

## Extracorporeal Life Support Organization (ELSO)

## ELSO SARS-CoV-2 Addenda 04/01/2021

For all comments, questions and concerns please email <a href="mailto:registrysupport@elso.org">registrysupport@elso.org</a>

## **ELSO SARS CoV-2 Addenda**

This form collects information about the patient during the admission for COVID-19.

This is a guick form, please complete the entire FLSO Registry Data form for the patient as soon as possible.

This is a quick for	orm, please complete the entire ELSO Registry Dat	a form for the	patient as soo	n as possible.	
Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
SARS-CoV-2 Diagnostic Testing (only applicable for MIS-C patients)	This field clarifies diagnostic testing performed on MIS-C patients  Select all that apply:  Active SARS-CoV-2 infection confirmed by PCR  Prior SARS-CoV-2 infections confirmed by IgG / IgM serology testing  MIS-C suspected without positive laboratory testing	This field is only applicable (and only appears) for self-selected MIS-C patients.	06/15/2020 - present	COVID.CovidAddendum	ActiveSARS PriorSARS MISCsuspected
SARS-CoV-2 Organ System Involvement (only applicable for MIS-C patients)	This field collects information MIS-C organ involvement Select all that apply:  Cardiovascular: If Cardiovascular is selected, please select all clinical manifestation that apply: Systolic ventricular dysfunction by echocardiogram (moderate or severe or ejection fraction <50%) Conduction system disturbance Hemodynamically significant arrhythmia Vasomotor dysfunction / vasoplegia Coronary artery ectasia or aneurysm Renal Respiratory Hematological Gastrointestinal Dermatological Neurological	This field is only applicable (and only appears) for self-selected MIS-C patients.	06/15/2020 - present	COVID.SARSOrganSystem COVID.SARSCardiac	Lookup table: COVID.SARSOrganSystemCodes Cardiovascular=1, Renal=2, Respiratory=3, Hematological=4, Gastrointestinal=5, Dermatological=6, Neurological=7 Systolic ventricular dysfunction by echocardiogram (moderate or severe or ejection fraction <50%)=1, Conduction system disturbance=2, Hemodynamically significant arrhythmia=3, Vasomotor dysfunction / vasoplegia=4,

				Coronary artery ectasia or aneurysm=5
SARS-CoV-2 Vaccination History	This field collects information regarding vaccination history of the patient:  Select the most appropriate choice: Yes: the patient has received a full vaccination course No: the patient has not received any vaccination dose Partial: the patient received at least one vaccination dose, but did not complete the full vaccination schedule Unknown	Only one choice may be selected	04/01/2021 – present Question added	

Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
SARS-COV-2 COVID Comorbidity	This field collects any comorbidities existing prior to ECLS but during the same hospitalization as the ECLS run.  Select Yes or No If Yes, select all that apply:  Cancer: Broad term for any proliferative abnormal growth of cells. Previously diagnosed  Pregnancy: Patient was pregnant at time of admission with COVID-19. If delivered prior to ECLS, still indicate pregnancy.  Immunocompromised: Patients who are immuno-compromised are considered vulnerable and may include:  a. Persons with primary or acquired immunodeficiency b. Persons on anti-rejection therapy following solid organ transplant or bone marrow transplant c. Persons on biologic therapeutic agents such as tumor necrosis factor inhibitors d. Persons with malignancy and ongoing or recent chemotherapy e. Persons receiving systemic immunosuppressive therapy, including corticosteroids equivalent to 20 mg/day of prednisone for ≥2 weeks  Chronic heart disease: Chronic Heart Failure is a condition in which the heart has consistently decreased function over a	If Yes selected, then at least one must be selected.	03/23/2020 - present  04/19/2020 - present Hypertension added	COVID.CovidAddendum COVID.Comorbidity	CovidComorbidity  Lookup Table: COVID.ComorbidityCodes  Cancer - 1 Pregnancy - 2 Immunocompromised - 3 Chronic heart disease - 4 Diabetes - 5 Chronic lung disease - 6 Chronic renal insufficiency - 7 Fraility - 8 Obesity (BMI > 30 kg/m2) - 9 Asthma - 10 Hypertension - 11

prolonged period of time. This may have acute onset or can develop slowly over a long period of time. Symptoms include shortness of breath, problems exercising, fatigue, and swelling of the feet, ankles, and abdomen. Chronic heart failure may be the result of a congenital anomaly or by acquired disease such as coronary artery disease, dysrhythmia, or hypertension.

Chronic lung disease (excluding asthma): Chronic Lung Disease is a disorder that affects the lungs and other parts of the respiratory system, usually develops slowly, and may get worse over time. Chronic lung disease can occur in both adults and in children. It can be developmental or acquired. Types of chronic lung disease include: pulmonary hypertension, chronic obstructive pulmonary disease (COPD), pulmonary fibrosis, asbestosis, pneumonitis, and other lung conditions. This also includes, but not limited to, patients requiring oxygen >30 days due to a primary pulmonary problem.

**Asthma:** Previously diagnosed condition characterized by bronchial responsiveness, prolonged expiratory phase and wheezing. **Diabetes:** Previously diagnosed and managed either with medication or diet.

Chronic renal insufficiency: A condition resulting in progressive and likely irreversible decreased renal function. This may be either from a primary renal problem (e.g., glomerulonephritis) or secondary (i.e., heart failure) and can be developmental or acquired. Diagnostic indicators include persistent abnormalities (>90 days) in BUN and Cr, urine concentration defects or production abnormalities, and/or abnormal imaging or biopsy results which predict insufficiency. This includes but is not limited to all patients receiving chronic renal replacement therapies (e.g., hemodialysis, peritoneal dialysis, etc.)

**Frailty:** Patients > 65 years of age with three or more of the following:

- a. Unintentional weight loss of 10 or more pounds in past year
- b. Self-reported exhaustion
- c. Weakness (grip strength)
- d. Slow walking speed
- e. Low physical activity

Reference: Linda P. Fried, Catherine M. Tangen, Jeremy Walston, Anne B. Newman, Calvin Hirsch, John Gottdiener, Teresa Seeman, Russell Tracy, Willem J. Kop, Gregory Burke, Mary Ann McBurnie, Frailty in Older Adults: Evidence for a Phenotype, The Journals of

Gerontology: Series A, Volume 56, Issue 3, 1 March 2001, Pages	
M146–M157, https://doi.org/10.1093/gerona/56.3.M146	
Obesity: Patients with a calculated Body Mass Index (BMI) > 30	
kg/m <sup>2</sup>	
Hypertension: Blood pressure 140/90 mm Hg or taking	
antihypertensive medications.	
Reference: Ong, K.L., Cheung, B.M.Y, Man, Y.B., Lau, C.P., & Lam,	
K.S.L. (2007). Prevalence, awareness, treatment and control of	
hypertension among United States adults 1999-2004.	
Hypertension, 49(1), 69-75. doi:	
https://doi.org/10.1161/01.HYP.0000252676.46043.18	

Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
SARS-CoV-2 Co-infection	This field collects information regarding concern the patient has another infection in addition to COVID.  Select Yes or No If Yes, check any that apply:  Bacterial pneumonia Co-viral infection Blood stream infection Urinary tract infection  Further define the infection as one of the following:  Culture confirmed	If Yes selected, then at least one must be selected	03/23/2020 present	COVID.CovidAddendum	Colnfection BacterialPneumonia CoViral BloodStream UrinaryTract  Lookup Culture confirmed – 1 Suspected – 2
	Confirmed with Reverse Transcriptase Polymerase chain reaction (RT PCR) Suspected				
SARS-CoV-2 Acute Co- diagnoses	This field collects any secondary diagnoses in addition to COVID.  Check any that apply:		03/23/2020 present	COVID.CoDiagnoses	Lookup table: COVID. CoDiagnosesCodes
	<ul> <li>ARDS: per Berlin Definition of ARDS:</li> <li>a. Timing: within 1 week of a known clinical insult or new or worsening respiratory symptoms,</li> <li>b. Chest Imaging: bilateral opacities not fully explained by effusions, lobar/lung collapse or nodules</li> </ul>				ARDS - 1 Septic Shock - 2 Heart Failure - 3 Pneumothorax - 4 Pneumonia - 5

c. Origin of edema: respiratory failure not fully explained	N	Myocarditis – 6
by cardiac failure or fluid overload (need objective	A	Acute Renal Failure
assessment such as echocardiography to exclude		- 7
hydrostatic edema if no risk factor is present		None of these – 8
d. Oxygenation:		volle of these o
$Mild$ : 200 mm Hg < PaO <sub>2</sub> /FiO <sub>2</sub> $\leq$ 300 mm Hg with		
PEEP or CPAP $\geq$ 5 cm H <sub>2</sub> 0		
Moderate: 100 mm Hg < PaO <sub>2</sub> /FiO <sub>2</sub> ≤ 200 mm Hg		
with PEEP ≥ 5 cm H <sub>2</sub> 0		
Severe: PaO <sub>2</sub> /FiO <sub>2</sub> ≤ 100 mm Hg with PEEP ≥ 5 cm		
H <sub>2</sub> O		
Reference: Rubenfeld G, Thompson T, Ferguson N, et al.		
Acute respiratory distress syndrome. The Berlin definition.		
JAMA 2012; 307(23): 2526-33.		
Pneumonia		
Septic shock: per Sepsis-3 International Consensus Criteria:		
Life threatening organ dysfunction caused by a dysregulated		
host response to clinical infection and where profound		
circulatory, cellular, and metabolic abnormalities exist. In the		
absence of hypovolemia, septic shock can be clinically		
identified by the presence of a vasopressor requirement		
required to maintain a mean arterial pressure of 65 mm Hg		
or greater and serum lactate level greater than 2 mmol/L		
(>18 mg/dL).		
Reference: Singer M, Deutschman CS, Seymour CW, et al. The		
Third International Consensus Definitions for Sepsis and		
Septic Shock (Sepsis-3). JAMA. 2016;315(8):801-810.		
Myocarditis		
iviyocui uitis		
Heart failure		
Acute renal failure related to current illness: AKI can be		
diagnosed if any one of the following is present:		
a. Increase in SCr by ≥0.3 mg/dl (≥26.5 µmol/l) within 48		
hours		
b. Increase in SCr to ≥1.5 times baseline, which has		
occurred within the prior 7 days		
c. Urine volume < 0.5 ml/kg/h for 6 hours		
5. 5 15.5		

Reference: Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. Kidney inter.		
Pneumothorax		

Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
SARS-CoV-2 Pre- intubation Respiratory Support	This field collects information on whether the patient received high flow or non-invasive ventilation <b>prior to intubation?</b> Select <b>Yes</b> or <b>No</b> If <b>Yes</b> , check all that apply:  BiPAP: Non-invasive ventilation where breathing support is delivered via two alternating levels of airway pressure CPAP: Non-invasive ventilation where breathing support is offered via a single continuous airway pressure  Heated high flow nasal cannula: Non-invasive breathing support provided by heated, humidified air and oxygen, generally allowing for tolerance of higher rates of flow	If Yes selected, then at least one must be selected	03/23/2020 present	COVID.CovidAddendum	PreIntRespSupp  BiPAP CPAP HeatedNasalCannula
SARS-CoV-2 Renal Replacement Therapy Required	This field collects information on whether the patient received renal replacement therapy while on ECLS (can be Peritoneal Dialysis (PD), Continuous Venovenous Hemodiafiltration (CVVHD), Continuous Venovenous Hemofiltration (CVVHF) or Continuous Venovenous Hemodiafiltration (CVVHDF) or Hemodialysis (HD) based on the patient's ultimate mode of therapy).  Select <b>Yes</b> or <b>No</b>		03/23/2020 present	COVID.CovidAddendum	RepTherapyRequired

Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
SARS-CoV-2 Immunomodulator and therapies	This field collects information about any immunomodulator that was started as treatment during the admission for COVID.  Select Yes or No If Yes, check all that apply:  Steroids: Systemic Glucocorticosteroids IVIG: Intravenous Immunoglobulin Selective cytokine blockade (Anakinra or Tocilizumab) JAK inhibition: Januse Kinase or JAK inhibitors belong to a family of medicine called DMARDs (disease-modifying antirheumatic drugs) and may include methotrexate, baricitinib (Olumiant), tofacitinib (Xeljanz), and upadacitinib (Rinvoq) Chloroquine/ Hydroxycholoquine Remdesivir Lopinavir/Ritonavir (Kaletra) Convalescent Plasma: transfusion with convalescent plasma containing SARS-CoV2 specific antibodies Aspirin	If Yes selected, then at least one must be selected	03/23/2020 – present  04/18/2020 – present Convalescent Plasma added 6/15/2020 – present Aspirin added	COVID.CovidAddendum COVID.ImmunomodulatorT herapies	CovidImmunomodulatorTherapies  Lookup Table: COVID.ImmunomodulatorTherapiesCodes Steroids: Systemic Glucocorticosteroids – 1 IVIG: Intravenous Immunoglobulin– 2 Selective cytokine blockade (Anakinra or Tocilizumab) – 3 Lopinavir/Ritonavir (Kaletra) – 4 JAK inhibition – 5 Chloroquine/Hydroxychloroquine – 6 Remdesivir – 7 Convalescent Plasma – 8 Aspirin – 9

Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
SARS-CoV-2 CRP day of intubation	This field collects a C-reactive protein level drawn within 24 hours of intubation (either pre or post). If multiple values are available, please select the one closest to intubation (pre or post).  If not drawn, please check not measured	Precision 1 decimal point US units of Entry Reference range 0.8 – 3.1 mg/L 0.0 – 0.6 mg/dL (multiply by 10 to get to mg/L)  Precision 1 decimal point International Units Reference range 0.76-28.5 nmol/L (divide by 9.524 to get to mg/L)	03/23/2020 present	COVID.CovidAddendum	CRPDayOfIntubation CRPDayOfIntubationNM
SARS-CoV-2 CRP pre-ECLS	This field collects a C-reactive protein level drawn within 24 hours pre-ECLS start. If multiple values are available, please select the one closest to and before ECLS start.  If not drawn, please check not measured	Precision 1 decimal point US units of Entry Reference range 0.8 – 3.1 mg/L 0.0 – 0.6 mg/dL (multiply by 10 to get to mg/L)  Precision 1 decimal point International Units Reference range 0.76-28.5 nmol/L (divide by 9.524 to get to mg/L)	03/23/2020 present	COVID.CovidAddendum	CRPPreEcmo

Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
SARS-CoV-2	This field collects a Procalcitonin	Precision 1 decimal	03/23/2020	COVID.CovidAddendum	CRPProcDayOfIntubation
Procalcitonin day of	level drawn within 24 hours of	point	present		CRPProcDayOfIntubationNM
intubation	intubation (either pre or post). If	US units of Entry			·
	multiple values are available, please	Soft Limit:			
	select the one closest to intubation	< 0.10 or > 10.0 ng/mL			
	(pre or post).				
		Precision 1 decimal			
	If not drawn, please check <b>not</b>	point			
	measured	International Units			
		Soft Limit:			
		< 0.10 or > 10.0 mcg/L			
SARS-CoV-2	This field collects a Procalcitonin	Precision 1 decimal	03/23/2020	COVID.CovidAddendum	CRPProcPreEcmo
Procalcitonin pre-	level drawn within 24 hours pre-	point	present		CRPProcPreEcmoNM
ECLS	ECLS start. If multiple results, please	US units of Entry			
	choose the one closest to and	Soft Limit:			
	before ECLS start.	< 0.10 or > 10.0 ng/mL			
	If not drawn, please check <b>not</b>	Precision 1 decimal			
	measured	point			
		International Units			
		Soft Limit:			
		< 0.10 or > 10.0 mcg/L			

Data Field	Definition/ Explanation/ Example	Data Entry Rules	Collection / Modification	Table Name	Column Name/ Stored Values
SARS-CoV-2 Pre-ECLS Anticoagulation	This field collects information about any anticoagulation that was prescribed after hospital admission before ECLS support  Select one of the following:  None: No additional anticoagulant agents added after hospitalization prior and prior to ECLS  Prophylactic Anticoagulation: anticoagulation agents prescribed without defined metrics of therapeutic effect  Targeted Treatment  Anticoagulation: anticoagulation agents prescribed with defined goals of therapeutic effect	If Prophylactic or Treatment selected, then at least one agent must be selected	06/15/2020 – present	COVID.Anticoagulation	CovidAnticoagulation  Lookup Table: COVID.AnticoagulationCodes Heparin=1, Low-Molecular-Weight Heparin =2, Direct Thrombin Inhibitor=3, Novel Oral Anticoagulants (NOAC) =4, Other=5
	If Prophylactic or Targeted Treatment Anticoagulation selected, check all that apply: Heparin (continuous infusion) Low-Molecular-Weight Heparin Direct Thrombin Inhibitor (bivalirudin, argatroban, etc.) Novel Oral Anticoagulants (NOAC) Other				