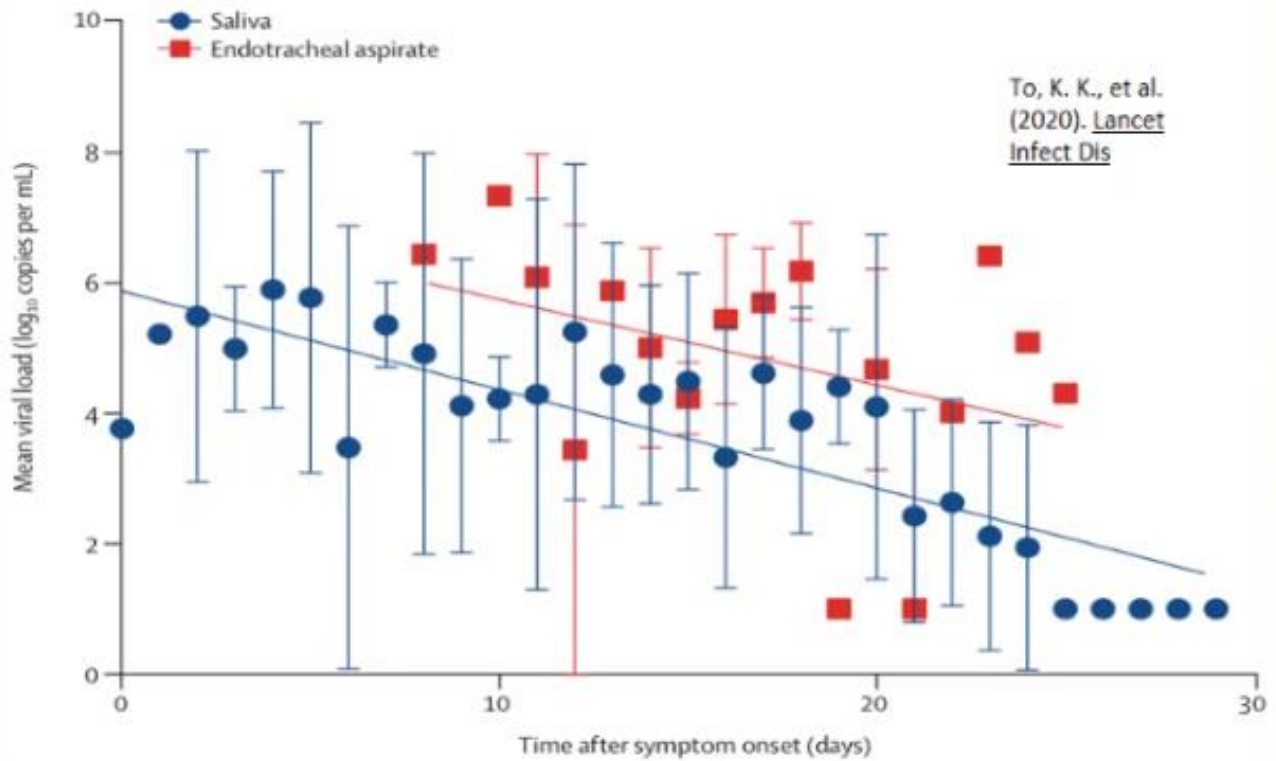
- PCR testing is >99% specific
- Sensitivity varies by:
  - Severity of disease



SARS-CoV 2 PCR Testing

- In COVID-19, viral replication **begins 24-48 hours** prior to symptoms and **peaks at 3-5 days** after symptom onset

- PCR testing is >99% specific
- Sensitivity varies by:
  - Severity of disease
  - Specimen type (URT vs. LRT)
  - Specimen quality
  - Assay type and analytical sensitivity



Sensitivity: Optimal Specimens

- **Upper respiratory tract specimens**
  - Easier to collect
  - NP, anterior nasal or mid-turbinate (MT) swabs most sensitive
  - Saliva: variable sensitivity – issues with collection
    - One study: higher VL in saliva than NP swab in 38 matched specimens (Wyllie et al)
- **Lower respiratory tract specimens**
  - Collected if URT negative and suspicion for COVID moderate to high
  - Higher sensitivity but biased by severity

URT	Oral	Nasal	NP	Saliva	MT
Sensitivity (95% CI)	**56%** (35 to 77%)	**76%** (59 to 94%)	**97%** (92 to 100%)	**85%** (69 to 94%)	**100%** (93 to 100)

LRT	Sputum	BAL
Sensitivity	**72-89%**	**93-100%***

Hanson ., et al. (2020) Clin Inf Dis.

Wang, W., et al. (2020) JAMA.

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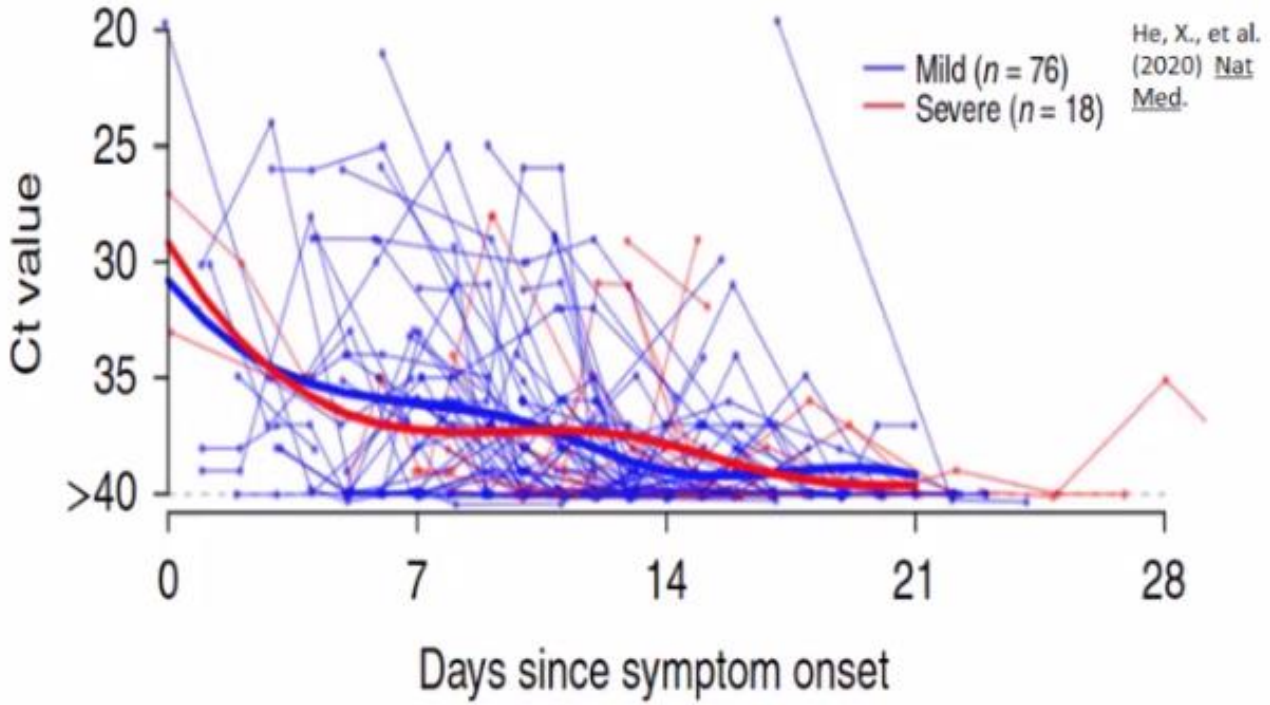
Prolonged PCR Positivity & Transplant Considerations

- PCR may remain detectable for weeks
- Viral shedding may be longer in SOT recipients
  - Mean 28 days vs. 12 days*



He, X., et al. (2020) Nat Med.

*Zhu, L., et al. (2020). " Eur Urol.

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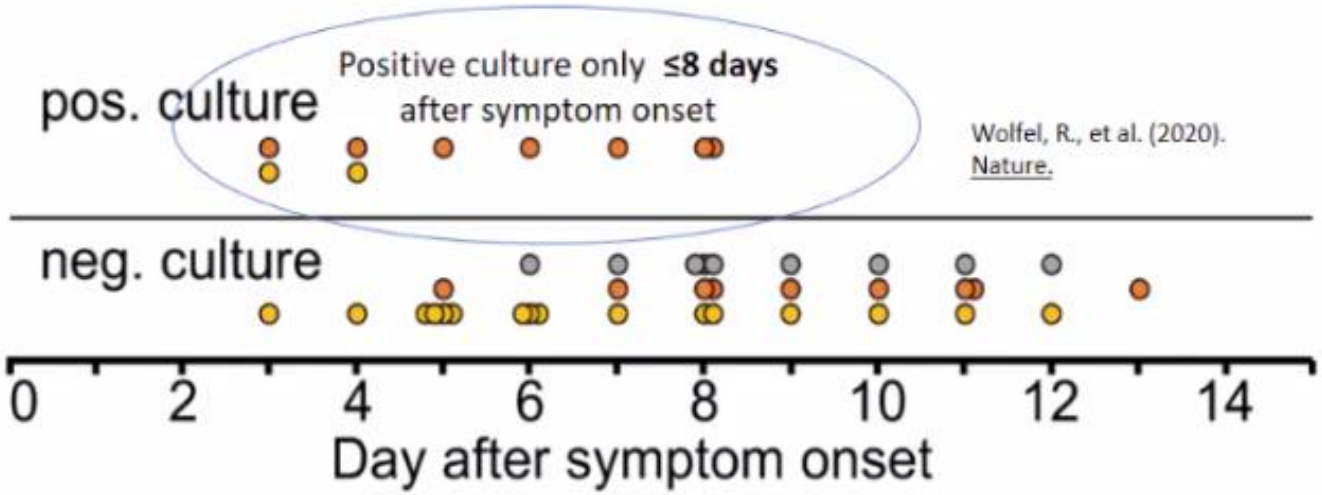
Prolonged PCR Positivity & Transplant Considerations

- PCR may remain detectable for weeks
- Viral shedding may be longer in SOT recipients
  - Mean 28 days vs. 12 days*
- Significance unclear but may not indicate live, infectious virus



Wolfel, R., et al. (2020). Nature.

*Zhu, L., et al. (2020). " Eur Urol.

Making Sense of the Tests: Serology

Howard M. Gebel, Ph.D.
Professor of Pathology
Emory University Hospital
Atlanta, GA

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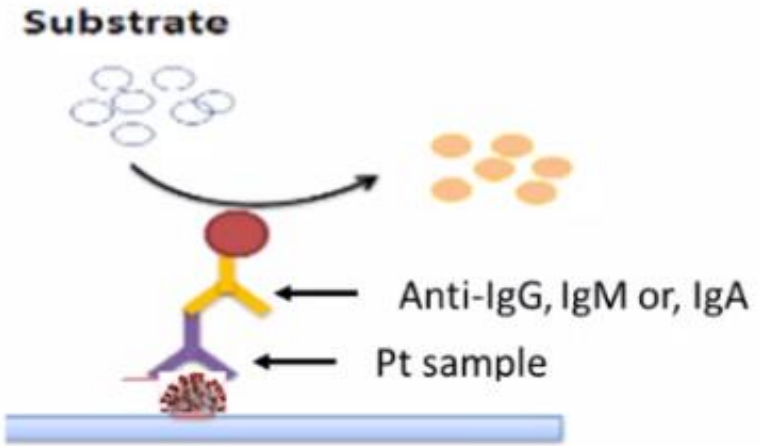
Antibody Testing for SARS Covid-2

On 03/16/20, the FDA issued a policy with the regulatory flexibility which would lead to more rapid testing capacity in the U.S.

148 tests have not been reviewed by the FDA.

160 different tests are available

Antibody assays



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Antibody Testing for SARS CoV-2

What information do we have?

Yes/No

What information don't we have?

Titer

Stability

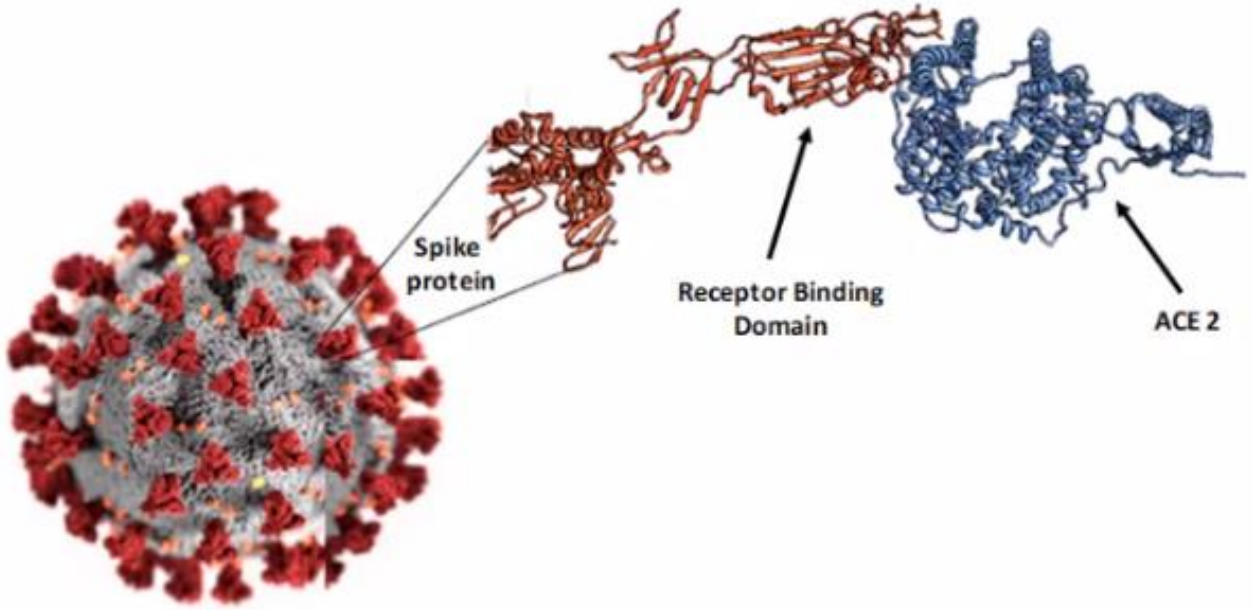
Subclass (for IgG, IgA)

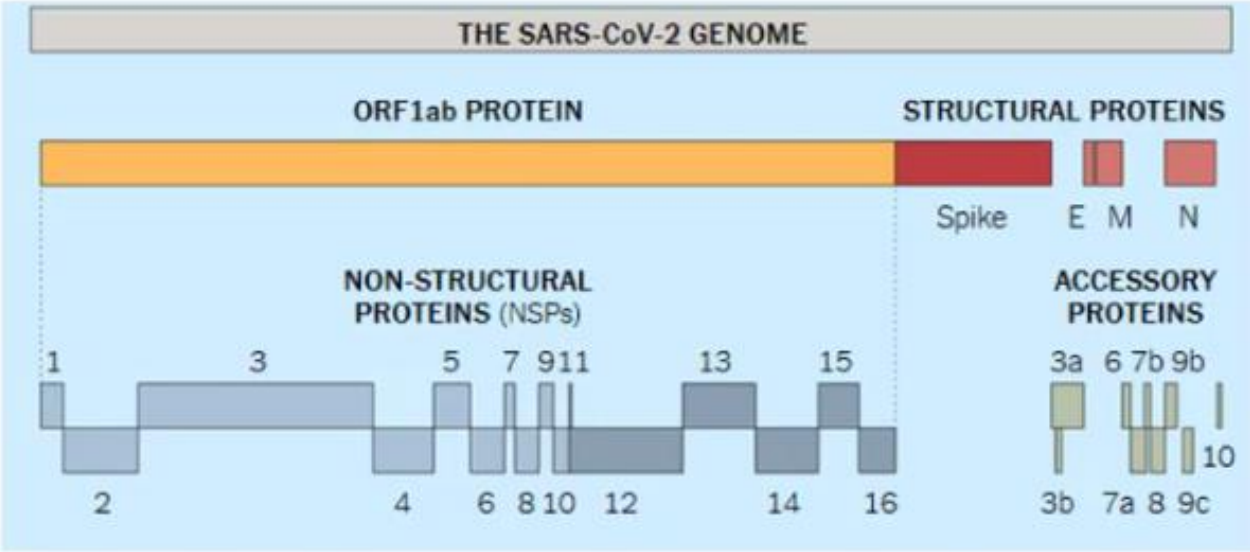
Functional properties/Fine specificity

- Complement fixation
- Neutralizing

PROTECTIVE?

What else don't we know?





In theory, there is no difference between theory and practice.
In practice, there is!

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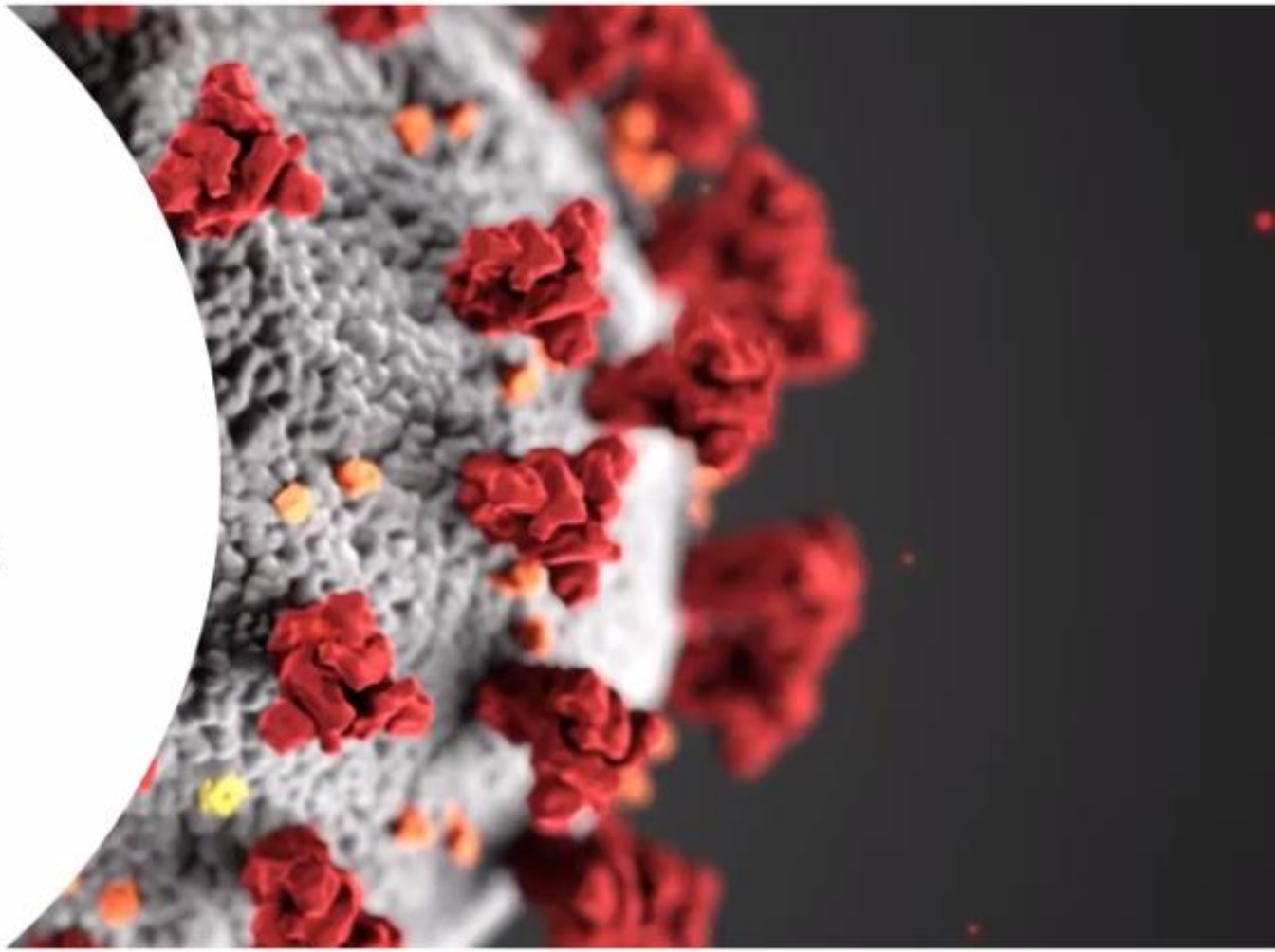
COVID-19:
Moving into the Future



Moderated by:
Luciano Potena MD PhD
Medical Director Heart Transplant Program
Bologna Academic Hospital in Bologna, Emilia-Romagna, Italy

Returning to Transplant: The Tongji Experience with Resuming Transplant Activities after COVID-19

Lan Zhu, MD

Associate Professor of Surgery

Institute of Organ Transplantation

Tongji Hospital of Tongji Medical College

Huazhong University of Science and Technology

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2020 Transplants in Tongji Hospital

5 LTx, 12 KTx

All the staffs in hospital must be screened for PCR and Abs before returning to work

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Donor/Recipient & Companion Screening

Potential Donor

- Naso-swab PCR
- IgM/IgG

(-)

1-3 days

Re-examine

- Naso-swab PCR
- IgM/IgG

(-)

Donation

Admitted in observational ward

(-)

- Naso swab PCR
- IgM/IgG
- Chest CT

3 days

Re-examine

- Naso swab PCR
- IgM/IgG

Tx in Isolation OP

(-)

Regular Ward

Tx in Regular OP

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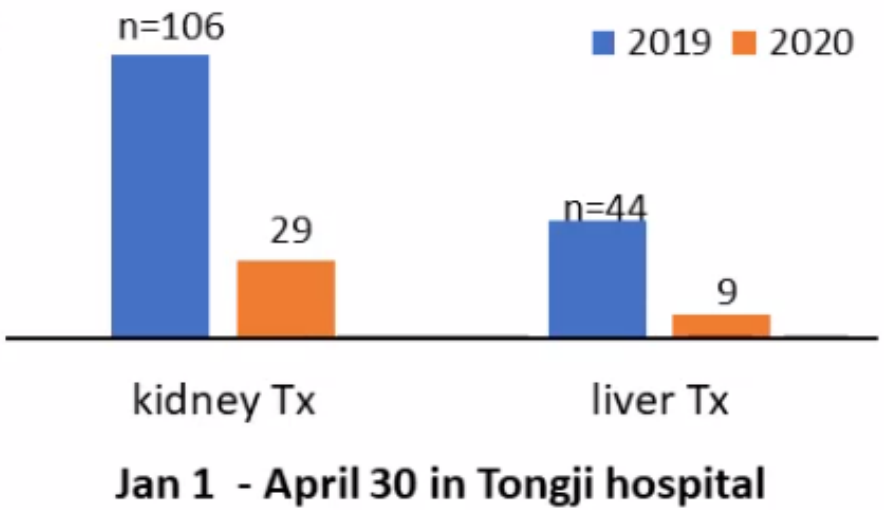
Summary

- Triple check for D/R/medical workers
- D/R must be negative for both PCR/Abs
- Medical workers must be negative for PCR/IgM
- Operation under Level 3 protection if still in 3 days observational



Jan 1 - April 30 in Tongji hospital

Impact of COVID-19 on Donor and Transplant Numbers: OPTN Update

David Klassen, M.D.

Chief Medical Officer, UNOS

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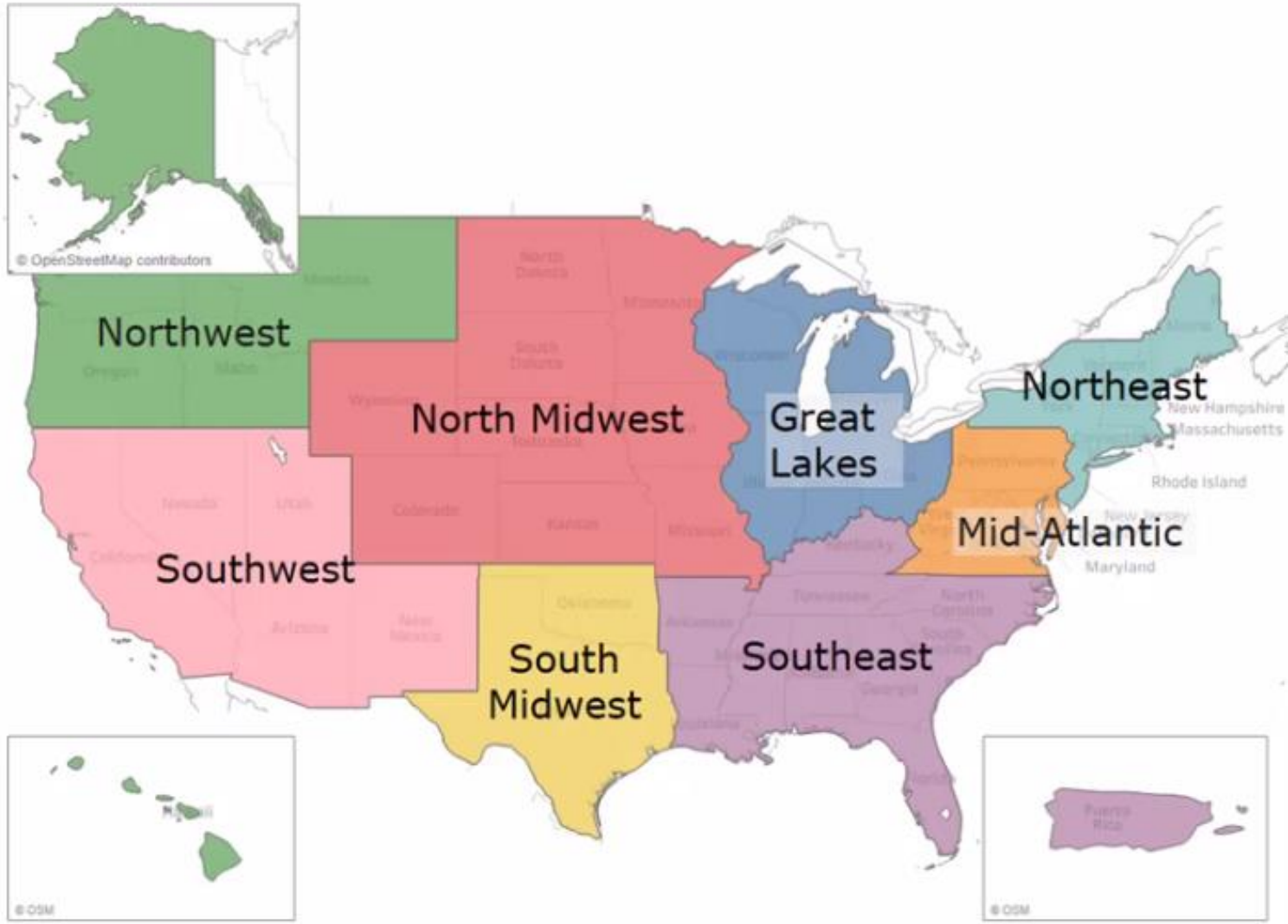
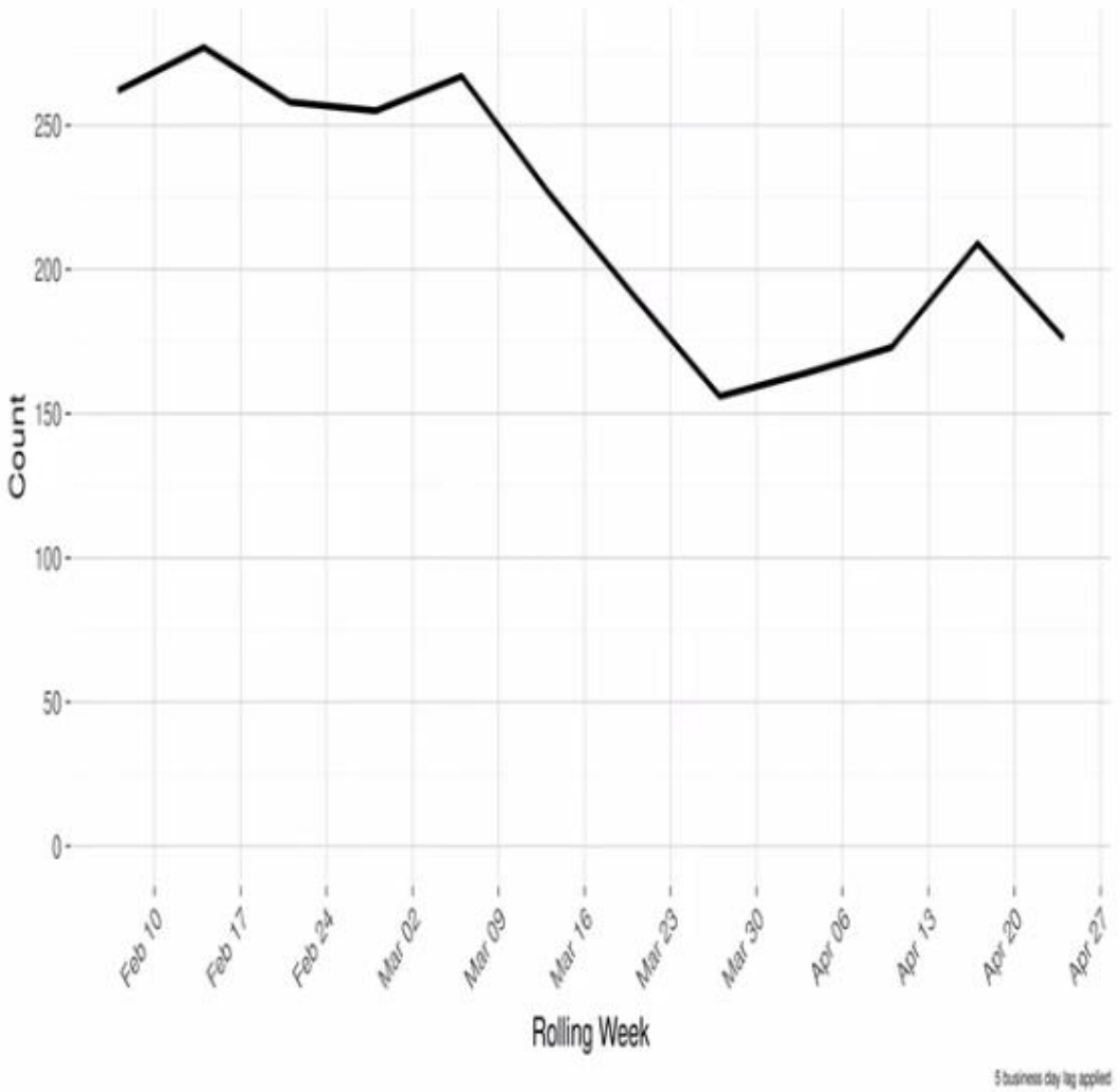
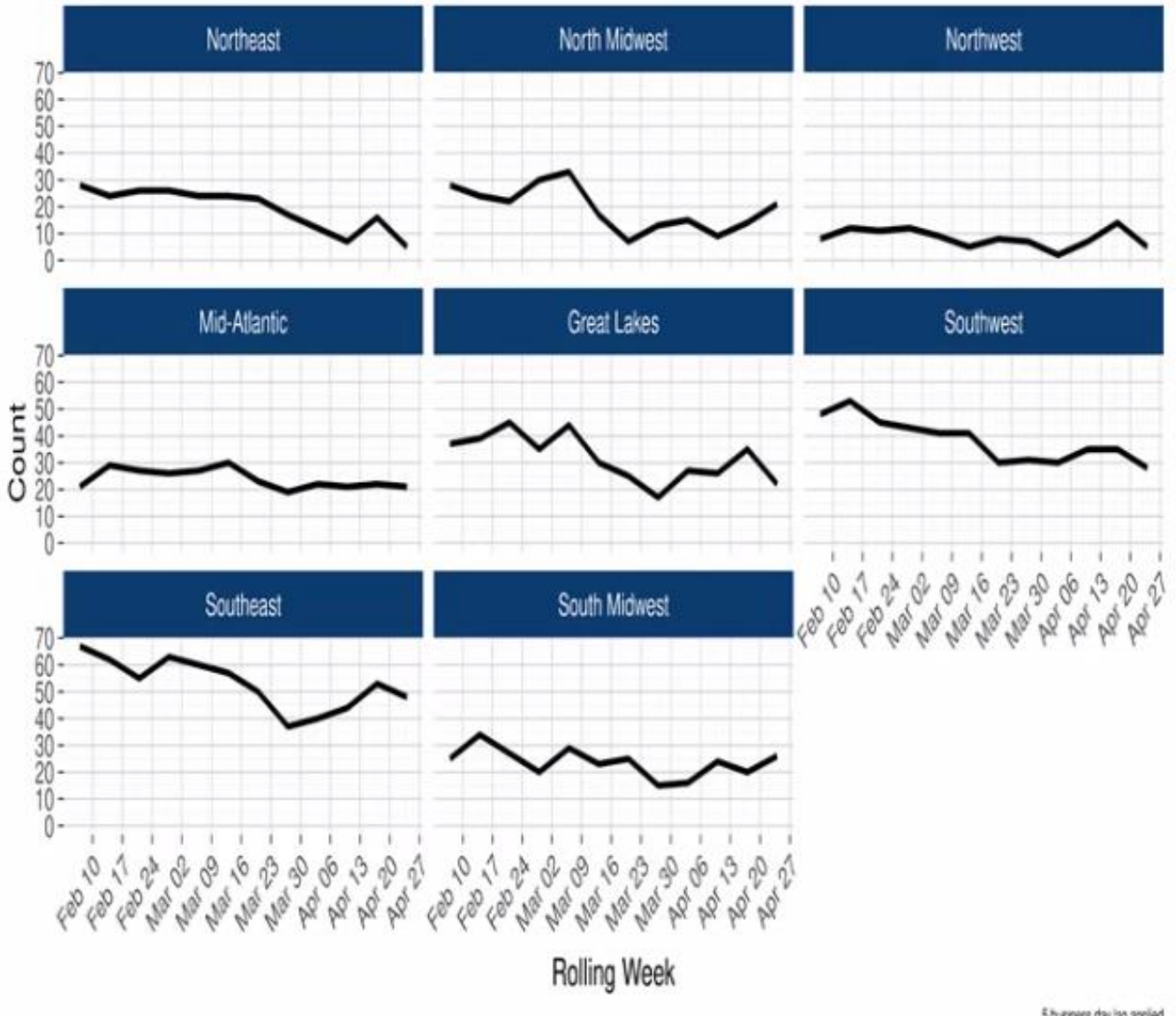
Map of Geographic Regions for this Analysis

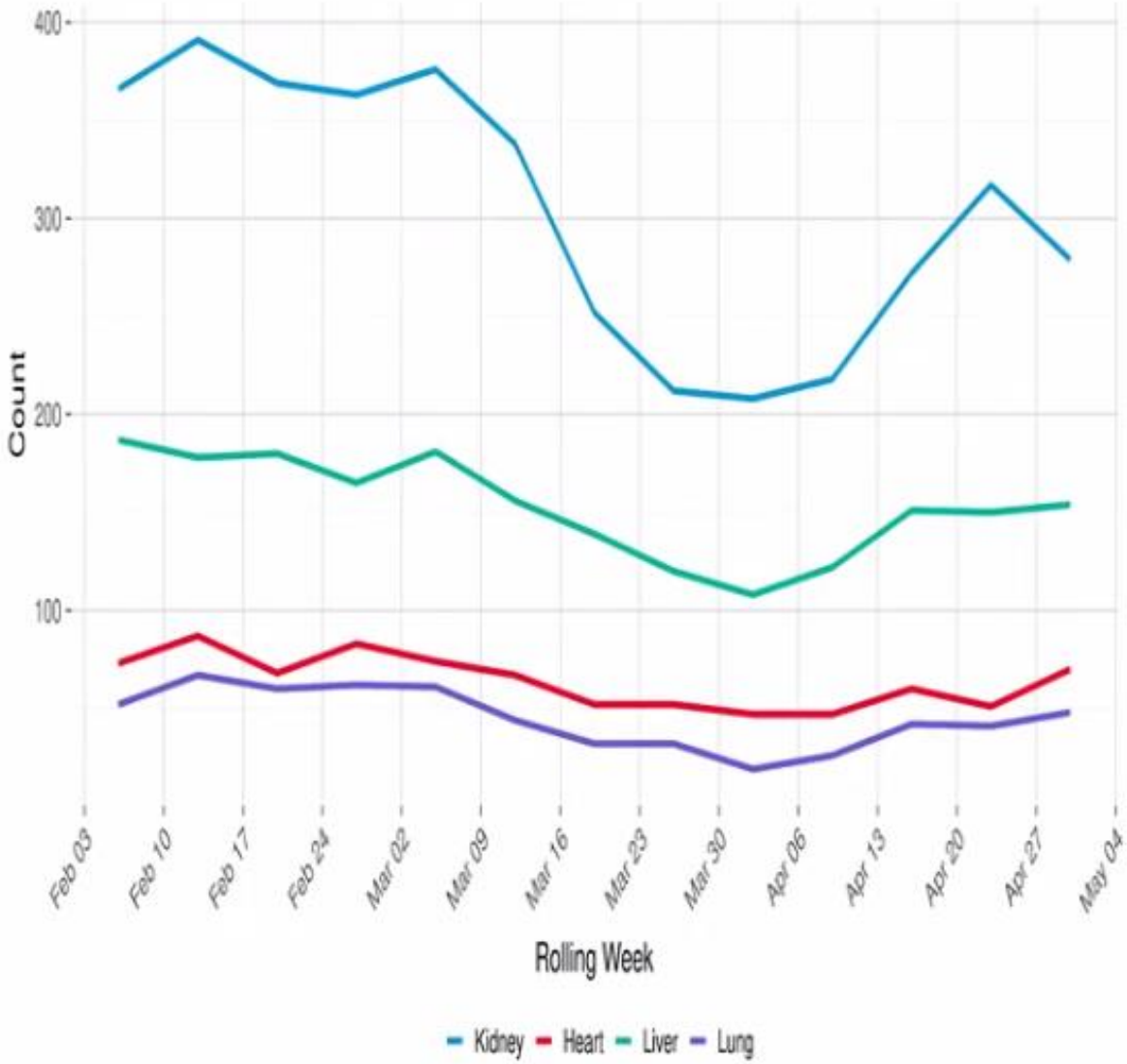


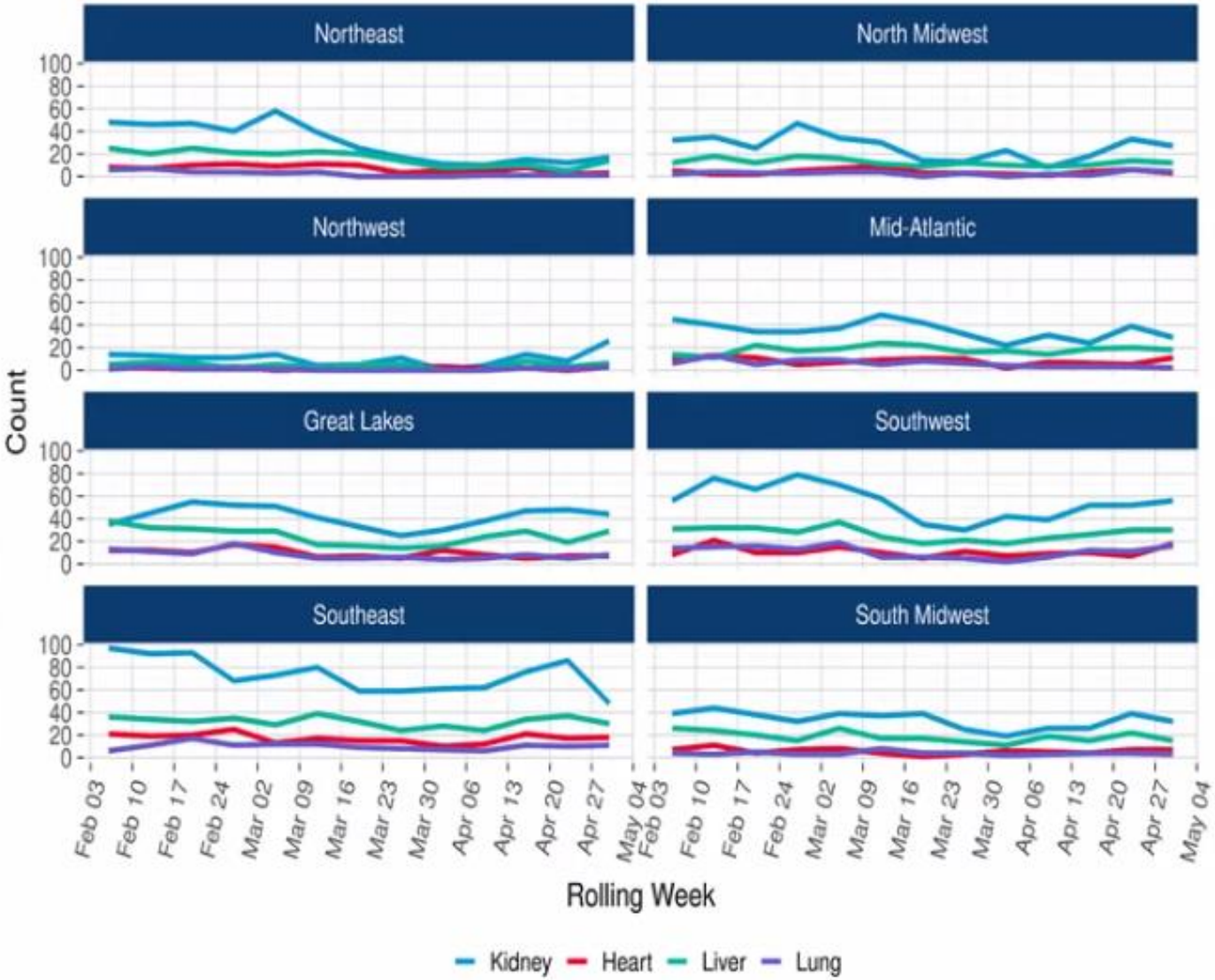
Deceased Donors Recovered by Week



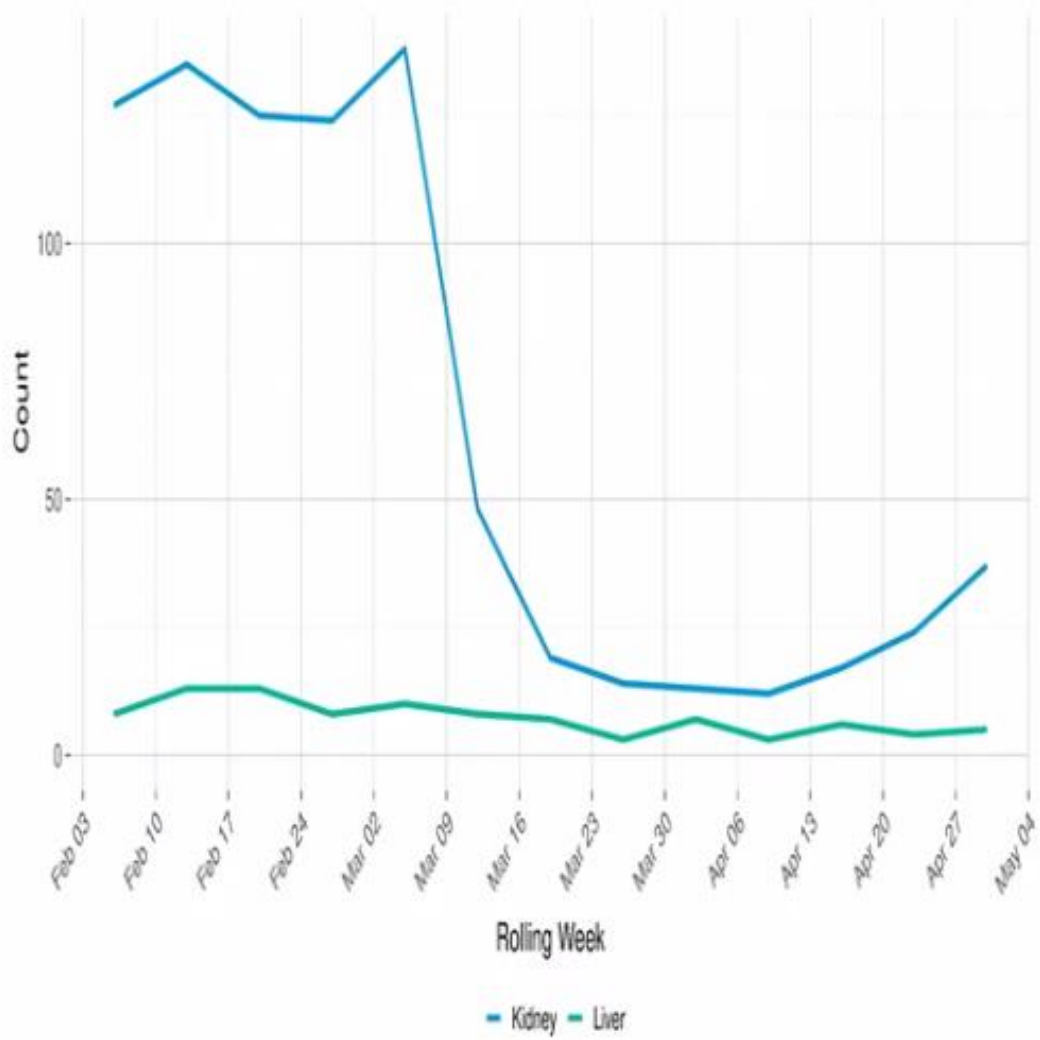


Deceased Donor Transplants by Week, Geography, and Organ Type

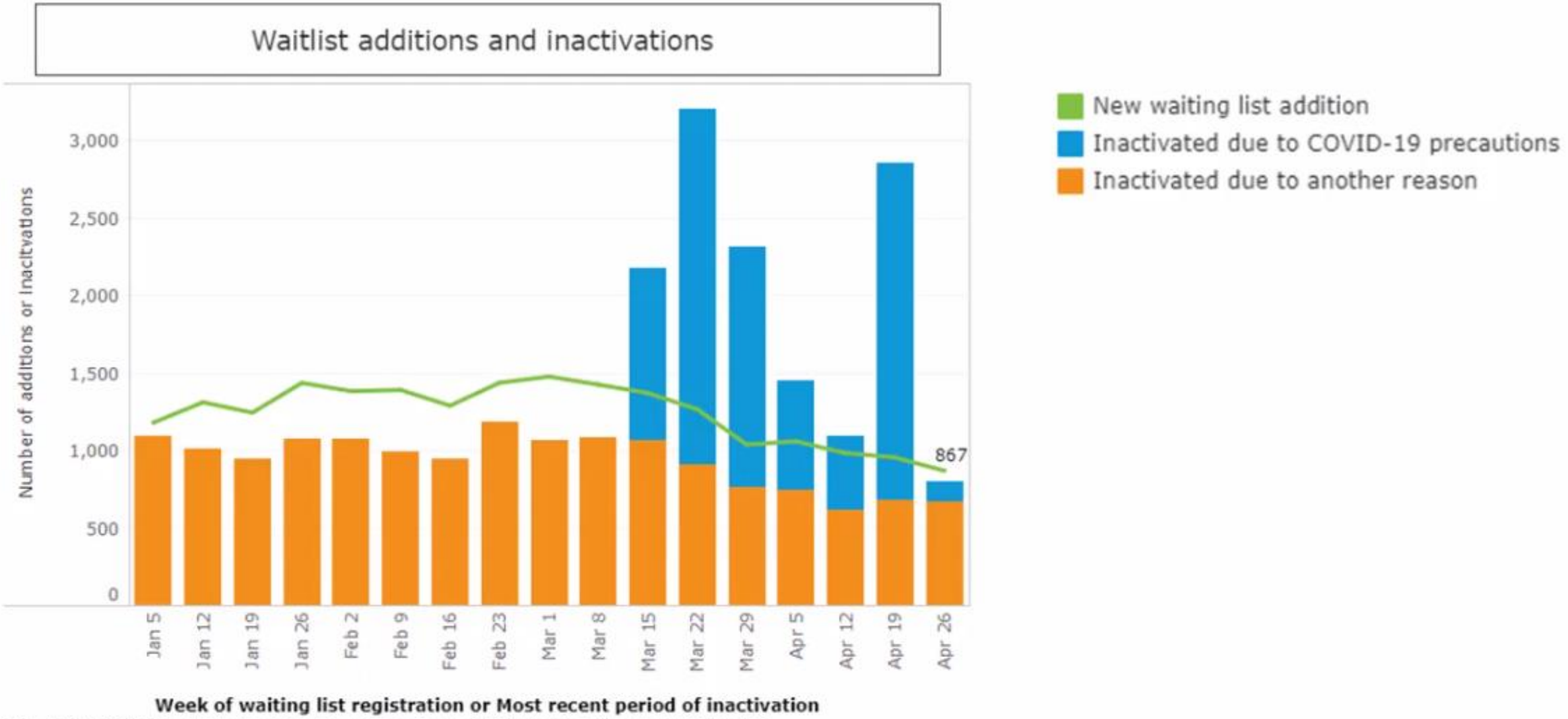




Living Donor Transplants by Week, Geography, and Organ Type

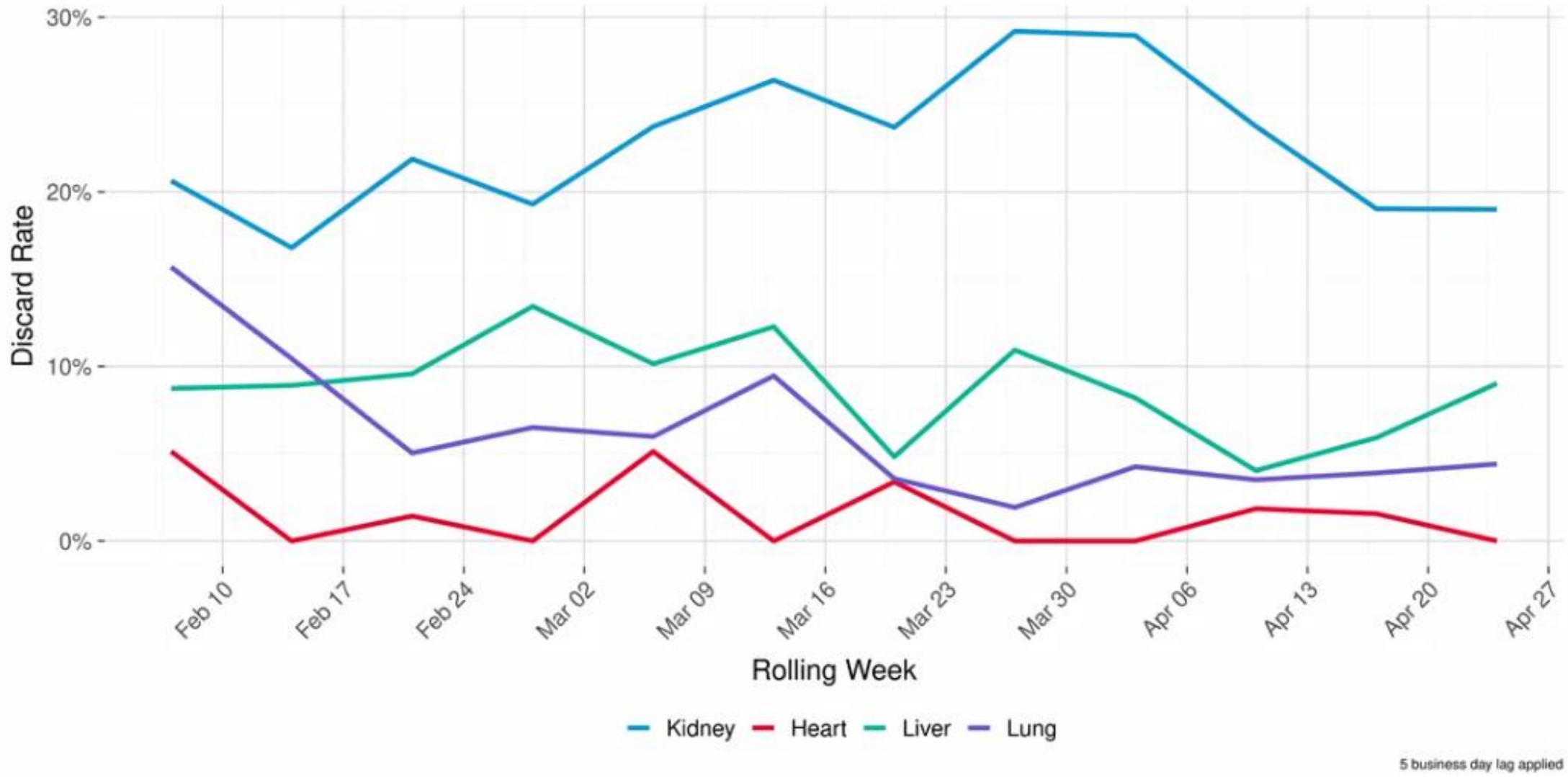


Waiting List Additions and Inactivations by Week



*The COVID-19 Precaution inactive reason became available in UNet the week of Mar 15.

Deceased Donor Discard Rate by Week



5 business day lag applied

EMERGING FROM QUARANTINE

How do we know when we can scale up?

European experience: Spain

Beatriz Domínguez-Gil

Director General

Organización Nacional de Trasplantes

Madrid, Spain

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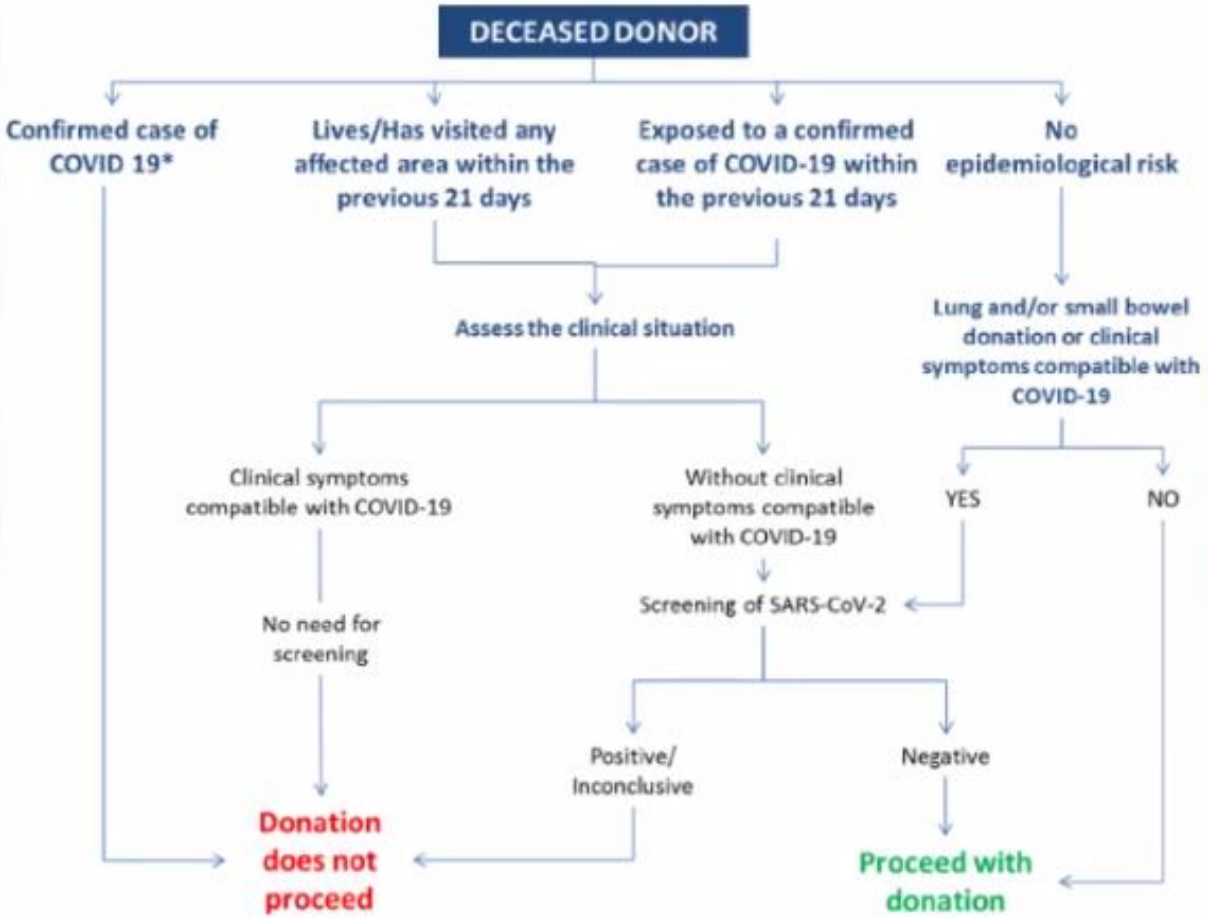
COVID-19: SAFETY STANDARDS

Safety period of 21 days to exclude outliers

RT-PCR test on BAL/BAS/ oro&nasoph. samples obtained <24h donation



**Cured cases will be considered on a case-by-case basis after 21 days*

TRANSPLANT:

- **Screening for SARS-CoV-2: RT-PCR in oro&nasoph. Sample prior to transplant**

- **LOCAL RECOVERY**

Domínguez-Gil B. et al, Am J Transplant 2020

COVID-19 TRANSPLANT PATIENTS IN SPAIN: PRELIMINARY DATA

- 15% Nosomial; 85% Community acquired; No suspected donor-derived COVID-19
- Time since tx: 63 (IQR 21-138) months; 16 cases (2%) 1st month postx

	CASES	FOLLOW UP	HOSPITALIZED	CRITICAL CARE	MECHANICAL VENTILATION	CURED	DEATHS
TOTAL	**802**	**665**	**608**	**73**	**89**	**401**	**185**
KIDNEY	558	509	468	59	78	294	140
LIVER	85	53	49	3	3	39	13
JEART	21	19	18	3	3	6	13
LUNG	43	28	23	3	0	21	7
PANCREAS	5	3	3	1	1	3	0
MULTIVISCERAL	1	1	0	0	0	1	0
HSC	89	52	47	4	4	37	12

CASE-FATALITY RATIO:

23 - 28%

Source: Organización Nacional de Trasplantes

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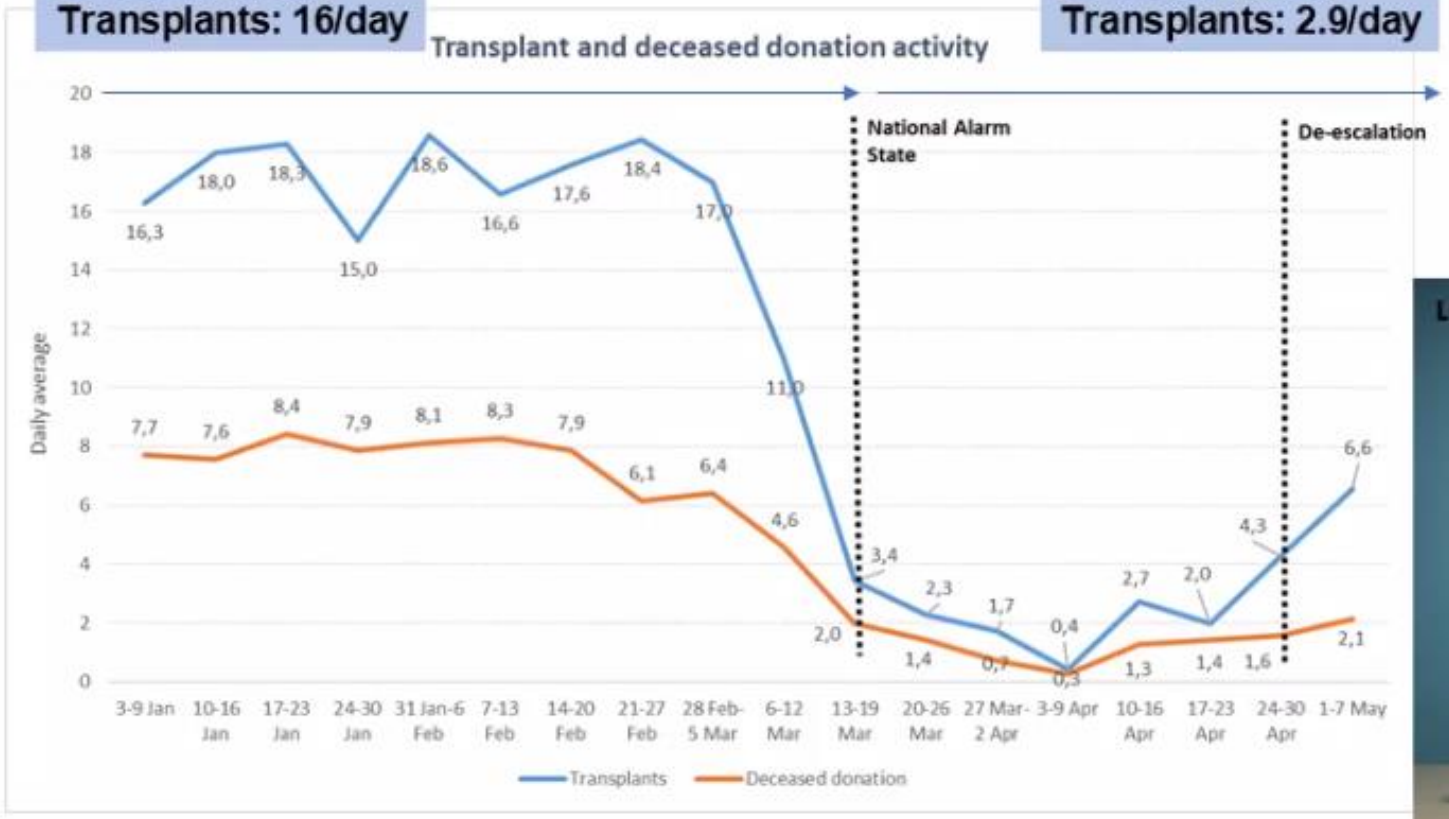
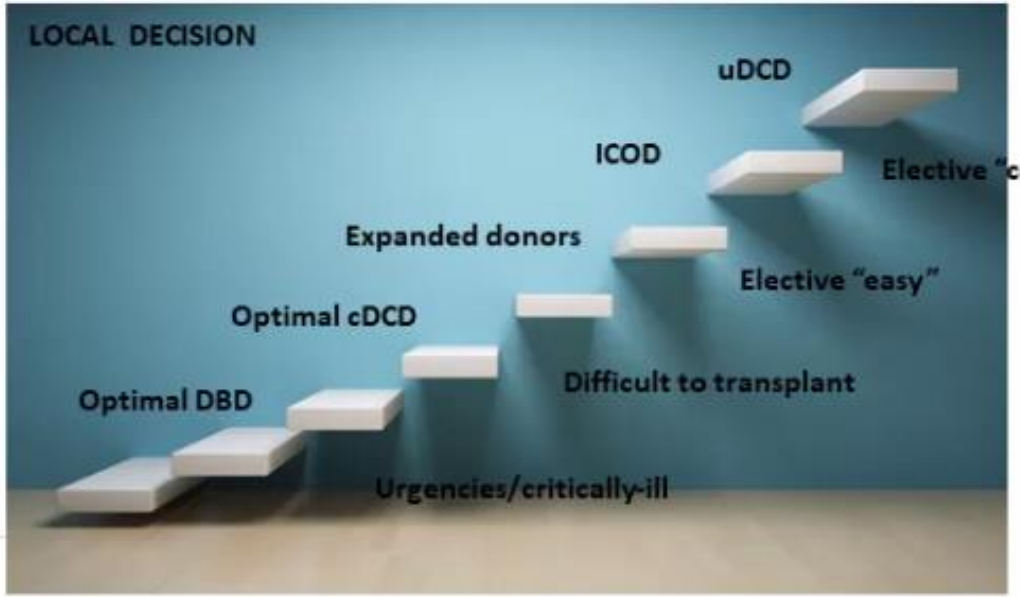
D&T ACTIVITIES IN SPAIN 2020

Donors: 7.2/day
Transplants: 16/day

Donors: 1.4/day
Transplants: 2.9/day



…an excellent thermometer of what happens in the hospital



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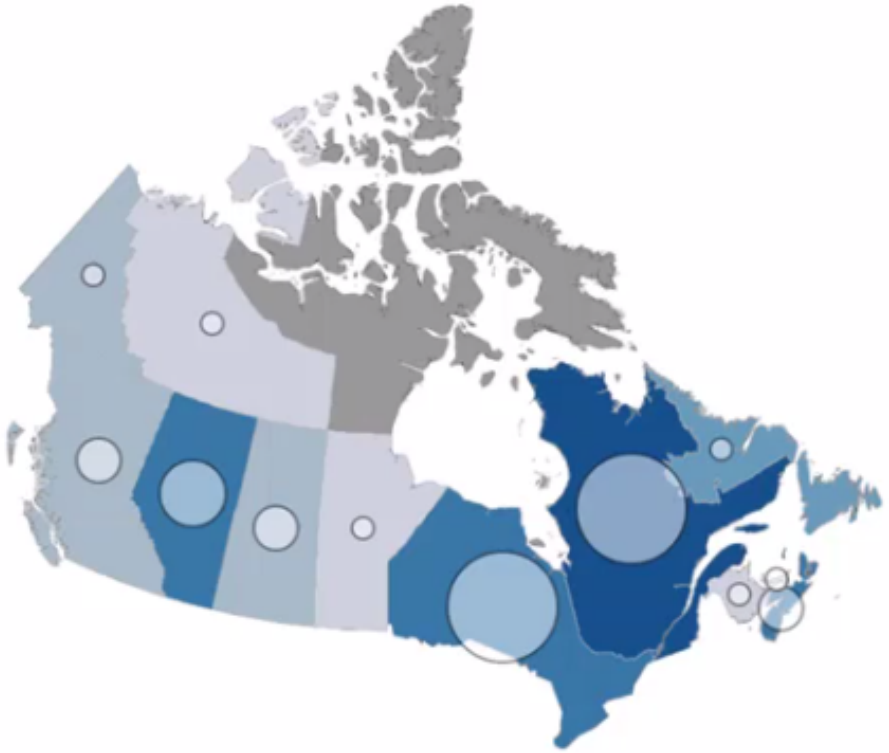
Phasing Up Transplant Activity in Ontario, Canada

Darin Treleaven, MD, MSc

Associate Professor, Dept. of Medicine, McMaster University,

Chief Medical Officer, Transplantation, Trillium Gift of Life Network



Credit: A collaboration between Public Health Agency of Canada, Statistics Canada and Natural Resources Canada.
Powered by: ESRI Canada and Amazon Web Services (AWS)

McMaster University HEALTH SCIENCES

Trillium Gift of Life Network

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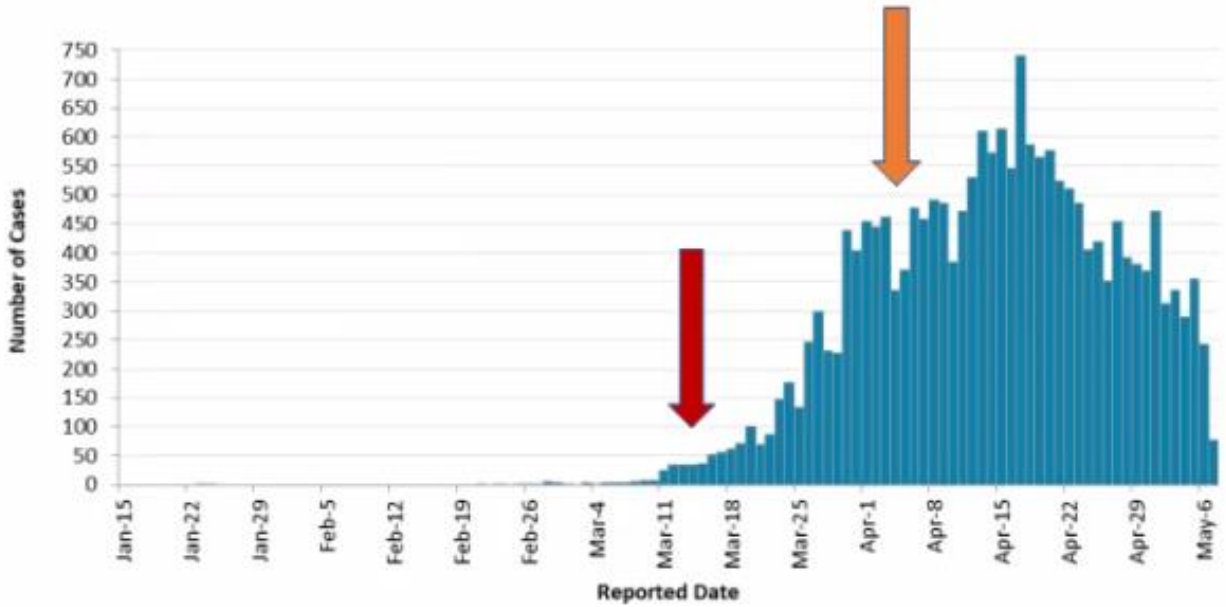
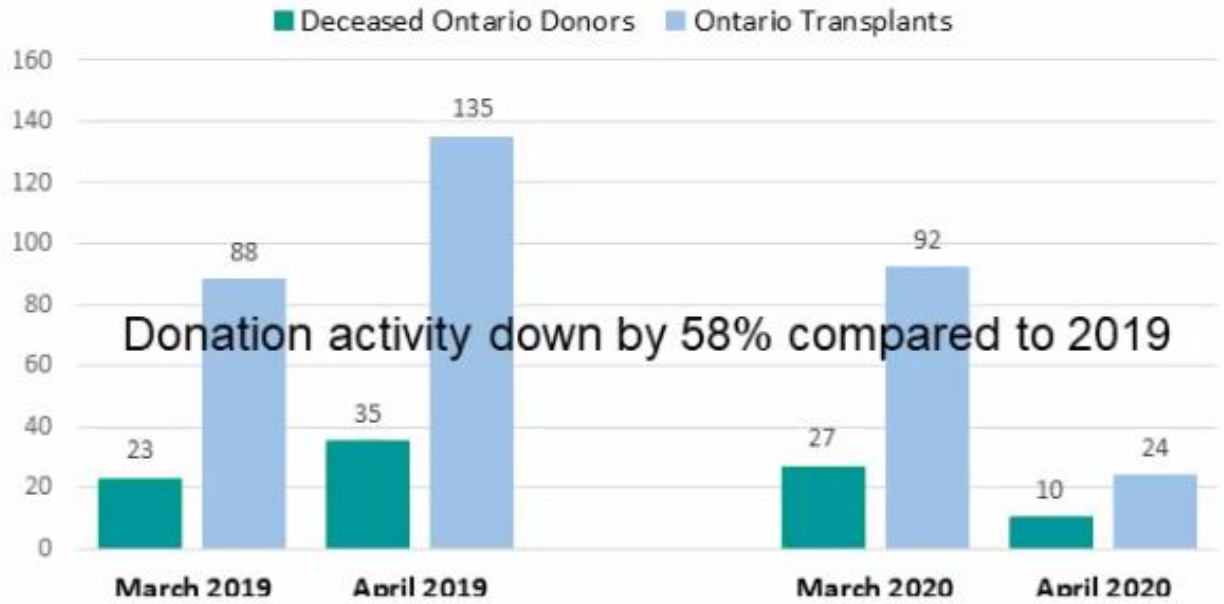
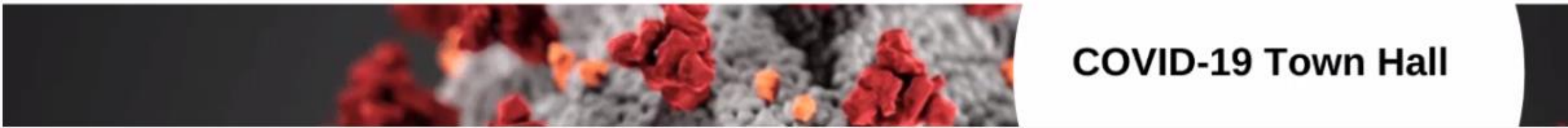
Figure 1. Confirmed cases (n=19,598) of COVID-19 by reported date: Ontario, January 15, 2020 to May 7, 2020[1]





- Ontario is Canada's most populous province, with 38.3 percent of the country's population
- 8 transplant programs: adult, pediatric, heart, lung, liver, pancreas, kidney and small bowel
- COVID Management System: Daily calls supported by OPO (TGLN)
- All programs participated, incl crit care, ID, TGLN leadership
- Mar 15: unanimous decision to limit transplant activity
    - High status: heart, liver, lung
    - cPRA 99/100, medically urgent



April 6 PhaseUp Plan: Key considerations

- Alignment with Ontario public health, hospital critical care and surgery command table ramp up planning
- Recipient selection to minimize complications and resource use
- Safe recovery strategy
- Donor screening tool: contact, history, ETA/NPS, imaging
- Rapid turn around for SARS-CoV-2 pcr results
- Advance communication with screened, eligible recipients

RED: current conditions. Increasing or uncertain conditions limiting transplant

ORANGE: stable conditions with stable and predictable rate of new hospital and ICU admissions with significant transplant hospital capacity

YELLOW: improving conditions with decreasing rate of hospitalization and ICU admissions with sufficient transplant hospital capacity

GREEN: sustained decline and near normal hospital activity

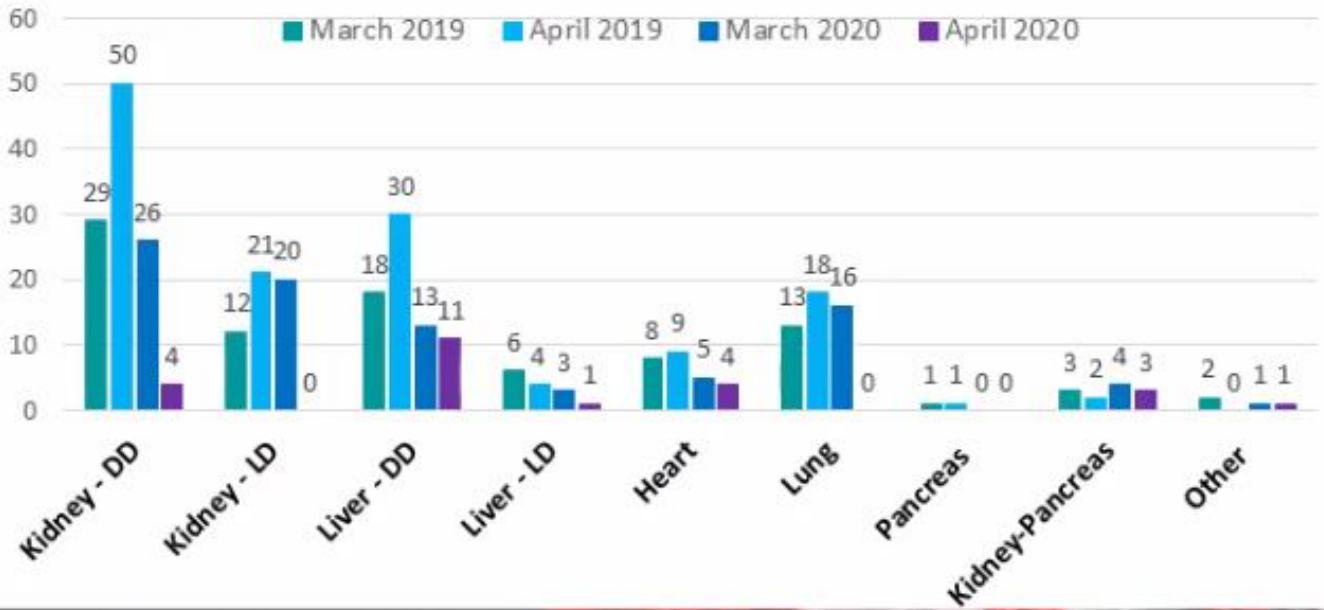
Stages would be re-considered at each transplant hospital each week using these criteria.

Adult Recipient Transplants:

- Kidney Transplant
  - No living donor activity;
  - Allow NDD-SCD and MAID DCD deceased donors to recipients based on wait list priority (exclude ECD eligible recipients);
  - Medically Urgent and HSP recipients (PRA >94%) eligible for all NDD-SCD, NDD-ECD and MAID DCD donors
- Liver Transplant
  - Living donor activity for moderate to severe sick recipients only
  - Deceased donor activity; NDD; DCD < age 50
- Heart Transplant
  - (*Activity tied to ICU/CV ICU activity see Appendix A: Heart Program Restart Plan)
- Lung Transplant
  - Status 3 patients, Driving distance NDD donors, No DCD, No NPOD, No out of province
- Pancreas and Kidney-Pancreas Transplant
  - NDD- SCD and DCD <age 35 activity for SPK only as outlined for kidney; PAK for cPRA >94 and no PTA activity
- Small Bowel Transplant
  - No activity unless combined with liver
- Islet Transplant
  - No Activity

Transplant Program	Kidney	Pancreas and KP	Liver	Heart	Lung	Small Bowel
University Health Network	🟠	🟠	🟠	🟡	🟠	🟠
London Health Sciences Centre	🟠	🟠	🟠	🟡		
Hospital for Sick Children	🔴	🟠	🟡	🟢	🟠	🟢
Ottawa Heart Institute				🟡		
The Ottawa Hospital	🔴					
St. Michael's Hospital	🟠					
Kingston General Hospital	🟠					
St. Joseph's Healthcare - Hamilton	🟠					

LEGEND	Description of Transplant Activity
🟢	Moderate to near normal transplant activity
🟡	Limited to moderate increase in transplant activity
🟠	Very limited increase in activity
🔴	Limited transplant activity



1. Speeding up is harder than slowing down
2. Implementation requires multi-level (local and provincial) coordination of surgical services
3. Local hospital and dialysis unit outbreaks have moved programs between stages already
4. It has helped immensely to have guiding principles and key considerations from other jurisdictions
5. Monitoring: COVID, WL deaths, WL impact

Moving Into the Future-Preparing our Health Care Facilities to Manage both COIVD-19 and Transplant - When to Scale Up: Upscaling OR capacity

Surgical Prioritization in a Global Pandemic

Talia B Baker, MD, FACS

Surgical and Program Director, Liver Transplant

University of Chicago Medicine

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Simple Allocation Principles & Schemes

Ethical Principle		Example Allocation Scheme
Equity (treating people equally)		"first-come, first serve" (ICU beds normally, kidney allocation)
Prioritarianism (favoring the worse off)	Sickest First	Liver allocation (MELD score)
	Youngest first	Pediatric priority (kidney)
Utilitarianism (maximizing total benefit)		Wounded soldiers on battlefield
Promoting and rewarding "social usefulness"		Prior living kidney donor priority points

Principles of Allocation of Scarce Medical Interventions
Persad G, Wertheimer A, Emanuel EJ: Lancet 2009;373:423-431

“No single principle is sufficient to incorporate all morally relevant considerations”

Ethical Principle		Disadvantages	
Equity (treating people equally)		Hard to achieve in practice	Ignores other relevant principles
Prioritarianism (favoring the worse off)	Sickest First	Ignores Scarcity!	
	Youngest first	Age-discrimination	
Utilitarianism (maximizing total benefit)		Exacerbate existing social inequities	
Promoting and rewarding “social usefulness”		Vulnerable to abuse, too subjective	

Principles of Allocation of Scarce Medical Interventions
Persad G, Wertheimer A, Emanuel EJ: Lancet 2009;373:423-431

Surgical Prioritization In A Global Pandemic - MeNTS

ARTICLE IN PRESS

SPECIAL ARTICLE

Medically Necessary, Time-Sensitive Procedures: Scoring System to Ethically and Efficiently Manage Resource Scarcity and Provider Risk During the COVID-19 Pandemic

Vivek N Prachand, MD, FACS, Ross Milner, MD, FACS, Peter Angelos, MD, FACS, Mitchell C Posner, MD, FACS, John J Fung, MD, FACS, Nishant Agrawal, MD, FACS, Valluvan Jeevanandam, MD, FACS, Jeffrey B Matthews, MD, FACS

Hospitals have severely curtailed the performance of nonurgent surgical procedures in anticipation of the need to redeploy healthcare resources to meet the projected massive medical needs of patients with coronavirus disease 2019 (COVID-19). Surgical treatment of non-COVID-19 related disease during this period, however, still remains necessary. The decision to proceed with medically necessary, time-sensitive (MeNTS) procedures in the setting of the COVID-19 pandemic requires incorporation of factors (resource limitations, COVID-19 transmission risk to providers and patients) heretofore not overtly considered by surgeons in the already complicated processes of clinical judgment and shared decision-making. We describe a scoring system that systematically integrates these factors to facilitate decision-making and triage for MeNTS procedures, and appropriately weighs individual patient risks with the ethical necessity of optimizing public health concerns. This approach is applicable across a broad range of hospital settings (academic and community, urban and rural) in the midst of the pandemic and may be able to inform case triage as operating room capacity resumes once the acute phase of the pandemic subsides. (J Am Coll Surg 2020;■:1−8. © 2020 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

THE UNIVERSITY OF CHICAGO MEDICINE

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Surgical Prioritization in a Global Pandemic - MeNTS

- Scoring system based on recognition that decision to proceed with operative treatment in the setting of all phases of the COVID-19 Pandemic requires incorporation of factors previously not overtly considered by surgeons
  - Resource limitations (testing, PPE, ICU beds, ventilators, personnel)
  - Risk to the health care team
  - COVID-19 specific perioperative risk

- Three categories of factors associated with poorer outcomes, increased COVID-19 risk to providers, and/or increased resource utilization
  - Procedure
  - Disease
  - Patient

Surgical Prioritization in a Global Pandemic - Procedure

	1	2	3	4	5
OR Time	< 30 min	30-60 min	60-120 min	120-180 min	≥ 180 min
LOS	Outpatient	23hrs	24-48 hrs	≤ 3d	> 4d
Post-Op ICU need	Very Unlikely	< 5%	5-10%	10-25%	≥ 25%
Bleeding Risk/EBL	< 100cc	100-250cc	250-500cc	500-750cc	≥ 750cc
Surgical Team Size	1	2	3	4	> 4
Intubation Probability	≤ 1%	1-5%	5-10%	10-25%	≥ 25%
Surgical Site	None of the following	Abdominopelvic MIS Surgery	Abdominopelvic Open Surgery, Infraumbilical	Abdominopelvic Open Surgery, Supraumbilical	OHNS/Upper GI/Thoracic

- Higher score for each factor in the procedure score is associated with
  - poorer outcome,
  - increased risk to providers,
  - and/or increased hospital resource utilization during COVID-19 Pandemic
- Total score range is 7 – 35

* Transplant cases (all organs) usually >30

Surgical Prioritization in a Global Pandemic - Disease

	1	2	3	4	5
Non-Operative Treatment Option EFFECTIVENESS	None available		Available, 50% effective as compared to surgical treatment		Available, equally effective
Non-Operative Treatment Option RESOURCE/EXPOSURE RISK	Significantly worse		Equivalent		Significantly better
Impact of 2wk delay in DISEASE outcome	Significantly worse		Moderately worse		Minimally worse
Impact of 2wk delay in SURGICAL outcome	Significantly worse		Moderately worse		Minimally worse
Impact of 6wk delay in DISEASE outcome	Significantly worse		Moderately worse		Minimally worse
Impact of 6wk delay in SURGICAL outcome	Significantly worse		Moderately worse		Minimally worse

- Higher score for each factor related to the disease score indicates less harm to the patient if non-operative treatment is pursued and/or surgical treatment is delayed
- Total score range is 10 – 30
- Transplant score will range by organ type (based on assumptions of organ quality/ availability / alternative treatments, etc)

Surgical Prioritization in a Global Pandemic - Patient

	1	2	3	4	5
Age	<20 yo	20-40yo	40-50yo	50-65yo	>65yo
Lung Disease (asthma, COPD, CF)	None			Minimal (rare inhaler)	> Minimal
OSA	Not present			Mild/Moderate (no CPAP)	On CPAP
CV Disease (HTN, CHF, CAD)	None	Minimal (no meds)	Mild (≤ 1 med)	Moderate (2 meds)	Severe (≥ 3 meds)
Diabetes	None		Mild (no meds)	Moderate (PO meds only)	> Moderate (insulin)
Immunocompromised*	No			Moderate	Severe
ILI Sx's (fever, cough, sore throat, body aches, diarrhea)	None (Asymptomatic)				Yes
Exposure to known COVID+ Pt (14d)	No	Probably not	Possibly	Probably	Yes

- Higher score for each factor in the patient score is associated with poorer outcome, increased risk to providers, and/or increased resource use during COVID-19 Pandemic
- Total score range is 8-40

* Transplant cases (all organs) usually >35

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Surgical Prioritization in a Global Pandemic- MeNTS Scoring System

- Procedure + Disease + Patient = Total MeNTS Procedure Score (25-105) (Transplant >70)
- Score thresholds (*surgical justification*) can be adjusted in real time based on local resources and conditions in the context of the COVID-19 pandemic and can be shifted dynamically towards higher scores during recovery

Surgical Prioritization in a Global Pandemic- MeNTS Scoring System

- **Strengths**
  - Transparency (surgeons, hospital, patients, public)
  - Dynamic flexibility based on resources and conditions
  - Integration of decision-making factors not usually considered in routine clinical judgement
  - 5-point scale allows greater nuance than binary choices
  - Disease and procedure “agnostic”
  - Can be applied both within and across surgical specialties
  - Offloads some emotional and ethical workload
- **Weaknesses**
  - Factor score may not be statistically proportionate within group (*transplant)
  - Inaccurate and disproportionate weighting of factors is inevitable

COVID-19 Town Hall

Surgical Prioritization in a Global Pandemic- Solid Organ Transplant

- Transplant must also must consider (organ specific decisions)
  - Donor organ quality/ risk of exposure
  - Donor team AND recipient team exposure (travel, etc)
  - Likelihood of another donor becoming available
  - Alternative treatment options and exposure risk (ie HD)
  - Consequent mortality risk with no transplant

Thank you

tbaker1@surgery.bsd.uchicago.edu

COVID-19 Town Hall

When Can Patients Return to Clinic/Phlebotomy

"Operation Task Force" is the post-surge COVID-19 response team activated to re-launch the transplant institute safely

Barry Friedman

Executive Director

AdventHealth Orlando Transplant Institute

COVID-19 Town Hall

Strategic Initiatives

Executive Task Force

Hospital

- ED
- Procedural (Organ Transplant)
- Ancillary
- Ops Visitors

Ambulatory

- Rehab, Lab, Imaging, Pharm
- Post-Acute
- CentraCare
- AHMG (Organ Transplant)

Physician

- Volume & Finance
- Clinical & Backlog
- Physician Stabilization
- Facility & Staff Capacity

Consumer

- Consultant review
- External Communication
- Validation
- Marketing

Support

- Safety
- Supplies
- People
- Finance
- Testing

New Normal

(Post Covid Surge)

For Patients and Staff

COVID-19 Town Hall

New Normal

- Post COVID Patient Scheduling –scheduling flow
  - In Office Visits vs. Telemedicine
  - lab draw in office prior to visit vs. lab draw during visit

- Office visit (no waiting) **car** to **exam room** to **car**

- Elective Surgeries & Procedures Testing

- New Normal will require a phased approach of staffing requirements (work from home vs in the clinic/hospital)

Pre-Appointment Entry Screening

- All patients will be prescreened via phone call or Phreesia using current screening questions prior to in office appointments

- Entry screening of all patients, visitors and vendors includes temperature monitoring and screening questionnaires in each office

- Patients are offered hand sanitizer and a mask prior to entering

Employee Testing, Masking, and Temperature Monitoring

- Covid 19 testing (sputum).
- Temperature monitoring is completed with all Providers and Team Members prior to entering the office.
- Providers and Team Members with temperature above 100.0 will follow the preregistration process for COVID testing.
- All Providers and Team Members will be masked while in the practice regardless of patients present or not.
- All Administrative employees will be screened and masked prior to entering Administrative areas.

Personal Protective Equipment

- Provide facemasks to all Team Members
- Team Members are always required to wear face masks correctly
- Other types of PPE such as gowns, goggles, face shields are worn when exposure to bodily fluids is expected or when contact with a suspected/confirmed COVID patient
- N95 masks are available in the practices for use with exposure to airborne diseases

Practice Disinfection Process SOP

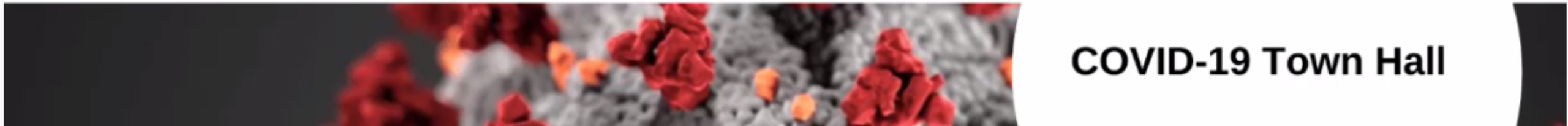
- Comprehensive disinfection of exam room after each patient
- Disinfection of waiting area and Front Desk check in
- Disinfection of other areas patients may have touched
- End of morning and end of day disinfect and document on Duty

Phressia

Summary:

To provide a safe modified environment for patients and team members.

- Virtual registration, check in, consents and collection of money
- Offers COVID screening questions
- Dashboard to monitor status of registration and patient arrival
- Interactive bi-directional texting with patient



Reopening Checklist

Open-Door Validation Tracer Checklist

Scheduling & Registration	Findings / Comment	NA	Follow-up Y / N	Resolved Y / N
Entity Uses virtual registration tool or telephone pre-registration*				
Entity is using telehealth and remote appointments when possible*				
Patient insurance information updated virtually during registration*				
Scripting reference available for scheduler to cover critical points*				
Patients are asked COVID screening questions when scheduling*				
Patients are asked about recent travel when scheduling*				
Patients are informed of policies on social distancing, PPE and hand hygiene*				
Posted signs provide instructions to remain in vehicle and call/text a phone number*				
Scheduling Templates modified As/If Needed				
Arrival at appointment & Entry				
Building access points are limited & controlled by screeners*				
Screening table at entry way with adequate number of attendants always present				
Screening questions are posted and visible				
Everyone is asked the COVID screening questions (Staff, providers, patients, visitors)				
All arrivals are screened for temperature per thermometer manufact recommendations				
All arrivals have masks or are provided a mask				
All arrivals are offered hand sanitizer				

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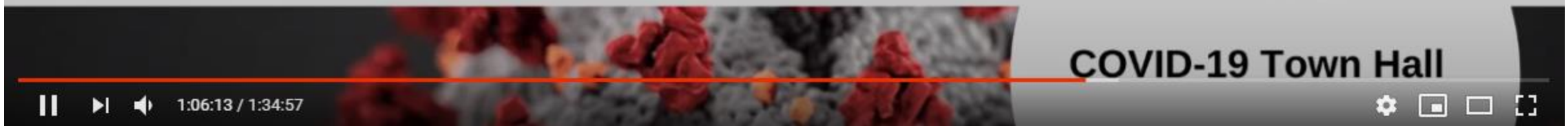
Floor tape

24x36 poster (easel or wall)

8.5x11 flyer

12X15 Chair Cover Sign

Floor stickers



Questions

Barry Friedman
Executive Director
AdventHealth Transplant Institute

Email
barry.friedman@adventhealth.com
Phone (407) 303-3609

Criteria to Remove Quarantine

Kathleen Murphy, MD

Assistant Professor of Clinical Medicine, Division of Infectious Diseases

Associate Hospital Epidemiologist

Hospital of the University of Pennsylvania

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What are our options for COVID+ patients?

Strategy	Criteria to Remove from isolation/quarantine
Time and Symptom -based	1. At least 3 days (72 hours) have passed *since recovery* defined as resolution of fever without the use of fever-reducing medications **and** improvement in respiratory symptoms (e.g., cough, shortness of breath); **and**, 2. At least 10 days have passed *since symptoms first appeared*
Test-based	1. Resolution of fever **without** the use of fever-reducing medications **and** improvement in respiratory symptoms (e.g., cough, shortness of breath), **and** 2. Negative results of an FDA Emergency Use Authorized COVID-19 molecular assay for detection of SARS-CoV-2 RNA from at least two consecutive respiratory specimens collected ≥24 hours apart

- Practices currently vary widely between institutions
- How to apply to different patient populations?
  - Hospitalized vs home
  - Congregate facilities (SNF, HD unit)
  - Unique considerations for immunocompromised patients and providers

Challenges of a test-based strategy

- Clinical implications of prolonged viral shedding?
  - Assessment of infectivity has been limited
    - Very few studies looking at viral culture
  - Quantitative information not known in the clinical setting (ie receive “positive” or “negative” result)
- Upper vs lower respiratory tract specimens
- Patient access to testing, care coordination
- Specimen quality, sensitivity
- EMR or health system flag for infection status

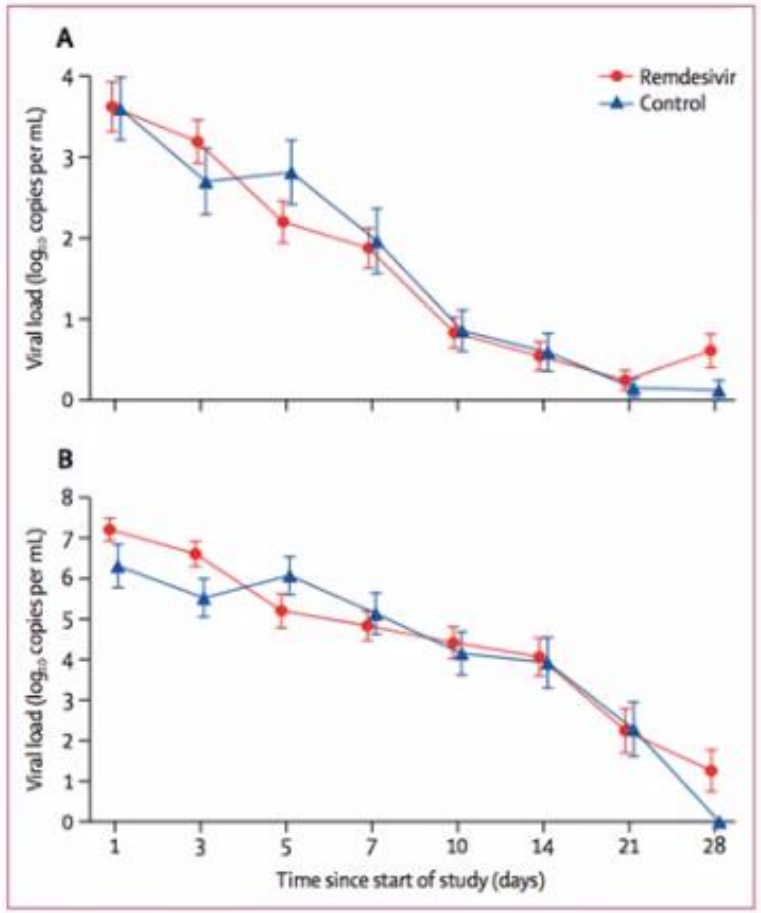


Figure 3: **Viral load by quantitative PCR on the upper respiratory tract specimens (A) and lower respiratory tract specimens (B)**
Data are mean (SE). Results less than the lower limit of quantification of the PCR assay and greater than the limit of qualitative detection are imputed with half of actual value; results of patients with viral-negative RNA are imputed with 0 $\log_{10}$ copies per mL.

Wang et al, Lancet 2020.

Concerns specific to transplant population…

- How to optimize protection of healthcare workers, clinic and hospital staff, other patients (esp immunocompromised)
- Challenges of managing patients via telehealth
- Immunosuppression management if reduced with COVID-19 infection
- Impact on future procedures or clinical care (ie bronchoscopy, biopsies, labs, rejection management)
- Varying practices between institutions (COVID care outside of home transplant center)
- Pre-transplant COVID+ recipient, living donor evaluation and safety

What to do with COVID-19 survivors in need of transplantation
How do we know when they are ready ?

Paolo Antonio Grossi

Professor of Infectious Diseases

Director of Infectious and Tropical Diseases Unit

University of Insubria, Varese, Italy

COVID-19 Town Hall

Outcome of patients with COVID-19

- Critical patients with the 2019 coronavirus disease (COVID-19), even those whose nucleic acid test results had turned negative and those receiving maximal medical support, have been noted to progress to irreversible fatal respiratory failure.
- Lung transplantation as the sole therapy for end-stage pulmonary fibrosis related to acute respiratory distress syndrome has been considered as the ultimate rescue therapy for these patients.

Lung transplantation as therapeutic option in acute respiratory distress syndrome for COVID-19-related pulmonary fibrosis

- From February 10th to March 10th, 2020, three male patients were urgently assessed and listed for transplantation.
- Two of the three recipients survived post-LT and started participating in a rehabilitation program.
- **Conclusions:** Lung transplantation can be performed in end-stage patients with respiratory failure due to COVID-19-related pulmonary fibrosis. If confirmed positive-turned-negative virology status without organ dysfunction, LT provided the final option for these patients to avoid certain death, with proper protection of transplant surgeons and medical staffs.

Chen Jingyu, et al. Chinese Medical Journal, Publish Ahead of Print DOI: 10.1097/CM9.0000000000000839

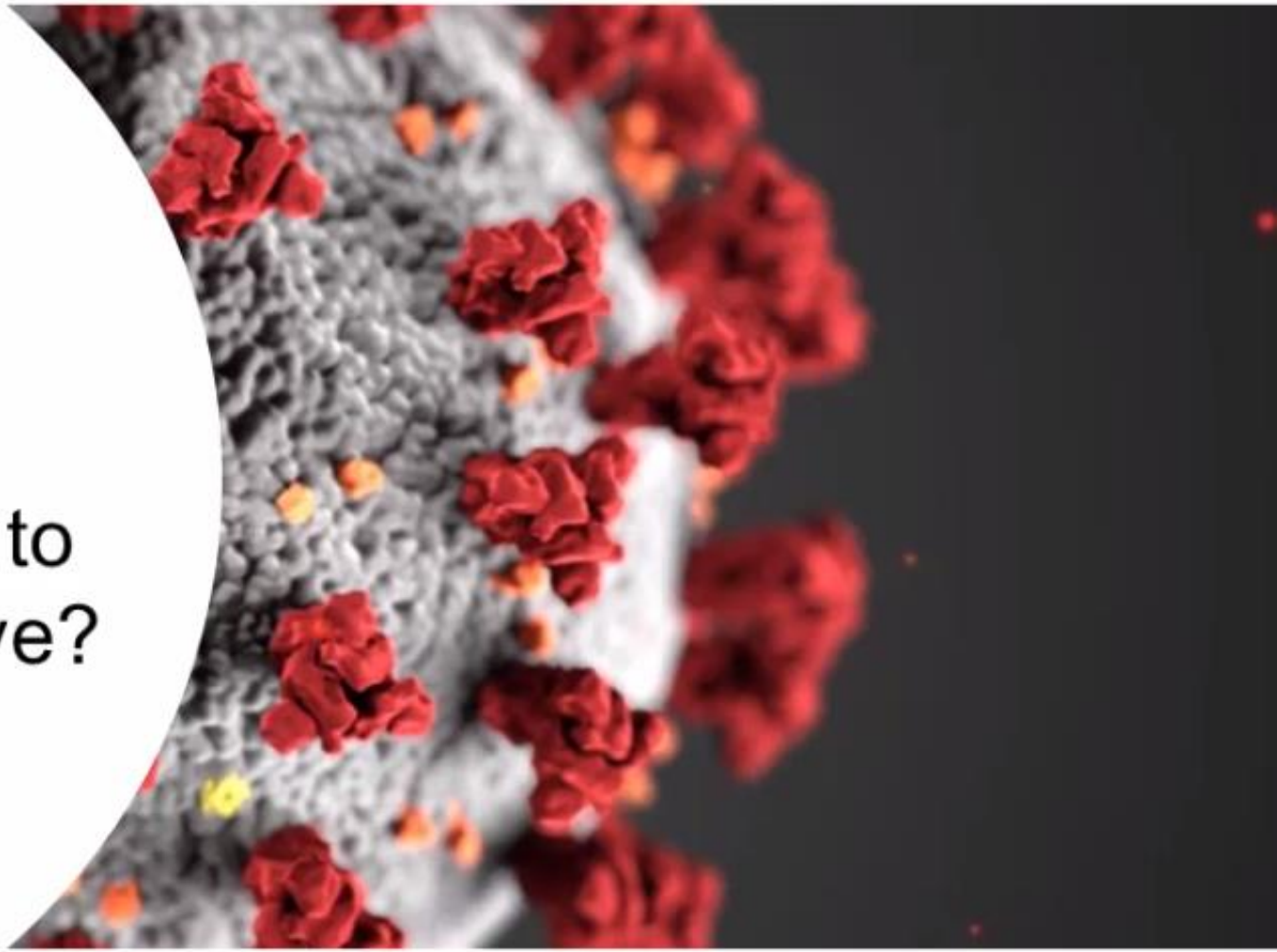
Challenging Case

- 18-year-old male admitted on March 6th because of 7 days of fever, cough and progressive dyspnea.
- On March 8th, intubated because of worsening dyspnea, despite C-PAP.
- Treated with lopinavir/ritonavir and Anakinra and antibiotics.
- On March 24th, VV ECMO because of lack of response to mechanical ventilation.
- Impossible to wean from VV ECMO because of severe irreversible lung damage.
- The patient was listed for lung tx on April 28th. Still waiting on VV ECMO.
- Plan to take tissue samples from the native lungs for PCR and viral culture for SARS-CoV-2.

Date PCR testing	BAL	NPS	Pleural effusion	Plasma	Rectal swab	Stools
4/10	Neg	Neg	28	Neg	Neg	
4/14	Neg	Neg	Neg	Neg	Neg	Neg
4/17		345	Neg	Neg	Neg	Neg
4/21	495*	Neg	Neg*	Neg	Neg	

*** Viral culture = Neg**

COVID-19:
What Have We Learned to Prepare for the Next Wave?



Moderated by:
Lewis Teperman, MD, FACS
Professor of Surgery and Medicine, The Zucker School of Medicine at Hofstra/Northwell
Director of Transplantation, Northwell Health

Donors with History of COVID-19

Fernanda P. Silveira, MD, MS, FIDSA

Associate Professor of Medicine

University of Pittsburgh and UPMC, Pittsburgh, USA

Donors with History of COVID-19

- Two subgroups:
  - Positive PCR at the time of donation
  - Negative PCR at the time of donation
- Positive PCR at the time of donation
  - Donor-derived infection not reported by conceivable
  - Risk of transmission to recovery teams, healthcare personnel and nosocomial transmission
  - Lack of effective prophylaxis and treatment
  - These donors should not be utilized

Shah M et al. AJT 2020

COVID-19 is a Systemic Disease

- Lungs are the primary site affected
- Multi-organ involvement increasingly recognized
  - Liver injury, acute kidney injury, and cardiac dysfunction
  - Viral RNA found in blood (symptomatic and pre-symptomatic)
  - Viral RNA or particles found in liver, kidney and heart

- Long-term sequelae? Does the absence of laboratory abnormalities and evidence of organ dysfunction rule out organ involvement?

Huang C et al. Lancet 2020
Chang L et al. Emerg Infect Dis 2020
Wichmann D et al. Ann Intern Med 2020
Farkash EA et al. J am Soc Nephrol 2020

Donors with Negative PCR at Time of Donation

- Graft quality will likely depend on dysfunction suffered during episode of COVID-19 and possibly time from illness
- Lungs and hearts carry the highest risk – better evidence of direct effects
- Liver and kidneys probably OK
- Monitoring of graft and patient survival data

Donor Testing: What will be the standard moving forward?

Melissa A. Greenwald, MD

Associate Medical Director, Donor Alliance (Denver, CO)

Regulatory Consultant, VRL Eurofins (Denver, CO)

COVID-19 Town Hall

Current Testing Environment

- Multiple assays currently available via Emergency Use Authorization with FDA
- EUA is for use of investigational products only during public health emergencies, and a transition will need to be made to IND evaluation of performance characteristics
- In response to public health emergency declared by HHS Secretary Jan 31, 2020, guidance Issued March 16, with update May 4 containing EUA requirements

Current Donor Testing

- Donor Alliance: All donors receiving a nasal swab with PCR assay testing at VRL Eurofins, Denver
- Available: BD and BioRad SARS-CoV-2 assays (RT-PCR, nasal/nasopharyngeal/oropharyngeal swabs), Gold Standard (IgG and IgM)
- Organ donor testing availability is a separate supply chain from patient or contact testing

Research to Inform Future Testing Policy

- Full validation of assay performance characteristics
- Frequency viremia occurs; length of viremia
- SARS-CoV-2 tissue tropism
- Transmissibility via organs or blood
- Length of viral shedding
- Does RNA positivity on swab samples accurately measure infectivity
- Whether antibody prevents reinfection or transmission

COVID-19:
Organ Donation and Transplant Town Hall

Thank you for joining us!