

AASLD COVID-19 Clinical Oversight & Publications Subcommittee Presents

COVID-19 and the Liver: Reentry and Return to a Pre-Pandemic State

May 14, 2020 4-5 pm ET

Presenters:

Patricia Harren, DNP, DCC David C. Mulligan, MD, FAASLD Bilal Hameed, MD **Moderator:**

Kimberly Ann Brown, MD, FAASLD



Webinar Moderator

Kimberly Ann Brown, MD, FAASLD

Chief, Division of Gastroenterology & Hepatology

Henry Ford Health System





Patricia Harren, DNP, DCC

Clinical Director of the Center for Liver Disease & Transplantation / Clinical Director for Pediatric Transplantation & Adult Abdominal Organ Transplantation

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Professor of Surgery and Chief
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Bilal Hameed, MD Associate Professor of Medicine and the Hepatology Clinic Chief

University of California,
San Francisco





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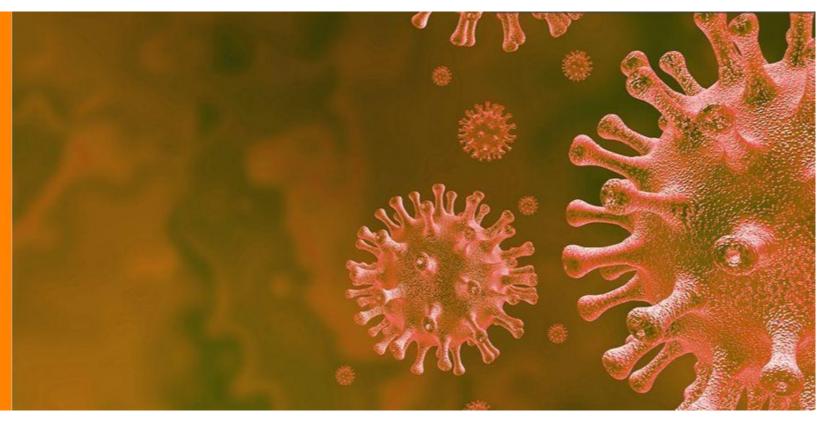


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AASLD-ALEH COVID-19 & the Liver in the Americas



AASLD-ALEH WEBINAR: COVID-19 AND THE LIVER IN THE AMERICAS







COVID-19 and the Liver: Reentry and Return to a Pre-Pandemic State



Webinar Agenda

- Webinar Contributors
- Presenter Introductions Dr. Kimberly Brown
 - Housekeeping Items
 - OpenSAFELY Study Dr. Kimberly Brown
- Expert Consensus Panel Update Dr. Oren Fix
 - Outpatient Dr. Bilal Hameed
 - Inpatient Dr. Patricia Harren
 - Transplant Dr. David Mulligan
 - Panel Discussion / Q&A



Clinical Oversight & Publications Subcommittee

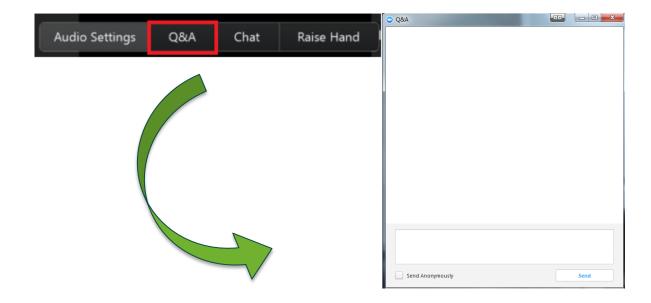
- Co-chair, Oren K. Fix, MD, MSc, FAASLD, Swedish Medical Center (Washington)
- Co-chair, Elizabeth C. Verna, MD, MS, Columbia University (New York)
- Kimberly Brown, MD, Henry Ford Health System (Michigan)
- Jaime Chu, MD, Icahn School of Medicine at Mount Sinai (New York)
- Bilal Hameed, MD, University of California (California)
- Laura M. Kulik, MD, Northwestern Medical Faculty Foundation (Illinois)
- Ryan M. Kwok, MD, Uniformed Services University (Maryland)
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- Jennifer Price, MD, MBA, FACP, University of California, San Francisco (California)
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- Nancy S. Reau, MD, Rush University (Illinois)
- Mark W. Russo, MD, MPH, FAASLD, Carolinas Medical Center (North Carolina)
- Michael Schilsky, MD, FAASLD, Yale University (Connecticut)
- Norah Terrault, MD, MPH, FAASLD, Keck Medical Center of USC (California)
- Andrew Reynolds, (Patient Advocate)
- Raymond Chung and K. Rajender Reddy (ex-officio)



Webinar Q&A

Submit your questions in the Q&A box at the top or bottom of your screen.



Questions will be answered at the end of the presentation.



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Webinar Panelist

- Oren K. Fix, MD, MSc, FAASLD, Swedish Medical Center (Washington)
- Elizabeth C. Verna,
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- Karen Hoyt, BA,
 Patient Advocate

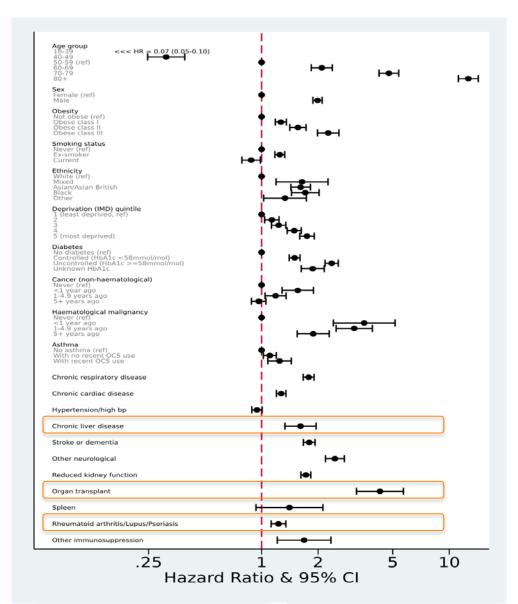
- Guadalupe Garcia-Tsao,
 MD, FAASLD, Yale
 University (Connecticut)
- Ryutaro Hirose, MD,
 University of California,
 San Francisco (California)
- K. Gautham Reddy, MD,
 FAASLD, University of Chicago Medical Center (Illinois)



- OpenSAFELY: Factors associated with COVID-19-related hospital deaths in the linked electronic health records of 17 million adult NHS patients
 - 17,425,445 adults
 - Feb 1, 2020 to April 25, 2020
 - Primary outcome death in hospital in patients with confirmed COVID-19 (5683 deaths)

https://doi.org/10.1101/2020.05.06.20092999







- Largest cohort study to date evaluating a variety of clinical factors for death from COVID-19
- Asians and blacks appear to be at increased risk of in-hospital death with only partial attribution to pre-existing clinical risk factors or deprivation
- Patients with pre-existing liver disease, transplantation or on immunosuppression appear to have increased risk of in-hospital death when adjusted for age/sex alone or fully adjusted
- Strengths
 - Largest cohort study to date representing 40% English population
 - Inclusion of variables including liver disease, transplant for analysis
- Weaknesses
 - Deaths related to patients with false-negative tests or died without testing would be missed
 - Censoring patients at date of death from other causes or outside the hospital stopped 9 days short of study end
 - Cohort limited to those practices using the EHR software SystmOne Some variable were assumed absent if missing
 - Characterization of "liver disease" is general and not complete
- Further characterization of liver disease and potential risks due to etiology, MELD, etc will be helpful in future studies



Expert Panel Consensus Statement

- First published online March 23rd
- New update posted today:
 - www.aasld.org/covid19
- Spanish and Portuguese translations available online
- Hepatology manuscript published online





Released: May 14, 2020

CLINICAL BEST PRACTICE ADVICE FOR HEPATOLOGY AND LIVER TRANSPLANT PROVIDERS DURING THE COVID-19 PANDEMIC: AASLD EXPERT PANEL CONSENSUS STATEMENT

This is a "living" document that will continue to evolve and will be updated as new information becomes available.

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- Acknowledgement of possible link between COVID-19 and Kawasaki-like pediatric multisystem inflammatory syndrome
- Italian autopsy series describing involvement of hepatic vasculature including acute portal and sinusoidal thrombosis
- Introduction of SARS-CoV-2 antigen testing in addition to increasing availability of antibody testing

WWW.AASLD.ORG

https://www.health.ny.gov/press/releases/2020/docs/2020-05-06_covid19_pediatric_inflammatory_syndrome.pdf Sonzogni et al Preprints 2020

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-antigen-test-help-rapid-detection-virus-causes

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- OpenSAFELY study from the UK: chronic liver disease is a risk factor for in-hospital death from COVID-19
- Large US study also showed that chronic liver disease and cirrhosis are associated with higher COVID-19 mortality



- Clarification that treatment of hepatitis B is not contraindicated in patients with or without COVID-19
- Recommendations regarding use of masks for patients and caregivers as well as providers in the clinic or hospital setting



- Evolving data on hydroxychloroquine suggesting it should no longer be used outside RCTs
- New data on triple therapy with lopinavir-ritonavir, ribavirin and interferon-beta-1b showing more rapid viral clearance compared to lopinavir-ritonavir (phase 2 RCT)
- Reentry



Impact of COVID-19 on Liver Disease: Safe Outpatient Re-Entry Process

Associate Professor of Medicine
Clinic Chief, Hepatology
University of California, San Francisco



Outline

- The COVID-19 effects on liver care
- Recommendations for re-entry and re-opening facilities
- Ambulatory re-entry and recovery challenges and plan at UCSF
- Gradual re-entry of liver patients in the ambulatory setting



The Untold Toll — The Pandemic's Effects on Patients without COVID-19

The Washington Post

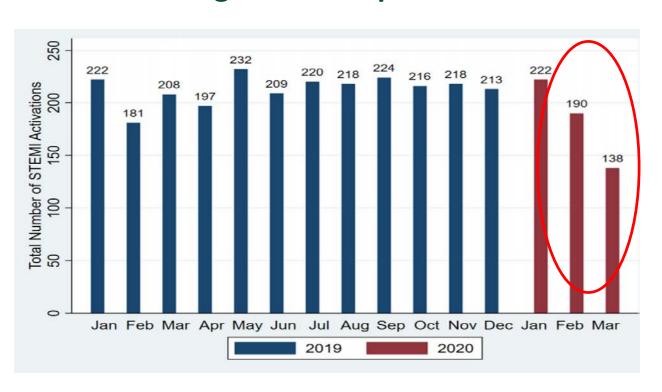
Patients with heart attacks, strokes and even appendicitis vanish from hospitals



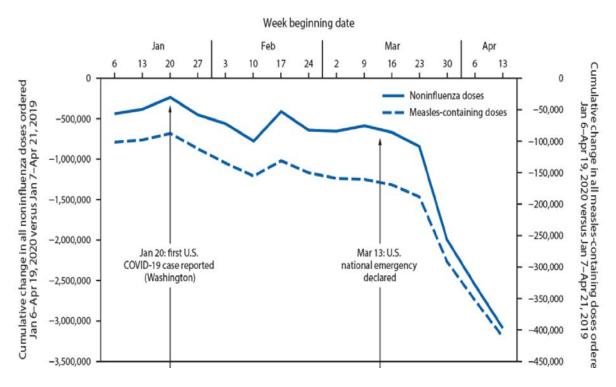


The Pandemic's Effects on Patients without COVID-19

38% reduction in STEMI activations in the US during COVID-19 pandemic



Decrease in routine pediatric vaccination during COVID-19





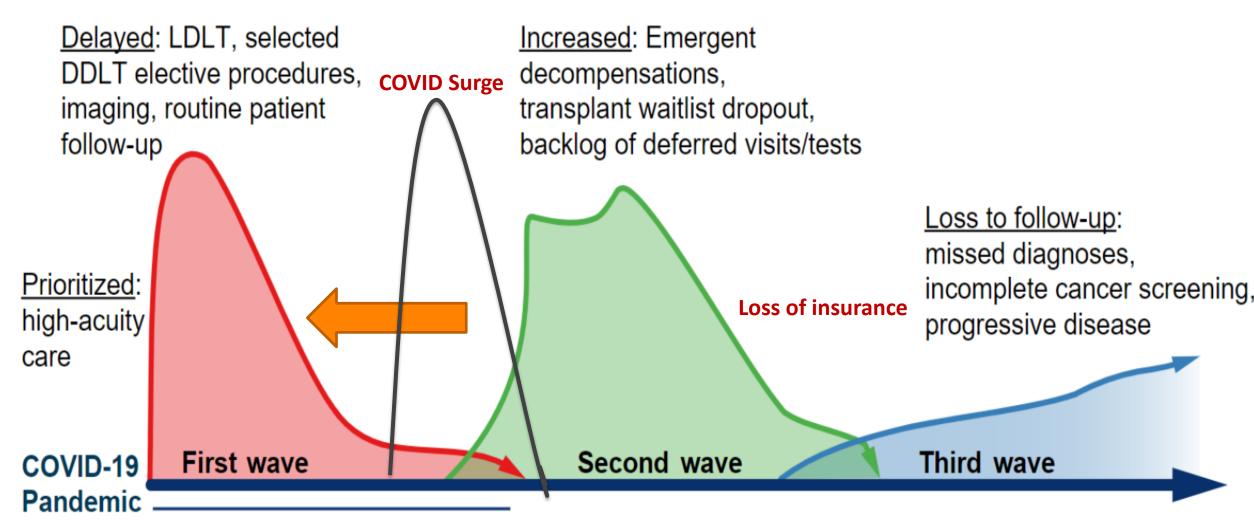
Unexpected Consequences of the Pandemic

- To expand capacity for COVID-19 patients, on March 18th CMS recommended limiting non-essential care and procedures
 - > 8 week pause in usual care activities
 - > Fear of returning to care
 - Change in patient's perception of risk/benefit
- Areas with low/stable incidence of COVID-19, CMS allowing non-emergent, non-COVID-19 healthcare





COVID-19 Pandemic: Impact on the Cirrhosis Care



Physical distancing policies

Tapper E.B. et al. Journal of Hepatology. April 2020



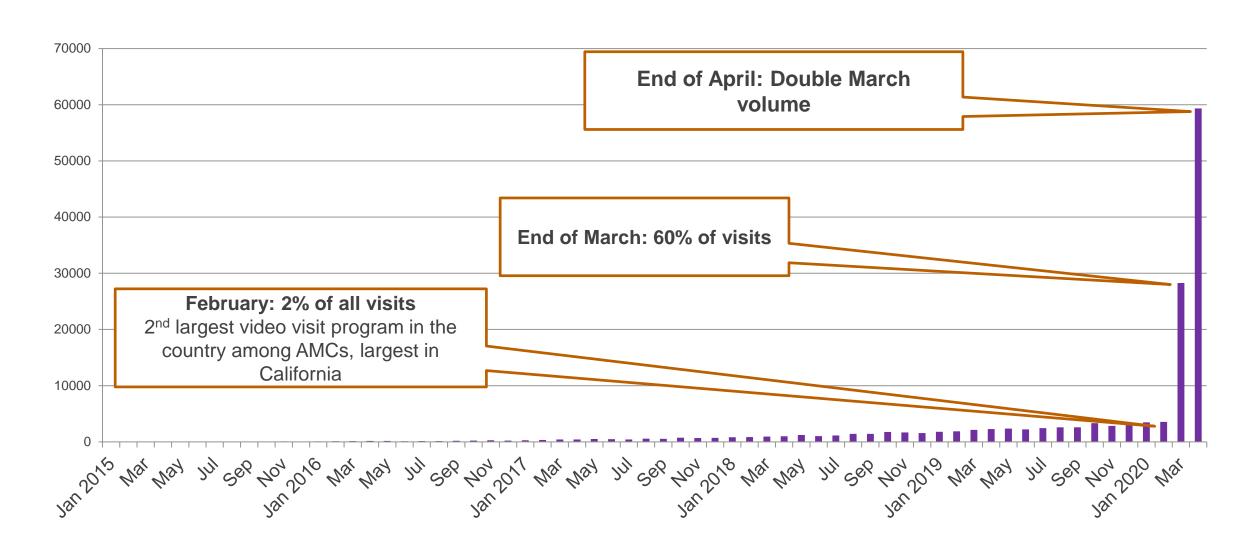
Outpatient Impact of COVID-19 Pandemic: UCSF Experience

Maximizing Appropriate Use of Video Visits during Re-entry

| Prior State | Current State | Future State |
|--|---------------------------------------|---|
| ~20% of total visits were video visits | ~95% of total visits are video visits | Appropriate mix of telehealth visits ~50% Continue expanding to: |
| | | -Patients that live far away -Post-ops & post-discharge follow-up -Chronic disease management (NAFLD/HBV/HCV etc) -Free up clinic space |

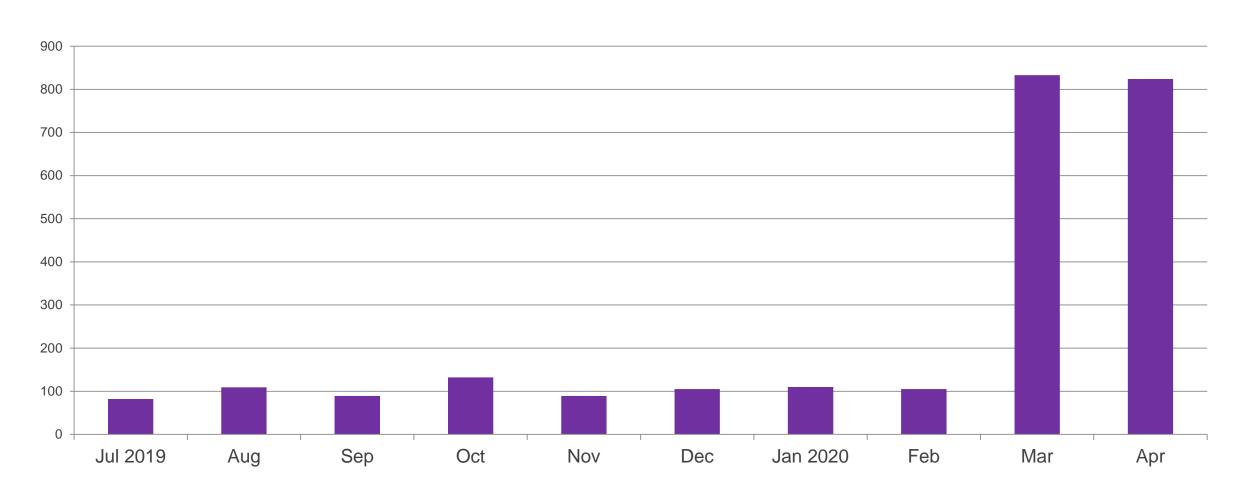


UCSF Video Visits by Month (Jan 2015-April 2020)





Hepatology Video Visits by Month at UCSF



Able to see the same number of patients even during pandemic

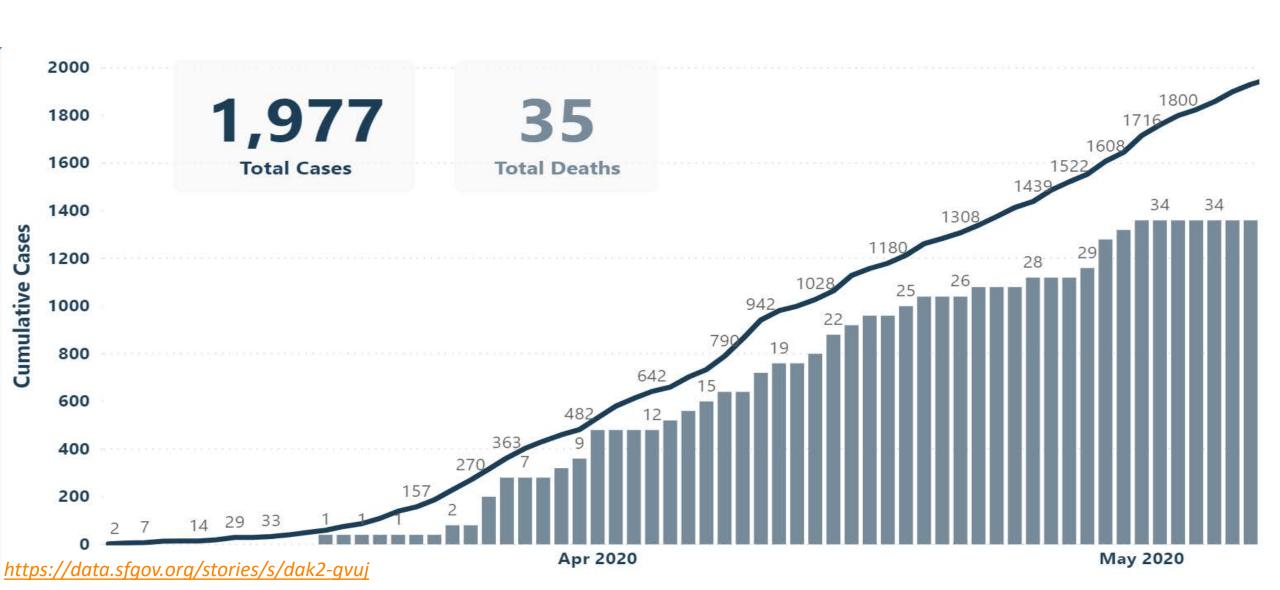


CMS Phase I Recommendations: Re-opening Facilities for Non-emergent Non-COVID-19 Healthcare

- In coordination with State and local public health officials, evaluate the incidence and trends for COVID-19 in the area
- Prioritize surgical/procedural care and high-complexity chronic disease management and select preventive services
- Consider establishing Non-COVID Care (NCC) zones that would screen all patients for symptoms of COVID-19
- Sufficient resources should be available across phases of care, including PPE, healthy workforce, testing capacity etc, and without <u>jeopardizing</u> surge capacity



San Francisco COVID-19 Numbers





Ambulatory Re-entry and Recovery – Cascaded Principles

Strategies to limit unnecessary exposure while continuing to provide high-quality care for our liver patients

- Ensure morbidity and mortality do not increase due to liver related illness and provide care in a safe manner
- Continue to prioritize the health and safety of workforce
- Prioritize urgent patients
- Communicate consistently and transparently
- Invest appropriately in services and improvement efforts



Ambulatory Recovery Challenges and Plan Providing Best Care While Living with COVID-19

Patient

Care

- COVID symptoms check protocol
- Social distancing in clinic
- Masking and safety policies
- Waiting rooms changes
- Visitor policies

Staff and
Patient
Safety

Clinic Work Flows

- Prioritize urgent patients
- Back log data and referrals
- Pre-clinic communication
- In clinic flow (Echeck in, rooming and check out policies)

 Optimization and flexibility of schedules (hours/weekend?)

- Utilization of clinic space
- Sustain telehealth
- Digital technology for symptoms monitoring
- Staff redeployment

Resource Utilization

Support and Education

- Patient communication is the key
- Staff anxiety and stress reduction
- Focus on vulnerable population
- Physician burn out and health needs
- Trainees re-entry and education

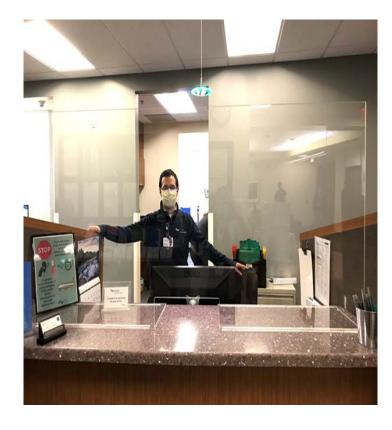


Physical Distancing & Safety Guidelines





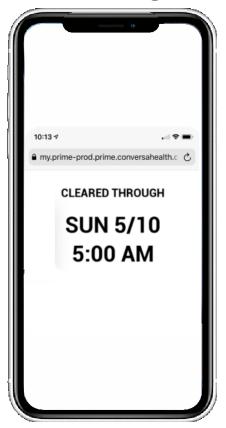






Innovation and Improving Operations

Conversa Employee Screening



Mychart Screener



Apex texting for patients in nearby waiting areas



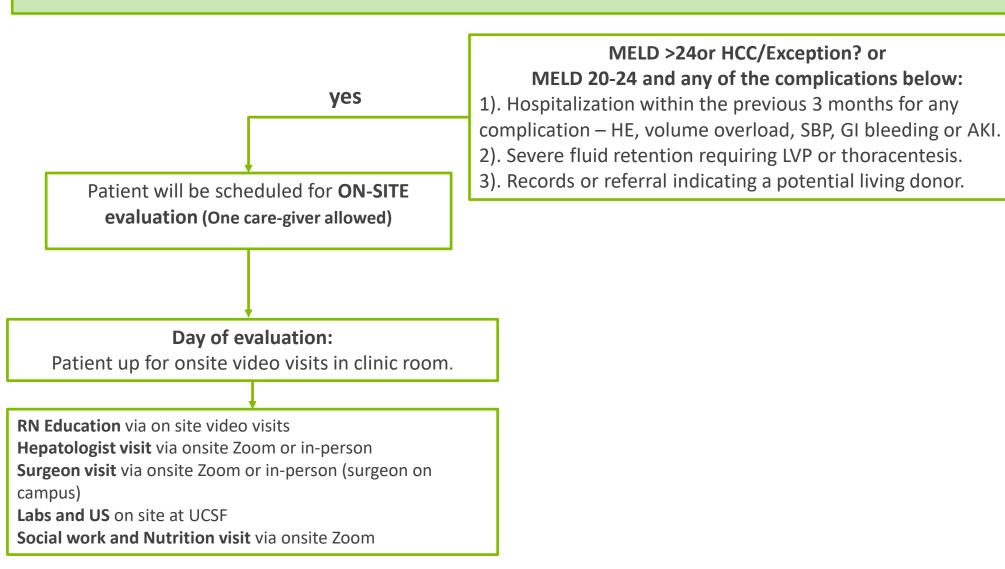


Gradual Re-entry of Liver Patients in the Ambulatory Setting



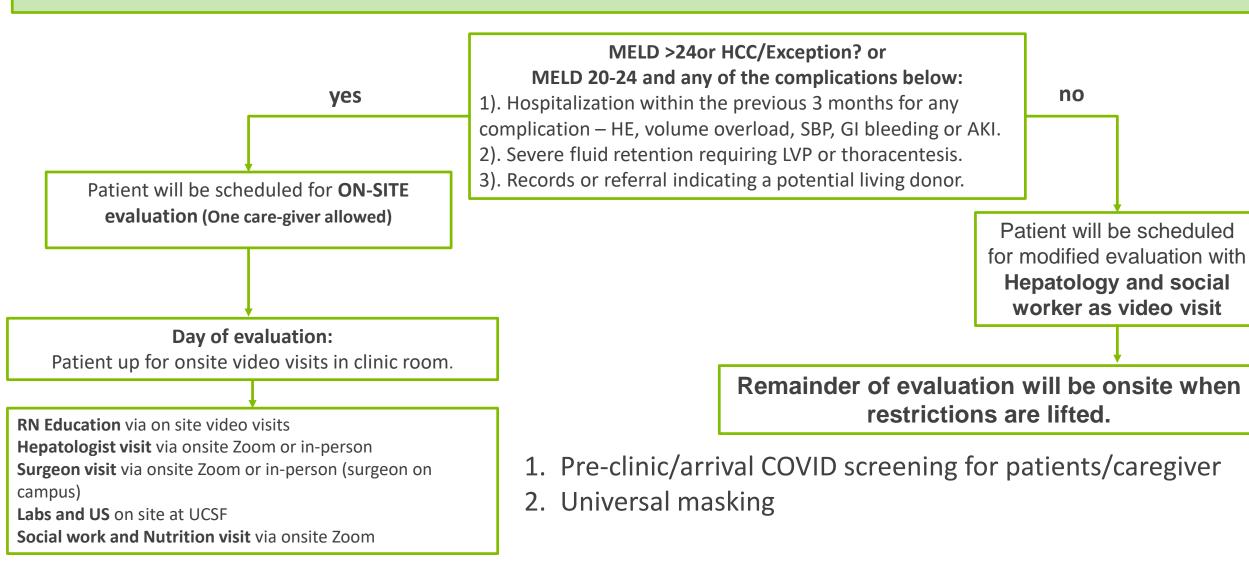
MELD >24or HCC/Exception? or

LIVER TRANSPLANT EVALUATION DURING COVID-19 WORKFLOW





LIVER TRANSPLANT EVALUATION DURING COVID-19 WORKFLOW





Re-entry of Liver Patients in Clinic: June 2020

- All new liver transplant evaluations and HCC diagnosis
- New decompensation or worsening symptoms
- Listed patients for transplant with decompensated cirrhosis
- Acute hepatitis or liver injury
- Early post transplant
- Patients with difficulty with telehealth



Re-entry of Liver Patients: HCC Surveillance

- HCC surveillance should continue as close to schedule (an arbitrary delay of 2 months were acceptable)
- Working on list of all delayed imaging and prioritizing them by risk categories
 - >Known HCC, surveillance for treatment response, elevated AFP
- Key is working with Radiology (Options of imaging locally)
- Communication with patients and documentation is important
- No delay in HCC treatment (risk/benefits discussion)



Re-entry of Liver Patients: Procedures

Liver Biopsies

- Rule out rejection or autoimmune hepatitis diagnosis
- Going over the back log and prioritizing biopsies (June 2020)
- Updating radiology protocols
- No COVID testing for outpatient biopsies (standard PPE)



Re-entry of Liver Patients: Procedures

Liver Biopsies

- Rule out rejection or autoimmune hepatitis diagnosis
- Going over the back log and prioritizing biopsies (June 2020)
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Fibroscan

- Not urgent but planning to start June-July 2020
- Huge back log
- Using radiology US protocol for PPE (mask/googles and gown)
- Flexible schedules based on safety guidelines





Reentry and Return to a Pre-Pandemic State

Inpatient Setting

Patricia Harren, DNP, DCC Clinical Director of Transplant Services Columbia University Medical Center



- Institutions are under major financial constraints due to the lack of operative and ambulatory services
- Increased cost of supplies and overtime staffing
- Increase need for expensive equipment: Beds/ventilators
- Increase in laboratory expenses for testing



Over Capacity Struggles:

- Emergency Department
- ICU (NYP 422 to 970 beds in 19 days)
 - OR suites still needed for ICU patients
 - Entire units still a mix of ICU and Step down patients
 - COVID Free ICU needed
- Dialysis both CVVH and HD staffing and supply issues.
- Beds
 - Still high volume of COVID patients admitted
 - Step down need for trached patients
 - Increased need for rehab beds
 - "Field Hospital" patients need disposition



PPE improving but still shortages

NYS Governor "suggestion/mandate":

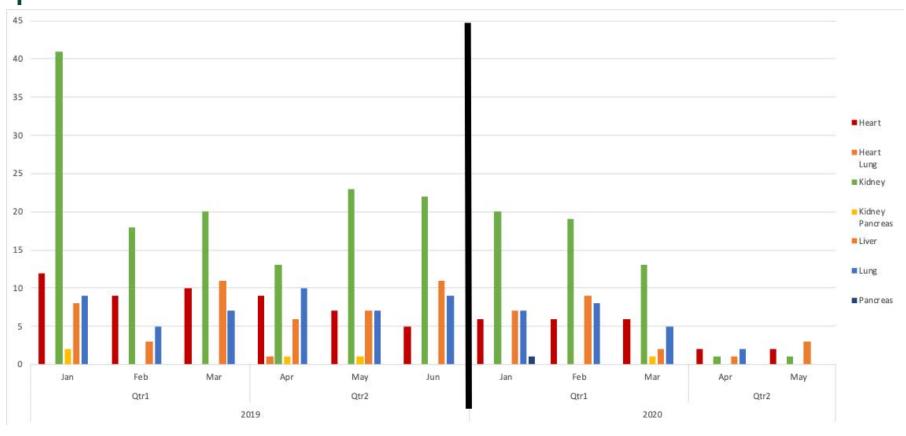
Institutions need a stockpile of 90 supply of all PPE equal to the amount used at PEAK:

Masks:100,000/day = 9,000,000 in reserve PLUS current needs met.

*This is compounded by increased prices and low availability.



o Transplant Cases 2019-2020





OR Schedule Restart:

- OR suites converted back from ICU to OR
- COVID Free ICU and Units
- Rapid COVID testing needed for aerosolized procedures
- Operational Radiology Department
- Operational Interventional Radiology
- Operational Cardiac Catherization Lab



COVID Testing

- Currently COVID negative needed within 48 hours
- Rapid PCR Test (2 hours) prior to procedures regardless of if aerosolized
- Consider Rapid testing for all elective admissions and transfers (hold in ED until testing results)
- Broader testing in the coming weeks to months needed to monitor for outbreaks



Staffing:

- Many redeployed employees from outpatient areas staffing units due to increased acuity still needed.
- Increase number of travel staff
- Units no longer specialized
- Employee PCR & Antibody testing.. When and how often?



Visitation Policy

- Current State: No visitors permitted unless on Palliative Care unit for end of life visit.
 - Patients hesitating to come to ED or Admission
 - Struggles with staff contacting families
 - Discharge coordination sometimes difficult



o Lessons Learned:

- Start with more restrictions and more protection and reduce as data indicates
 - Limited Visitors
 - More testing of staff
 - More testing not just with symptoms
 - Testing non COVID inpatients periodically especially prior to procedures
 - Secure your valuable PPE
 - Increase of Telemedicine is valuable and needed





Doctors worry the coronavirus is keeping patients away from US hospitals as ER visits drop: 'Heart attacks don't stop'

PUBLISHED TUE, APR 14 2020-3:40 PM EDT | UPDATED TUE, APR 14 2020-5:55 PM EDT



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Published: May 4, 2020

Is it safe to go to the hospital during COVID-19 pandemic? Doctors say yes

By American Heart Association News



o How to make patients feel safe to return?

- Project confidence
- People respond to tangibles:
 - Screening at entrances
 - Wearing masks every one all the time.
 - Doing testing pre admission/pre procedures
 - Observing good hand hygiene
 - Being consistent



Impact of COVID-19 on Liver Transplantation: Creating Safe Plans For ReEntry

David C. Mulligan, MD, FACS, FAASLD, FAST Professor and Chair, Transplantation and Immunology Yale University/Yale New Haven Health System



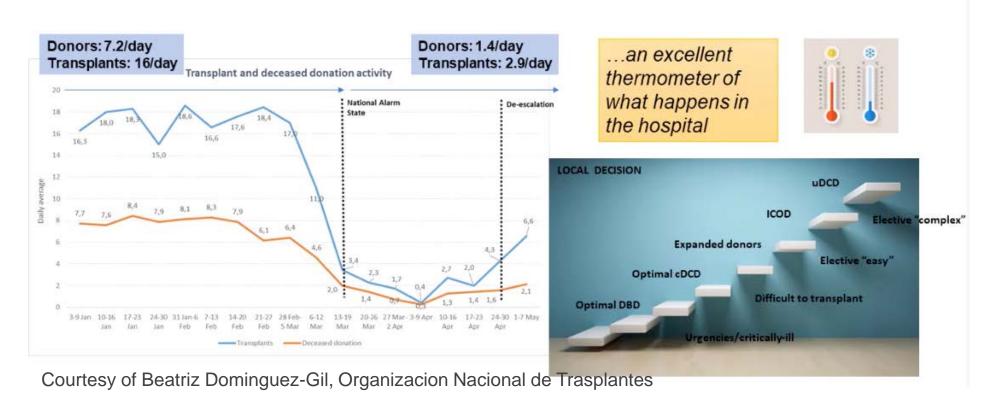
Impact of COVID-19 on Transplant 2020 Transplants in Tongji Hospital



Courtesy of Lan Zhu, MD, Tongji Hospital of Tongji Medical College

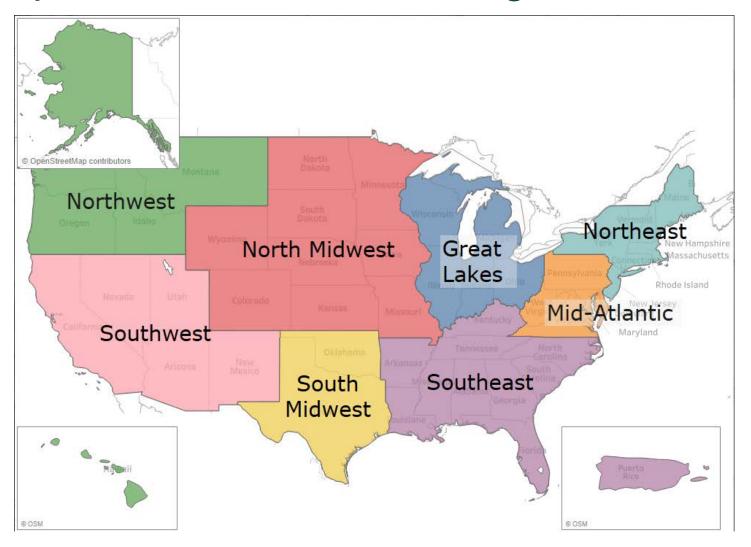


D&T ACTIVITIES IN SPAIN 2020

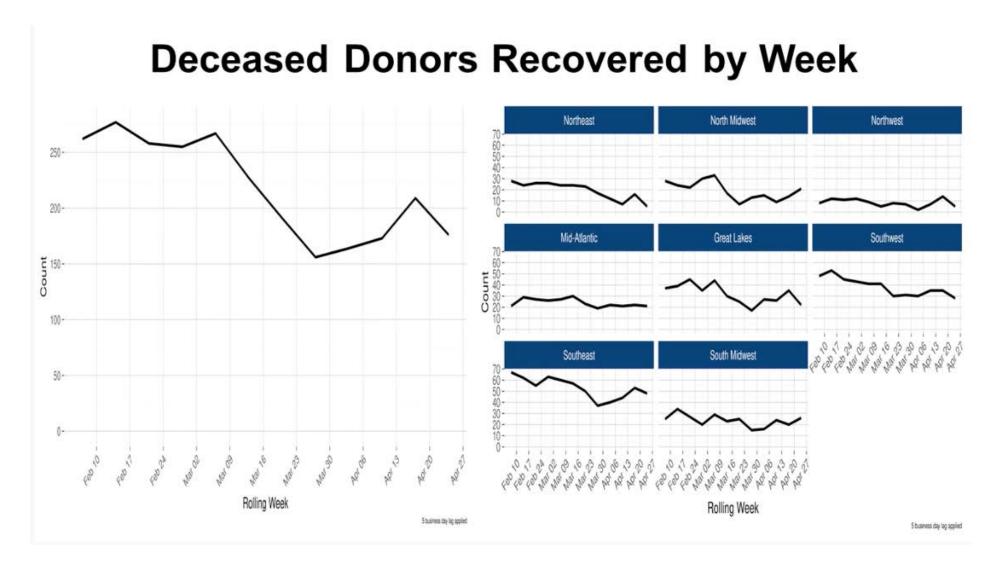




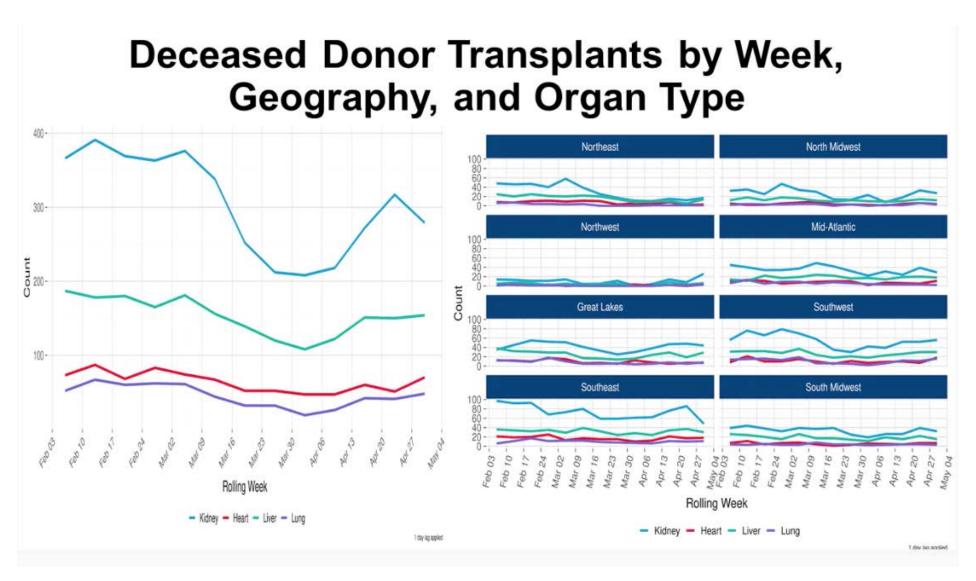
Impact of COVID-19 on Organ Donation





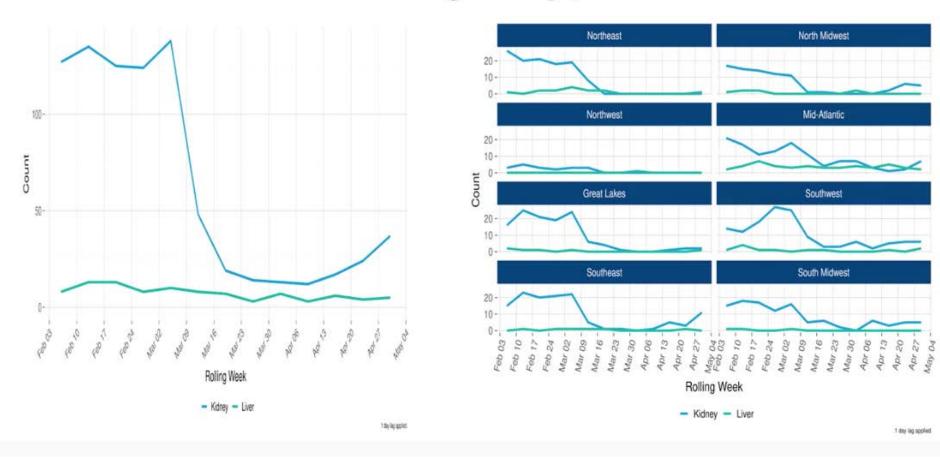








Living Donor Transplants by Week, Geography, and Organ Type





Variable Liver Transplant Activity

- Not all transplant centers decreased liver transplants
- Centers in COVID spared geographies and those with resources to minimize exposure to patients continued to transplant







Changes in liver transplant center practice in response to COVID-19: Unmasking dramatic center-level variability

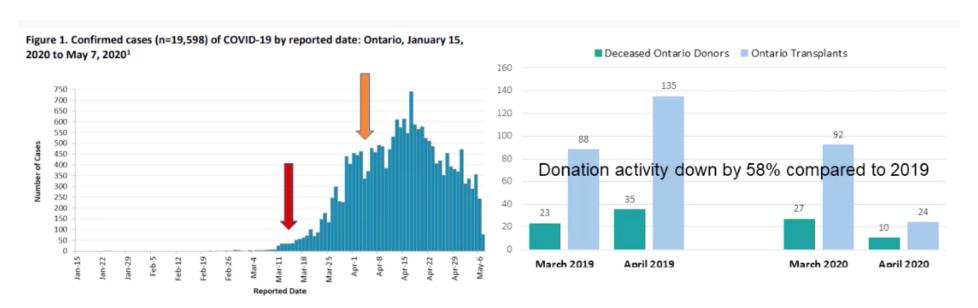
Vatche Agopian, Elizabeth Verna, David Goldberg

▼

First published:05 May 2020 | https://doi.org/10.1002/lt.25789



Impact of COVID-19 on Transplant in Ontario, Canada

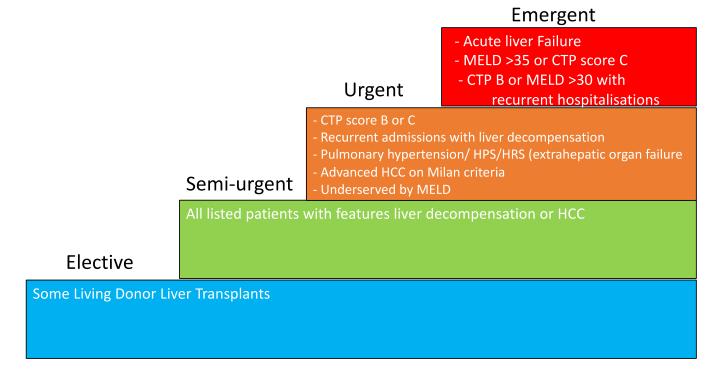


- Ontario is Canada's most populous province, with 38.3 percent of the country's population
- 8 transplant programs: adult, pediatric, heart, lung, liver, pancreas, kidney and small bowel
- COVID Management System: Daily calls supported by OPO (TGLN)
- All programs participated, incl crit care, ID, TGLN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

Courtesy of Darin Treleaven, MD, MSc, McMaster University



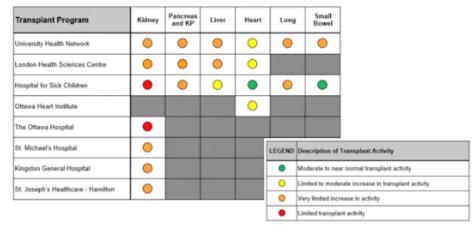
Liver Transplant C-19 Triage

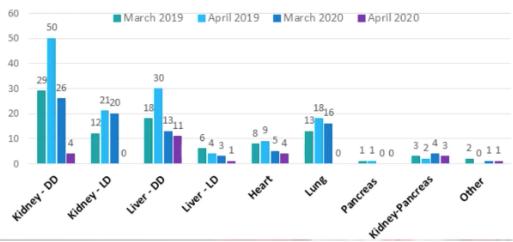




<u>Gastroenterology.</u> 2020 May 3. pii: S0016-5085(20)30585-0. doi: 10.1053/j.gastro.2020.04.064. [Epub ahead of print] Clinical Characteristics and Outcomes of COVID-19 Among Patients with Pre-Existing Liver Disease in United States: A Multi-Center Research Network Study. <u>Singh S</u>1, <u>Khan A</u>2.



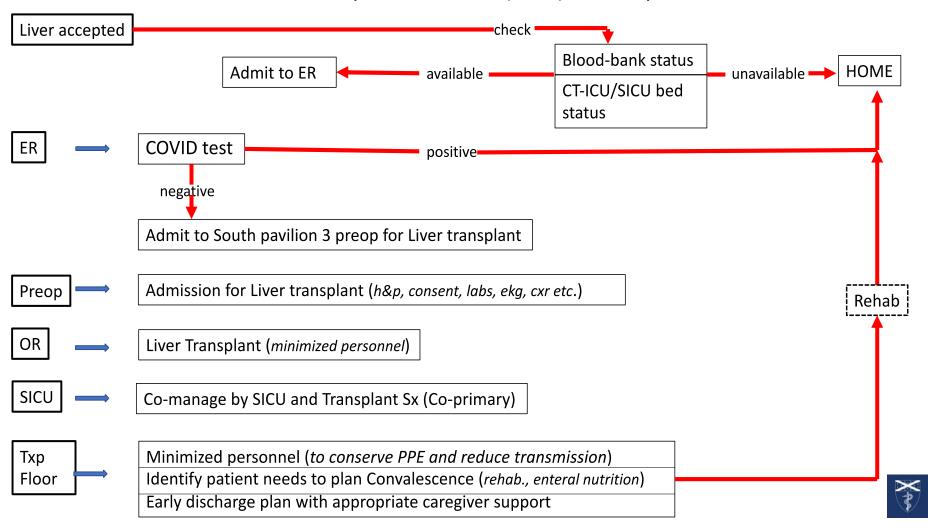




- Speeding up is harder than slowing down
- Implementation requires multilevel (local and provincial) coordination of surgical services
- Local hospital and dialysis unit outbreaks have moved programs between stages already
- It has helped immensely to have guiding principles and key considerations from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



Liver Transplant Covid-19 (C-19) Pathway





Additional Considerations

Recipient testing strategies

- Immediately prior to transplant
- Upon discharge?
- Need for direct vs. Telehealth visits postop
- Testing of caregiver(s) and quarantine?

Timing to restart living donation

- Testing of donor with quarantine prior to surgery
- Testing at discharge and quarantine for 2 weeks



Conclusions:

- Re-Entry is complex and difficult
- Effort to determine correct timing depending on:
 - COVID-19 prevalence
 - Hospital staff, space, supplies
 - Blood product supplies
 - Adequate pre- and post- testing
- Ability to be flexible on rebound to minimize COVID exposure

COVID-19 Task Force



- Chair: K. Rajender Reddy, MD, FAASLD;
 University of Pennsylvania Medical Center
- Chair: Raymond T. Chung, MD, FAASLD;
 Massachusetts General Hospital
- Emily Blumberg, MD; University of Pennsylvania Medical Center
- Robert S. Brown, MD, MPH, FAASLD; Weill Cornell Medical Center
- Jaime Chu, MD; Icahn School of Medicine at Mount Sinai
- David E. Cohen, MD, PhD, FAASLD; Weill Cornell Medical Center
- Oren K. Fix, MD, MSc, FAASLD; Swedish Medical Center
- Robert J. Fontana, MD, FAASLD; University of Michigan Hospitals and Health Centers
- Elizabeth K. Goacher, PA-C, MHS; Duke University
- Bilal Hameed, MD; University of California, San Francisco

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- David C. Mulligan, MD, VACS, FAASLD; Yale University
- Mark W. Russo, MD, MPH, FAASLD; Carolinas Medical Center
- Michael Schilsky, MD, FAASLD; Yale-New Haven Hospital
- Norah Terrault, MD, MPH, FAASLD; Keck Medical Center of USC
- o **David L. Thomas, MD**; Johns Hopkins Medicine
- Elizabeth C. Verna, MD; Columbia University
- Karen Hoyt; Patient Advocate



Panel Discussion

Please submit your questions to the Q&A Chat now.





AASLD's COVID-19 Resources

Follow/Share: COVID-19 Resources

Webpage: www.aasld.org/covid19

Join/Engage: COVID-19 Care Community on AASLD's online community, Engage. Open to all members. Log in to Engage with your AASLD user name and password: engage.aasld.org/covid19

Submit: Hepatology, Liver Transplantation, Hep Commun all accepting and fast tracking review of COVID-19 original articles, case reports

