



Extracorporeal Life Support Organization (ELSO)

ELSO SARS-CoV-2 Addenda
04/03/2022

For all comments, questions and concerns please email
registrysupport@elso.org

ELSO SARS CoV-2 Addenda

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

This is a quick form, please complete the entire ELSO Registry Data form for the patient as soon 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) | <p>This field clarifies diagnostic testing performed on MIS-C patients</p> <p>Select all that apply:</p> <p>Active SARS-CoV-2 infection confirmed by PCR</p> <p>Prior SARS-CoV-2 infections confirmed by IgG / IgM serology testing</p> <p>MIS-C suspected without positive laboratory testing</p> | 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) | <p>This field collects information MIS-C organ involvement</p> <p>Select all that apply:</p> <p>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</p> <p>Renal</p> <p>Respiratory</p> <p>Hematological</p> <p>Gastrointestinal</p> <p>Dermatological</p> <p>Neurological</p> | 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, |

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| | | | | | Coronary artery ectasia or aneurysm=5 |
| SARS-CoV-2 Vaccination History | <p>This field collects information regarding vaccination history of the patient:</p> <p>Select the most appropriate choice:</p> <p>Yes: the patient has received at least one shot, then choose:</p> <p>Partial: the patient received at least one vaccination dose, but did not complete the full vaccination schedule</p> <p>Completed Series: the patient received a full vaccination course</p> <p>Booster: the patient received a booster shot</p> <p>No: the patient has not received any vaccination dose</p> <p>Unknown</p> | Only one choice may be selected | 04/01/2021 – present Question added 2/20/22 - present added to Yes drop down - Partial, Completed Series. Added Booster as an additional choice | COVID.VaccinationHistory COVID.CovidAddendum | Lookup table: Yes=0, No=1, Partial=2, Unknown=3 |

| Data Field | Definition/ Explanation/ Example | Data Entry Rules | Collection / Modification | Table Name | Column Name/ Stored Values |
|------------------------------|--|---|--|--|--|
| SARS-CoV-2 COVID Comorbidity | <p>This field collects any comorbidities existing prior to ECLS but during the same hospitalization as the ECLS run.</p> <p>Select Yes or No If Yes, select all that apply:</p> <p>Cancer: Broad term for any proliferative abnormal growth of cells. Previously diagnosed</p> <p>Pregnancy: Patient was pregnant at time of admission with COVID-19. If delivered prior to ECLS, still indicate pregnancy.</p> <p>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</p> | <p>If Yes selected, then at least one must be selected.</p> <p>Hard Limit If pregnancy selected, patient must not be < 9 or > 70 years of age</p> <p>Soft Limit: If pregnancy selected, patient age is usually not <</p> | <p>03/23/2020 – present</p> <p>04/19/2020 – present Hypertension added</p> <p>04/03/2022- Present pregnancy age limits added</p> | COVID.CovidAddendum COVID.Comorbidity | <p>CovidComorbidity</p> <p>Lookup Table: COVID.ComorbidityCodes</p> <p>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</p> |

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| | <p>e. Persons receiving systemic immunosuppressive therapy, including corticosteroids equivalent to 20 mg/day of prednisone for ≥2 weeks</p> <p>Chronic heart disease: Chronic Heart Failure is a condition in which the heart has consistently decreased function over a 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.</p> <p>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.</p> <p>Asthma: Previously diagnosed condition characterized by bronchial responsiveness, prolonged expiratory phase and wheezing.</p> <p>Diabetes: Previously diagnosed and managed either with medication or diet.</p> <p>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.)</p> <p>Frailty: Patients > 65 years of age with three or more of the following:</p> <ol style="list-style-type: none"> Unintentional weight loss of 10 or more pounds in past year Self-reported exhaustion Weakness (grip strength) | 14 or > 50 years of age | | | |
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| | <p>d. Slow walking speed e. Low physical activity</p> <p><i>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</i></p> <p>Obesity: Patients with a calculated Body Mass Index (BMI) > 30 kg/m²</p> <p>Hypertension: Blood pressure 140/90 mm Hg or taking antihypertensive medications.</p> <p><i>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</i></p> | | | | |
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| Data Field | Definition/ Explanation/ Example | Data Entry Rules | Collection / Modification | Table Name | Column Name/ Stored Values |
|-------------------------------|---|---|---------------------------|---------------------|---|
| SARS-CoV-2 Co-infection | <p>This field collects information regarding concern the patient has another infection in addition to COVID.</p> <p>Select Yes or No If Yes, check any that apply:</p> <p>Bacterial pneumonia Co-viral infection Blood stream infection Urinary tract infection</p> <p>Further define the infection as one of the following:</p> <p>Culture confirmed Confirmed with Reverse Transcriptase Polymerase chain reaction (RT PCR) Suspected</p> | If Yes selected, then at least one must be selected | 03/23/2020 -- present | COVID.CovidAddendum | CoInfection BacterialPneumonia CoViral BloodStream UrinaryTract Lookup Culture confirmed – 1 Suspected – 2 |
| SARS-CoV-2 Acute Co-diagnoses | <p>This field collects any secondary diagnoses in addition to COVID.</p> <p>Check any that apply:</p> | | 03/23/2020 -- present | COVID.CoDiagnoses | Lookup table: COVID. CoDiagnosesCodes |

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| | <p>ARDS: per Berlin Definition of ARDS:</p> <ol style="list-style-type: none"> a. Timing: within 1 week of a known clinical insult or new or worsening respiratory symptoms, b. Chest Imaging: bilateral opacities not fully explained by effusions, lobar/lung collapse or nodules c. Origin of edema: respiratory failure not fully explained by cardiac failure or fluid overload (need objective assessment such as echocardiography to exclude hydrostatic edema if no risk factor is present d. Oxygenation: <ul style="list-style-type: none"> <i>Mild:</i> 200 mm Hg < PaO₂/FiO₂ ≤ 300 mm Hg with PEEP or CPAP ≥ 5 cm H₂O <i>Moderate:</i> 100 mm Hg < PaO₂/FiO₂ ≤ 200 mm Hg with PEEP ≥ 5 cm H₂O <i>Severe:</i> PaO₂/FiO₂ ≤ 100 mm Hg with PEEP ≥ 5 cm H₂O <p><i>Reference: Rubenfeld G, Thompson T, Ferguson N, et al. Acute respiratory distress syndrome. The Berlin definition. JAMA 2012; 307(23): 2526-33.</i></p> <p>Pneumonia</p> <p>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).</p> <p><i>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.</i></p> <p>Myocarditis</p> <p>Heart failure</p> <p>Acute renal failure related to current illness: AKI can be diagnosed if any one of the following is present:</p> | | | | <p>ARDS – 1</p> <p>Septic Shock – 2</p> <p>Heart Failure – 3</p> <p>Pneumothorax – 4</p> <p>Pneumonia – 5</p> <p>Myocarditis – 6</p> <p>Acute Renal Failure – 7</p> <p>None of these – 8</p> |
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| | <p>a. Increase in SCr by ≥ 0.3 mg/dl (≥ 26.5 μmol/l) within 48 hours</p> <p>b. Increase in SCr to ≥ 1.5 times baseline, which has occurred within the prior 7 days</p> <p>c. Urine volume < 0.5 ml/kg/h for 6 hours</p> <p><i>Reference: Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. Kidney inter.</i></p> <p>Pneumothorax</p> | | | | |
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| Data Field | Definition/ Explanation/ Example | Data Entry Rules | Collection / Modification | Table Name | Column Name/ Stored Values |
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| SARS-CoV-2 Pre-intubation Respiratory Support | <p>This field collects information on whether the patient received high flow or non-invasive ventilation prior to intubation?</p> <p>Select Yes or No If Yes, check all that apply:</p> <p>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</p> | 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 | <p>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).</p> <p>Select Yes or No</p> | | 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 | <p>This field collects information about any immunomodulator that was started as treatment during the admission for COVID.</p> <p>Select Yes or No If Yes, check all that apply:</p> <p>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 (Olmiant), tofacitinib (Xeljanz), and upadacitinib (Rinvoq) Chloroquine/ Hydroxychloroquine Remdesivir Lopinavir/Ritonavir (Kaletra) Convalescent Plasma: transfusion with convalescent plasma containing SARS-CoV2 specific antibodies Aspirin</p> | If Yes selected, then at least one must be selected | <p>03/23/2020 – present</p> <p>04/18/2020 – present</p> <p>Convalescent Plasma added 6/15/2020 – present</p> <p>Aspirin added</p> | <p>COVID.CovidAddendum</p> <p>COVID.ImmunomodulatorTherapies</p> | <p>CovidImmunomodulatorTherapies</p> <p>Lookup Table: COVID.ImmunomodulatorTherapiesCodes</p> <p>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</p> |

| Data Field | Definition/ Explanation/ Example | Data Entry Rules | Collection / Modification | Table Name | Column Name/ Stored Values |
|----------------------------------|--|---|---------------------------|---------------------|--|
| SARS-CoV-2 CRP day of intubation | <p>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).</p> <p>If not drawn, please check not measured</p> | <p>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)</p> <p>Precision 1 decimal point International Units Reference range 0.76-28.5 nmol/L (divide by 9.524 to get to mg/L)</p> | 03/23/2020 -- present | COVID.CovidAddendum | CRPDayOfIntubation CRPDayOfIntubationNM |
| SARS-CoV-2 CRP pre-ECLS | <p>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.</p> <p>If not drawn, please check not measured</p> | <p>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)</p> <p>Precision 1 decimal point International Units Reference range 0.76-28.5 nmol/L (divide by 9.524 to get to mg/L)</p> | 03/23/2020 -- present | COVID.CovidAddendum | CRPPreEcmo CRPPreEcmoNM |

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

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