Pediatric Heart Transplant Society

Manual of Operations

- **COVID-19 Patient Enrollment**
- **Form 6C: Infection (COVID-19 and MIS-C)**

To be used for all data entry in the
PHTS web based data entry system for COVID-19 Infections

Version 1.1.19

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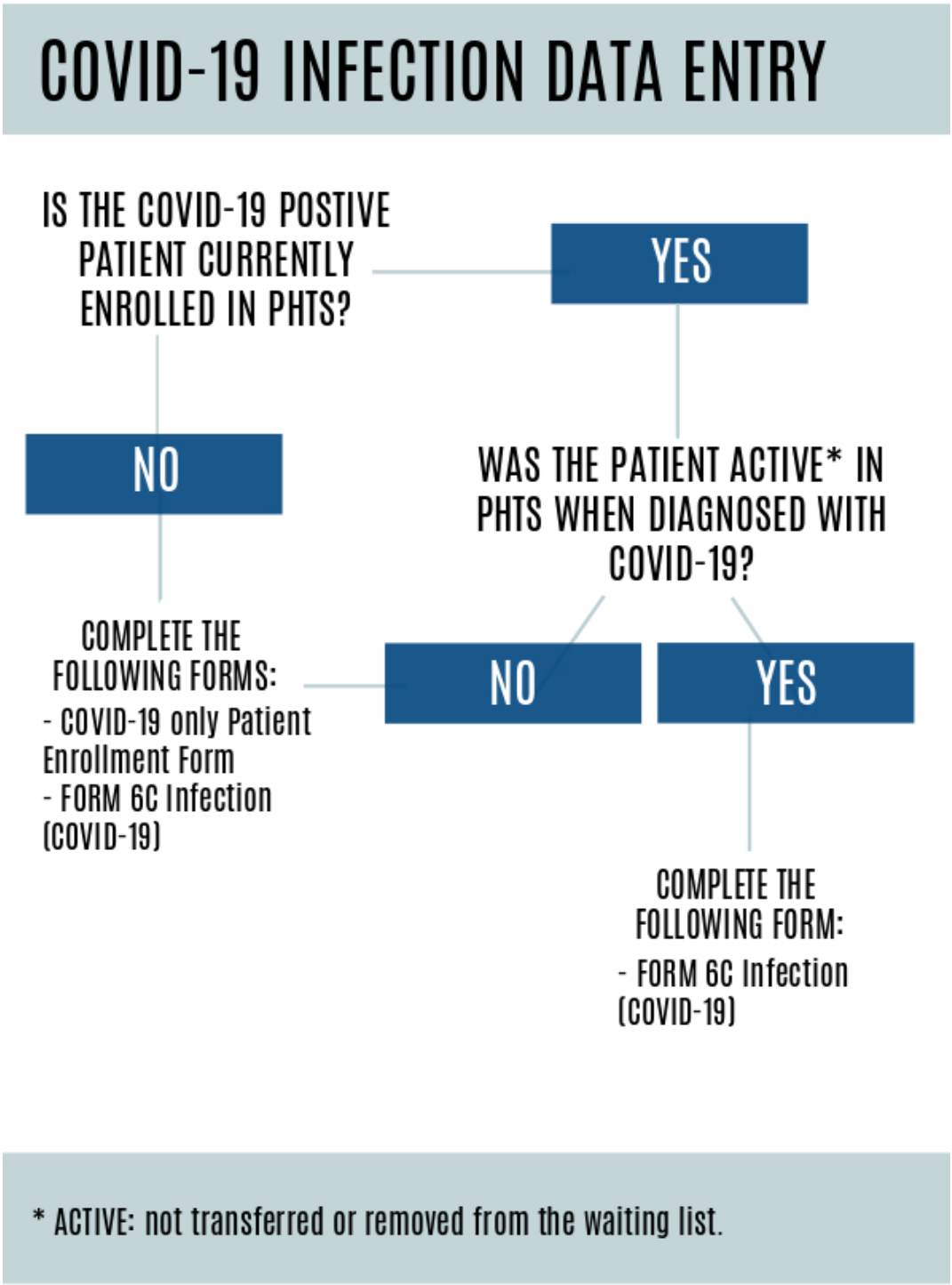
Pediatric Heart Transplant Society

Web Based Data Entry Diagram



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General Data Entry Instructions

Patient Eligibility

1. **Patients currently active in PHTS that are listed for transplant or have been transplanted**
    a. Patients in this category infected with COVID-19 should have the Form 6C: COVID-19 Infection Form entered for the existing patient number.

or

2. **Transplanted patients at PHTS sites that for some reason are not part of PHTS**
    - Sites may have transplanted patients that were not enrolled in PHTS previously. Reasons a patient might not have been enrolled include:
        - Declined consent or not approached for consent
        - Did not meet eligibility criteria at the time
            - Patients previously transplanted that were being relisted for transplant at a new site were ineligible prior to 2015
            - Prior to 2010, patients being listed for any simultaneous organ transplant were not eligible
            - ~~Heart/Lung listings are not eligible for enrollment in PHTS under the standard data entry rules. However, if a heart/lung patient has been infected with COVID-19, they can be entered in PHTS in this category.~~
            - Update February 2021: Covid-19 Heart/lung patients should NOT be entered in PHTS
            - Patient was listed for transplant prior to the site enrolling in PHTS.
    - Patients in this category infected with COVID-19 should be enrolled using the COVID-19 Patient Enrollment Form. Once that form is completed, the web based data entry system will automatically generate the Form 6C: Infection (COVID-19) form. These are the only two forms required for these patients.
    - Enrollment criteria for these patients is the same as PHTS standard enrollment criteria. Patients must be under the age of 18 at time of listing.

or

3. **Patients listed for transplant or transplanted at sites that are not participating in PHTS (including international sites) for standard data submission**
    - Patients in this category infected with COVID-19 should be enrolled using the COVID-19 Patient Enrollment Form. Once that form is completed, the web based data entry system will automatically generate the Form 6C: Infection (COVID-19) form. These are the only two forms required for these patients.

- The COVID19 Limited HIPPA waiver covers disclosure of PHI for Non-PHTS patients for the purposes of this data collection. https://www.hhs.gov/sites/default/files/hipaa-and-covid-19-limited-hipaa-waiver-bulletin-508.pdf

COVID-19 Infection Definition
Swab positive patients or those suspected to have COVID-19 on clinical grounds (diagnosed with COVID-19 without a positive test).

PHTS Patient Enrollment Form vs COVID-19 Patient Enrollment Form

- For existing **active** patients in the PHTS Web Based Data Entry System that are infected with COVID-19, a COVID-19 Infection Form should be added to the existing patient number.
- For existing PHTS patients that are **inactive** at the time the patient is infected with COVID-19, the patient should be added using the COVID-19 Patient Enrollment form and then the COVID-19 Infection Form
- Patients 'active' in the system is defined as not meeting a patient end point or censor point. End points or censor points include patient transfer and patient removal from the waiting list pre transplant.

Web Based Data Entry System

- Existing ACTIVE PHTS Patients
  - For active patients in PHTS that are infected with COVID-19, the Form 6C COVID-19 Infection form should be added to the existing patient number just as any form would be added. This is for patients active at the time of the diagnosis.
- Existing INACTIVE PHTS Patients
  - Once a patient encounters a censor point that changes the patient status to inactive, no more entry for events that have occurred after the censor date should be added to the existing patient number. For these patients infected with COVID-19, the new COVID-19 Patient Enrollment Form should be added and the subsequent COVID-19 Infection form as well.
  - See censor points: https://www.uab.edu/medicine/phts/images/training/2018-10-16/Censor_Points.pdf
- COVID-19 Only Patients (NEVER ENROLLED IN PHTS)
  - A new button has been added to the top of the wbde system to enroll COVID-19 only patients.
  - Once this enrollment form is completed and submitted, the Form 6C: COVID 19 Infection Form will be generated. These are the only two forms that are required for non PHTS patients that are having a COVID-19 diagnosis tracked in the PHTS data entry system.
- Site Dashboard
  - A new column has been added to the site dashboard that categorizes patients as 'Standard' or 'COVID-19'. Existing PHTS patients are categorized as 'Standard'.

Patients enrolled as COVID-19 Only patients are displayed categorized as 'COVID-19'.

- Patient Summary Reports
  - Patient Summary reports are not available at this time for COVID-19 only patients.
  - For existing PHTS patients, the Patient Summary Reports do not currently display the COVID-19 Infection information. This will be available soon.

Retrospective Data Entry

While the addition of this data collection started on April 30, 2020, sites with patients that have been diagnosed with COVID-19 prior to April 30, 2020 are strongly encouraged to enter these patients retrospectively.

Exclusion Criteria

- Heart/Lung listings
- Patients whose only indication for covid was a positive antibody test with no other signs or symptoms

Patient Enrollment (For COVID-19 Patients ONLY – not to be used for existing PHTS Patients) (April 30, 2020)

To be completed at time of patient enrollment.

Institution Code: Three letter institution code (pre-assigned by the DCC). This code will be pre-populated on the data entry screen and cannot be changed by the coordinator.

Patient Number: This number will be automatically assigned to each patient once the patient is enrolled. Once you click "Validate and Save" the new patient will be enrolled into the system. The patient number will display in the patient header.

Patient Information

1. **Patient Initials**: Indicate the patient's initials. If the patient does not have a middle initial, enter a dash (-) as the middle initial. All initials should be three characters in length.

2. **Age at Infection:** enter the patient's age at infection in either days, weeks, months, or years.
   - ○ < 1 month
   - ○ >= 1 month

   a. Age at infection (days)
   b. Age at infection (weeks)
   c. Age at infection (months)
   d. Age at infection (years)

3. **Sex:** Specify.
   - ○ Female
   - ○ Male

4. **Race:** Race AND ethnic data regarding Hispanic Origin must BOTH be completed (i.e. if you check "yes" to Hispanic origin, must also enter race).
   Please check ALL that apply, especially for biracial patients (these categories are identical to those used by U.S. Census Bureau).
   - ☐ African American/Black: racial origins in any of the black racial groups of Africa.
   - ☐ American Indian/Alaskan Native: racial origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.
   - ☐ Asian: racial origins in any of the original peoples of the Far East and Southeast Asia (examples include China, Japan, and Korea).

- ☐ Hawaiian or Pacific Islander: racial origins in any of the peoples of the Pacific Islands (examples include the Philippine Islands, Samoa, Guam and the Hawaiian Islands).
- ☐ Unknown/Undisclosed
- ☐ White: racial origins in any of the original peoples of Europe.
- ☐ Other, specify

5. **Hispanic origin (1993)**: Specify.
   - ○ Yes: if of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture of origin, regardless of race.
   - ○ No*:* if not.
   - ○ Unknown: if not known

6. **Patient Category**
   - ○ Waitlist for heart transplant
   - ○ Heart transplant recipient
   - ○ Non-waitlist, non-transplant

   6a. Age at transplant: If patient has been previously transplanted, enter the patient's age at transplant in either days, weeks, months, or years.
   - ○ < 1 month
   - ○ >= 1 month

   a. Age at transplant (days)
   b. Age at transplant (weeks)
   c. Age at transplant (months)
   d. Age at transplant (years)

7. **Primary Etiology:** Indicate ONE etiology as primary reason for transplant. If unclear, please confirm with your institution PI.
   - ○ Cardiac Tumor
   - ○ Cardiomyopathy
     - ○ ARVD/C: Arrhythmogenic right ventricular dysplasia or cardiomyopathy characterized by fibro fatty replacement of RV with aneurysmal dilation and arrhythmias
     - ○ Dilated
       - ○ Chemotherapy-Induced: replaces Adriamycin
       - ○ Conduction Defect: e.g. long QT syndrome
       - ○ Familial: documented family history or genetic defect
       - ○ Ischemic
         - ○ Kawasaki
         - ○ Unknown
         - ○ Other, specify

- Isolated/Idiopathic: no identifiable cause
- LVNC: Left Ventricular Non Compaction
- Metabolic/Syndromic/Mitochondrial
- Neuromuscular: e.g. Becker, Duchenne, etc.
- s/p Myocarditis: end-stage DCM following an episode of documented myocarditis
- Unknown
- Other, specify

- Hypertrophic: known by a number of names including Hypertrophic Obstructive Cardiomyopathy (HOCM), Idiopathic Hypertrophic Sub-Aortic Stenosis (*IHSS)* and Muscular Sub-Aortic Stenosis. The general term Hypertrophic Cardiomyopathy (HCM) is now most widely used.
  - Familial
  - Isolated/Idiopathic
  - Metabolic/Syndromic/Mitochondrial
  - Neuromuscular
  - Unknown
  - Other, specify
- Mixed
- Restrictive
  - Chemotherapy-Induced
  - Isolated/Idiopathic
  - LVNC: Left Ventricular Non Compaction
  - Metabolic/Syndromic/Mitochondrial
  - s/p Radiation
  - Unknown
  - Other, specify
- Unknown,
- Other, specify

- Congenital heart Disease: If checked, also check one of the subcategories. If patient's diagnosis does not fit into one of listed categories, please confirm with your institution PI.
  - ☐ ALCAPA
  - ☐ Aortic Atresia (almost exclusively single ventricle)
  - ☐ Aortic Regurgitation
  - ☐ Arch Hypoplasia/Interruption/Hypoplasia / Coarctation
  - ☐ ASD/VSD
  - ☐ AV Discordance
  - ☐ Bilateral SVC
  - ☐ Complete AV Septal Defect/AV Canal
  - ☐ Cong. Corrected Trans. (I-TGA) (CC-TGA)
  - ☐ Coronary Anomaly
  - ☐ Dextrocardia

- ☐ Double Inlet Left Ventricle (almost exclusively single ventricle)
- ☐ DOLV
- ☐ Ebstein's Anomaly
- ☐ Heart Block
- ☐ Heterotaxy
  - ☐ Asplenia or Right Isomerism
  - ☐ Polysplenia or Left Isomerism
  - ○ Unknown
- ☐ Hypoplastic Left Heart
- ☐ Hypoplastic Right Ventricle NOS
- ☐ Interrupted IVC
- ☐ Left SVC (no right SVC)
- ☐ Left Ventricular Outflow Tract Obstruction / Aortic Stenosis
- ☐ Marfan's Syndrome
- ☐ Mitral Atresia (almost exclusively single ventricle)
- ☐ Mitral Regurgitation
- ☐ Mitral Stenosis
- ☐ Right Aortic Arch
- ☐ PDA (not on PGE)
- ☐ Pulmonary Atresia (with complex heart disease, not intact septum or Tetralogy of Fallot)
- ☐ Pulmonary Atresia with IVS

  Pulmonary Atresia with IVS, RV dependent coronary Circulation:
  - ☐ Yes
  - ☐ No
  - ☐ Unknown
- ☐ Pulmonary Stenosis
- ☐ Shone's Syndrome
- ☐ Situs Inversus
- ☐ TAPVR
- ☐ PAPVR
- ☐ TOF/TOF Variant/DORV/RVOTO
- ☐ Transposition of the Great Arteries (d-TGA)
- ☐ Tricuspid Atresia (almost exclusively single ventricle)
- ☐ Truncus Arteriosus
- ☐ Unknown
- ☐ Other, specify

- ○ Single Ventricle
  - ○ Yes
  - ○ No
- ○ Unknown

- Myocarditis: Acute Myocarditis is indicated when the diagnosis is confirmed (i.e. lymphocytic infiltrate and/or positive viral PCR in heart tissue) by myocardial biopsy or by post-transplant pathological examination. Please do not list myocarditis if diagnosis is presumptive.
- Other, specify: e.g. endocarditis)

Questions and Answers

Question 4: Patient Initials

- **Q:** Can I edit the patient details, such as adding a middle initial after the form has been submitted?
- **A:** Yes, the forms will not be locked upon submission

Question 13: Primary Etiology

- **Q:** For the enrollment form, question 13 a ii in which I am to categorize the type of cardiomyopathy. The options are: familial, isolated/idiopathic, metabolic/syndromic/mitochondrial, neuromuscular, unknown, and other. What's the difference between unknown and idiopathic?
- **A:** Idiopathic should be used for patients with dilated cardiomyopathy who had a complete workup but no cause was found. Unknown should be used in patients in whom the etiology has not been completely investigated and additional testing is desired or ongoing.

- **Q:** If there is a patient that has an identifiable genetic mutation associated with cardiomyopathy that was not identified in parents would that be considered isolated or genetic mutations categorized under familial even if it isn't inherited?
- **A:** A patient who declined to undergo genetic testing, but otherwise had a complete evaluation for causes of dilated cardiomyopathy should be considered idiopathic. It will be up to the center to decide if investigation was completed.

Question 13: Single Ventricle (yes/no/unknown)

Q: Is that question getting at whether or not they are a true single ventricle like a hypoplast or if they are being staged even if their diagnosis isn't officially single ventricle?

A: Yes to both. It means that the patient was in the single ventricle "surgical path, leading to a goal of a Fontan", irrespective of the actual anatomy.

Pediatric Heart Transplant Society

Form 06C: Infection (COVID-19 and MIS-C) (April 30, 2020)

- ✓ **To be filled out pre AND post-transplant for COVID-19 and MIS-C Infections.**
- ✓ **If patient is re-infected with COVID-19 after initial infection has cleared, enter on additional form.**
- ✓ **ALL data on this form is specific to the COVID-19 Infection only. For example, an ICU stay is for days in ICU for COVID-19, not because of heart failure or post-transplant management.**

1. **Was patient managed with COVID-19 as inpatient only, outpatient only, or both?**
   - ○ Inpatient only
   - ○ Outpatient only
   - ○ Both

   Q: My patient was admitted for an unrelated infection to her COVID infection in the 30 day window post her positive COVID test. Should we say that admission was required for COVID infection or not?
   A: If the patient admission was not related to the COVID infection, it should be reported as outpatient. If there was a chance it was related to COVID, it should be entered as inpatient.

   1a. Date of Admission (same or different from date of infection)
   Enter as mm/dd/yyyy

2. **Date of Infection (date of diagnosis or clinical presentation, whichever is earliest)**
   Enter as mm/dd/yyyy
   If infection date is unknown, select 'unknown' as a missing reason. **(January 4, 2021)**

3. **Mode of Diagnosis**
   - ○ COVID-19 Test Positive
   - ○ Known Exposure to COVID-19 Positive Patient
   - ○ Presumed COVID-19 Positive Based on Symptoms, no known exposure or test

   3a. Mode of Testing
   - ○ PCR
   - ○ Antibody Testing
   - ○ Both PCR and Antibody Testing
   - ○ Antigen Test for SARS-CoV2

4. **Drug Therapy at time of infection**: Indicate if there was an ongoing prophylactic drug therapy at time (date) of infection diagnosis (i.e. valganciclovir for CMV prophylaxis post-transplant). Do not include drugs that have been prescribed to treat a specific previous infection unless that previous infection is considered to be resolved and the patient is now on long-term prophylaxis. Do not include therapy for the current infection.

a. **If yes, specify current medications at time of diagnosis of COVID-19 Infection:** Check all that apply.
   - ☐ ACEi
   - ☐ Acyclovir
   - ☐ Alemtuzumab (Campath)
   - ☐ ARB
   - ☐ ATGAM
   - ☐ Azathioprine (Imuran)
   - ☐ Basiliximab (Simulect)
   - ☐ Bortezomib (Velcade)
   - ☐ CMV Immunoglobulin, Cytogam
   - ☐ Cyclosporine
   - ☐ Cytoxan (cyclophosphamide)
   - ☐ Dapsone
   - ☐ Everolimus (Certican)
   - ☐ Fluconazole
   - ☐ Ganciclovir or Valganciclovir
     - ○ IV
     - ○ PO
   - ☐ Hydroxychloroquine (Chronic or prophylactic use)
   - ☐ Immunoglobulin, IV Ig
   - ☐ Methotrexate
   - ☐ Mycophenolate, MMF (Cellcept, Myfortic)
   - ☐ Nystatin
   - ☐ Oseltamivir
   - ☐ Pentamidine
   - ☐ Prednisone
   - ☐ Rituximab (Rituxan)
   - ☐ Sirolimus (Rapamycin)
   - ☐ Tacrolimus (Prograf, FK506)
   - ☐ Thymoglobulin/ATG
   - ☐ Trimethoprim-sulfamethoxazole, Septra
   - ☐ Valacyclovir
   - ☐ Other, specify

5. **Labs:** Report the highest and lowest lab values within the first 30 days of infection.

Q: We have a number of patients who had mild cases of COVID, they were not admitted, some had no labs done at all and there were others who only had labs done at the time of their positive test. In reporting lab results on the form where it asks for the lowest and highest result I am putting the same value for both since I only have the one result done during the infection. Is that correct?

A: Yes, entering the same lab result for the low and high value is the correct way to report in these infections where only one lab was done.

Lab	Question Added	Unit	Too low	Normal	Question Zone	Red Flag Zone
WBC – Low *Lowest count during infection*	May 1, 2020	cell / mm^3				
WBC – High *Highest count during infection*	May 1, 2020	cell / mm^3				
BUN/Urea *Blood urea nitrogen* *Lowest during infection*	September 28, 2020	mg/dL	< 0	4 to 20	> 40	> 120
		Urea mmol/L	< 0	1.4286 to 7.1429	> 14.286	> 42.857
BUN/Urea *Blood urea nitrogen* *Highest during infection*	September 28, 2020	mg/dL	< 0	4 to 20	> 40	> 120
		Urea mmol/L	< 0	1.4286 to 7.1429	> 14.286	> 42.857
Creatinine *Lowest during infection*	September 28, 2020	mg/dL	< 0	0.2 to 1.3	> 2.6	> 10
		umol/L	< 0	17.68 to 114.92	> 229.84	> 884
Creatinine *Highest during infection*	September 28, 2020	mg/dL	< 0	0.2 to 1.3	> 2.6	> 10
		umol/L	< 0	17.68 to 114.92	> 229.84	> 884
LDH *Lowest during infection*	May 1, 2020	un / L				
LDH *Highest during infection*	May 1, 2020	un / L				
ALT/SGPT *Alanine transaminase (also SGPT)* *Lowest during infection*	September 28, 2020	U/L	< 0	7 and 45	> 90	> 1000
ALT/SGPT *Alanine transaminase (also SGPT)* *Highest during infection*	September 28, 2020					
Bilirubin Total *Lowest during infection*	September 28, 2020	mg/dL	< 0	0.3 to 1.2	> 2.4	> 10
		umol/L	< 0	5.13 and 20.52	> 41.04	> 171
Bilirubin Total *Highest during infection*	September 28, 2020	mg/dL	< 0	0.3 to 1.2	> 2.4	> 10
		umol/L	< 0	5.13 and 20.52	> 41.04	> 171
CRP *C reactive protein -* *Lowest during infection*	September 28, 2020	mg/dL	< 0	0 and 0.5	> 5	< 50
		mg/L	< 0	0 and 5	> 50	> 500
CRP *C reactive protein -* *Highest during infection*	May 1, 2020	mg/dL	< 0	0 and 0.5	> 5	< 50
		mg/L	< 0	0 and 5	> 50	> 500

Procalcitonin *Lowest during infection*	September 28, 2020	ng/ml				
Procalcitonin *Highest during infection*	May 1, 2020	ng/ml				
BNP *B-type natriuretic peptide* *Lowest during infection*	September 28, 2020	pg/ml or ng/L	< 0	10 and 100	> 1000	> 10000
		pmol/L	< 0	84.6024 and 846.024	> 8460.24	> 84602.4
BNP *B-type natriuretic peptide* *Highest during infection*	September 28, 2020	pg/ml or ng/L	< 0	10 and 100	> 1000	> 10000
		pmol/L	< 0	84.6024 and 846.024	> 8460.24	> 84602.4
Pro BNP *Pro NT B-type natriuretic peptide* *Lowest During Infection*	September 28, 2020	pg/mL or ng/L	< 0	10 to 300	> 3000	> 30,000
		pmol/L	< 0	84.602 and 2538.1	> 25,380.7	> 253,807
Pro BNP *Pro NT B-type natriuretic peptide* *Highest During Infection*	September 28, 2020	pg/mL or ng/L	< 0	10 to 300	> 3000	> 30,000
		pmol/L	< 0	84.602 and 2538.1	> 25,380.7	> 253,807
Troponin *Lowest during infection*	September 28, 2020	ng/ml T/I				
Troponin *Highest during infection*	September 28, 2020	ng/ml T/I				
Platelet Count - Lowest *Lowest during infection*	May 1, 2020	cell / microliter				
Platelet Count - Highest *Highest during infection*	May 1, 2020	cell / microliter				
Hemoglobin - Lowest *Lowest during infection*	May 1, 2020	g/dL				
Hemoglobin - Highest *Highest during infection*	May 1, 2020	g/dL				

ECHO

6. **Was at least one echo done at the time of the evaluation for COVID-19?**
   - ○ Yes
   - ○ No
   - ○ Unknown

Q: This patient had an ECHO done a week before testing positive, and at the time of the ECHO, patient was negative COVID. The question asks specifically if patient had an ECHO done at the time of evaluation for COVID, this ECHO wasn't done to evaluate for COVID. However, ECHO did show moderately worse functions, but patient was found to have rejection

and is now on ECMO, but the last two COVID results were negative. Should I report this ECHO on the COVID form or no?
A: No

6a. Was the function on the worst echo mildly, moderately, or severely worse than pre-COVID-19?

- ○ Mildly Worse
- ○ Moderately Worse
- ○ Severely Worse
- ○ Unchanged
- ○ Unknown

6b. If the echo was changed from baseline, did it return to baseline before discharge?

- ○ Yes
- ○ No
- ○ Unknown

7. **COVID-19 Infection Involvement**
   - ☐ None **(Added 06/08/2020)**
   - ☐ Fever
   - ☐ Gastrointestinal infection (ie. Gastritis, colitis, infectious diarrhea)
   - ☐ Heart (includes endocarditis)
   - ☐ Respiratory (includes Pneumonia/ Bronchiolitis/Tracheitis/ Pleuritis)

8. **Were there other infections at the same time**
   Other infections during hospitalization with COVID-19. Select ALL additional organisms at the time of infection.

   Bacterial Infection Organisms
   - ☐ Bordatella Pertussis
   - ☐ Chlamydia
   - ☐ Clostridium Difficile
   - ☐ Enterobacter
   - ☐ Enterococcus (including VRE)
   - ☐ Escherichia Coli
   - ☐ Haemophilus influenzae
   - ☐ Haemophilus, NOS
   - ☐ Klebsiella, NOS
   - ☐ Moraxella
   - ☐ Myocoplasma pneumonia
   - ☐ Nocardia
   - ☐ Pseudomonas
   - ☐ Salmonella

- ☐ Serratia
- ☐ Staphylococcus Aureus, Methicillin/Oxacillin Resistant (MRSA)
- ☐ Staphylococcus Aureus, Methicillin/Oxacillin Sensitive (MSSA)
- ☐ Staphylococcus, Coagulase-Negative (Staph Epidermidis)
- ☐ Staphylococcus, Other
- ☐ Streptococcus Pneumoniae (Streptococcal Pneumonia)
- ☐ Streptococcus, Group A (S. pyogenes)
- ☐ Streptococcus, Viridians Group
- ☐ Streptococcus, NOS
- ☐ Streptococcus, Group B (S. agalactiae)
- ☐ Stenotrophomonas
- ☐ Mycobacterium tuberculosis (TB)
- ☐ Nontuberculous mycobacterium (NTM)
- ☐ Bacterial Organism(s) Unknown
- ☐ Other, specify

Fungal Infection Organisms

- ☐ Aspergillus
- ☐ Candida albicans
- ☐ Candida, Not Albicans/Other
- ☐ Coccidioidomycosis
- ☐ Cryptococcus
- ☐ Histoplasmosis
- ☐ Mucormycosis
- ☐ Pneumocystis (PCP/PJP)
- ☐ Fungal Organism(s) Unknown
- ☐ Other, specify

Protozoan Infection Organisms

- ☐ Cryptosporidium
- ☐ Giardia
- ☐ Toxoplasma (Toxo)
- ☐ Protozoan/parasitic Organism(s) Unknown
- ☐ Other, specify

Viral Infection Organisms

- ☐ Adenovirus
- ☐ Bk Virus
- ☐ Coronavirus ((Other than SARS-CoV-2)
- ☐ Coxsackievirus (all serotypes)
- ☐ Cytomegalovirus, CMV
- ☐ Enterovirus
- ☐ Epstein Barr Virus, EBV (symptomatic)

- ☐ Hepatitis A
- ☐ Hepatitis B
- ☐ Hepatitis C
- ☐ Hepatitis D
- ☐ HIV
- ☐ Human Herpes Simplex Virus, Type 1/Type 2
- ☐ Influenzavirus A
- ☐ Influenzavirus B
- ☐ Influenzavirus H1N1
- ☐ Influenzavirus, NOS
- ☐ Metapneumovirus (HMPV)
- ☐ Norovirus (Norwalk Virus)
- ☐ Parainfluenza
- ☐ Parvovirus
- ☐ Respiratory Syncytial Virus (RSV)
- ☐ Rhinovirus
- ☐ Rhino/Enterovirus, NOS
- ☐ Rotavirus
- ☐ Varicella (Chicken Pox/Shingles)
- ☐ West Nile Virus
- ☐ Viral Organism(s) Unknown
- ☐ Other, specify

8b. Was the additional infection treated with antibiotics?

- ○ Yes
- ○ No
- ○ Unknown

9. Location of exposure

- ○ Home
- ○ Community
- ○ In Hospital
- ○ Long Term Care Facility **(Added 09/28/2020)**
- ○ Unknown

Interventions

10. Drug Therapy to Treat Infection

- ☐ None **(Added 06/08/2020)**
- ☐ Hydroxychloroquine
- ☐ Azithromycin
- ☐ Anti-Viral, specify
- ☐ Hyperimmune Globulin
- ☐ Monoclonal Antibody Infusions **(Added 11/30/2021)**

- ☐ Remdesivir **(Added 11/30/2021)**

10a. Specify anti-viral

10b. Anti-viral administration method
- ○ IV
- ○ PO

11. Is the patient on baseline immunosuppression
- ○ Yes
- ○ No
- ○ Unknown

Q: At what point in time is this question referring to – at the start of the COVID infection? Or at the resolution of the infection
A: Start

11a. Indicate which Immunosuppressive drugs were reduced because of COVID-19
- ☐ None
- ☐ Unknown
- ☐ CNI
- ☐ Antimetabolite
- ☐ PSI/mTOR inhibitor
- ☐ Steroids

12. Did patient receive inotropic support?
- ○ Yes
- ○ No
- ○ Unknown

13. Other Interventions (This is for treatments only, not diagnostic procedures
- ☐ None **(Added 06/08/2020)**
- ☐ Newly required Dialysis
- ☐ Newly required mechanical support
- ☐ Non-invasive ventilation: NC O2
- ☐ Non-invasive ventilation: HF O2
- ☐ Non-invasive ventilation: CPAP
- ☐ Non-invasive ventilation: BIPAP
- ☐ Invasive Mechanical Ventilation
- ☐ Surgical therapy, specify *(Do not include invasive diagnostic procedure (i.e. biopsies) or short term device placement for therapy (i.e. central line placement, PD placement, or ECMO procedures)*

- ☐ Supportive Care Only (*In most cases, if "Supportive care only" is selected no other options should be selected. The exception is the rare case when a patient has two viral infections and one is treated while one is not. Please ensure that the selection of "Supportive Care Only" is appropriate in this clinical scenario.*)
- ○ Unknown
- ☐ Other, specify

13a. Specify Surgical Therapy

- ☐ Surgery
  - ☐ ENT
  - ☐ GI
    - ☐ Appendectomy
    - ☐ Other, specify
  - ☐ Dental
  - ☐ *Neurology (Brain, Peripheral/Spine)*
  - ☐ Cardiothoracic
  - ☐ Nephrology/Urology
  - ☐ Orthopedic
  - ☐ Ophthalmology
- ☐ New Device placed for treatment of infection
  - ☐ Chest tube
  - ☐ Long term central line
  - ☐ Other, specify
- ☐ Removal of pre-existing device
  - ☐ Replaced during same hospitalization or later?
    - ☐ Same hospitalization
    - ☐ Replaced after discharge
      - ☐ Permanent pacemaker/AICD
      - ☐ Long term PD catheter
      - ☐ Long term central line
      - ☐ VAD (complete Form 15)
      - ☐ Other, specify
- ☐ Non-invasive procedure, specify
- ☐ Advanced wound care
  - ☐ Drainage procedure, specify location
  - ☐ VAC placement, specify location
  - ☐ Debridement, specify location
  - ☐ Other, specify
- ☐ Unknown
- ☐ Other, specify

14. Days in ICU

Report the number of days in the ICU because of COVID-19, not for other medical reasons. If patient was not in the ICU, enter 0. If patient is still in the ICU at the time of the form submission, the form can be submitted with a missing reason of "still in hospital" selected. Then, the form can be updated at a later date with the total number of days.

15. Days intubated on ventilator

Report the number of days intubated on a ventilator because of COVID-19, not for other medical reasons. If patient was not on a ventilator, enter 0. If patient is still on a ventilator at the time of the form submission, the form can be submitted with a missing reason of "still in hospital" selected. Then, the form can be updated at a later date with the total number of days.

16. Days hospitalized

Report the number of days hospitalized because of COVID-19, not for other medical reasons. If patient was not hospitalized, enter 0. If patient is still hospitalized at the time of the form submission, the form can be submitted with a missing reason of "still in hospital" selected. Then, the form can be updated at a later date with the total number of days.

17. Outcome at 30 days' post-date of infection: Specify only one outcome.

- ○ Death - If death occurs related to this infection, complete Form 10: Death.
- ○ Resolution
- ○ Significant long term sequelae - is defined as any residual medical problem persisting from >30 days after the onset of the infection. Examples include persistent renal failure or respiratory failure, or significant disability due to the infection.
- ○ Unresolved at 30 days
- ○ Unknown

If patient Death

17a. Date of Death

17b. Primary Cause of Death

- ○ COVID-19
- ○ Cardiovascular
- ○ Pulmonary
- ○ MSOF
- ○ Renal
- ○ Neurologic

17b.i Did COVID-19 contribute to death?

- ○ Yes
- ○ No
- ○ Unknown

17c. Details of Sequelae (choose all that apply)

***All current definitions of pediatric ARF or AKI (including KDIGO AKI which is the current recommended definition by peds nephrology) are based on measurements within the first 2 weeks.*

***All current definitions of CKD (eGFR < 60 – measured by egfr = (0.413 * height) / creatinine) are based on eGFR < 60 persisting for 3 months*

Kidney Consequences at 30 days

- ☐ Acute Kidney Injury (Definition: serum creatinine >= 2 times baseline) that resolved by 30 days
- ☐ Acute Kidney Injury (Definition: serum creatinine >= 2 times baseline) still present at 30 days
- ☐ Chronic kidney insufficiency unchanged from before infection
- ☐ Worsened chronic kidney insufficiency
- ☐ Currently requiring dialysis

Neurological consequences at 30 days

- ☐ Neurological complication that resolved by 30 days and no longer requiring treatment (please specify complication)
- ☐ Encephalopathy with ongoing mental status changes or deficits
- ☐ Hydrocephalus requiring treatment or VP shunt
- ☐ Seizures requiring ongoing therapy
- ☐ Residual deficits from stroke

Respiratory Consequences at 30 days

- ☐ Need for invasive mechanical ventilation that resolved by 30 days
- ☐ Need for non-invasive mechanical (CPAP, BiPAP) ventilation that resolved by 30 days
- ☐ Ongoing need for non-invasive ventilation
- ☐ New or ongoing need for mechanical vent or trach

GI Consequences at 30 days

- ☐ GI symptoms that resolved by 30 days (please specify)
- ☐ Ongoing TPN
- ☐ Colostomy/ostomy

None of these

- ☐ None of these

MIS-C Infection

If a patient has an MIS-C infection, it should be reported here. If the patient first presents with an MIS-C infection and there is not information available for a positive COVID-19 test, only questions 18 and 18a should be completed. Questions 1-17 can be completed with the missing

reason of 'unknown'. If patient has a completed COVID-19 form and later has a positive MIS-C infection, the existing COVID-19 form should be updated to add the MIS-C infection.

CDC Definition of MIS-C

An individual aged <21 years presenting with fever*, laboratory evidence of inflammation**, and evidence of clinically severe illness requiring hospitalization, with multisystem (>2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND No alternative plausible diagnoses; AND

Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or exposure to a suspected or confirmed COVID-19 case within the 4 weeks prior to the onset of symptoms.
*Fever >38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours

**Including, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin.

18. Did this patient have MIS-C? (January 4, 2021)

- ○ Yes
- ○ No
- ○ Unknown

18a. Date of MIS-C Infection (January 4, 2021)

If 18 is 'yes', provide date of infection as mm/dd/yyyy

Questions and Answers

Question 3: Drug Therapy at time of infection

- **Q:** Is the form wanting us to list every drug the patient is on, or just the antibiotic type drugs?
- **A:** Drug therapy should include immune suppression and prophylaxis.

Form 12, Question 4: Status Change

- **Q:** I made a waitlisted patient status 7 because they were COVID positive and I went to capture it on the pre transplant status report.
- **A:** Report the reason for status change in 'other, specify'