ELSO Registry Change Document

*Updated July 19, 2020*

**July 2020 Summary:**

July 2020 brings one important upgrade to the main ELSO Registry:

1. Addition of the new ECLS Mode Venopulmonary (VP) to describe ECLS characterized by respiratory support via a membrane lung combined with partial, or complete, right heart support.

Additionally, the SARS-CoV-2 Addenda was originally added to the Registry in March of 2020 and updated in June of 2020.

These upgrades have been motivated by the goals of increasing ELSO Registry data integrity and by our constant mission to provide the most current, applicable information to member centers.

We welcome any questions or feedback you may have at registrysupport@elso.org

Thank you for your continued partnership.
Addition of ECLS Mode Venopulmonary (VP)
July 19, 2020

Background:

Evolving cannulation strategies have brought an increased incidence of support characterized by respiratory support via membrane lung combined with partial, or complete, right heart support. ECMO support of this type has been facilitated by both central cannulation and by percutaneous cannulation via an increased utilization of the LivaNova Protek Duo™ cannula. More than 340 ECMO runs have been reported to the Registry utilizing the Protek Duo cannula.

Feedback from member centers highlights a lack of clarity within the ECMO community regarding appropriate designation of this type of support. Support of this nature is not neatly defined as being either venoarterial or venovenous due to the degree of right heart support, without bypass of either the pulmonary circulation or the left ventricle.

Process:

Preliminary discussion among the ELSO Registry Database Development Sub-Committee reached consensus that a new ECLS Mode should be considered. The proposed ECLS Mode addition and definition were circulated to a group of stakeholders from varying specialties within the pediatric and adult ECLS communities. Based upon the feedback received, the following ECLS Mode was proposed to the ELSO Executive Committee for addition to the Registry:

**VP: Venopulmonary** is the application of extracorporeal circulation for combined respiratory and right heart support in which the extracorporeal circuit drains blood from the venous system and reinfuses into the pulmonary artery. VP ECMO provides partial or complete bypass of the right heart but operates in series with the lungs.

The working group further agreed upon updating Registry nomenclature to be consistent with the latest published literature (1, 2)
EXTRACORPOREAL LIFE SUPPORT ORGANIZATION

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With thanks to the consultation group:

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References:

2020 ELSO SARS-CoV-2 Addenda
July 19, 2020

**COVID-19 Questions added March 2, 2020**
**Multisystem Inflammatory Syndrome in Children (MIS-C) Questions added June 15, 2020**

**Background:**

In response to the SARS-CoV-2 pandemic, the ELSO SARS-CoV-2 Addenda was added to the Registry March 2, 2020. A team of clinical experts developed a questionnaire that would inform clinicians about this unique and rapidly evolving patient population. Preliminary information from the SARS-CoV-2 is available by dashboard reporting at ELSO.org

**Process:**

The first version of the SARS-CoV-2 Addenda (originally entitled COVID-19 Addenda) included data elements designed to inform the ECLS community about the incidence and general characteristics of the ECMO supported SARS-CoV-2 patient.

Data elements included in the original COVID-19 Addenda:

1. **Comorbidity** (cancer, pregnancy, immunocompromised state, chronic heart disease, chronic lung disease, asthma, diabetes, chronic renal insufficiency, frailty, obesity or hypertension*)
2. **Co-Infection** (bacterial pneumonia, co-viral infection, blood stream infection or urinary tract infection)
3. **Acute Co-Diagnoses** (ARDS, pneumonia, septic shock, myocarditis, heart failure, acute renal failure or pneumothorax)
4. **Pre-intubation Respiratory Support** (BiPAP, CPAP or Heated High Flow Nasal Cannula)
5. **Requirement for Renal Replacement Therapy (RRT)** (Yes or No)
6. **Immunomodulators and Therapies** (Steroids, IVIG, selective cytokine blockade, JAK inhibitors, Chloroquine / Hydroxychloroquine, Remdesivir, Lopinavir / Ritonavir or convalescent plasma*)
7. **Laboratory Markers on Day of Intubation** (CRP and Procalcitonin)
8. **Laboratory Markers Pre-ECLS** (CRP and Procalcitonin)

* Hypertension as a Comorbidity and Convalescent Plasma as a Therapy were added 04/19/2020
With clinical evolution of the ECLS-supported SARS-CoV-2 patient, and with increased recognition of Multisystem Inflammatory Syndrome in Children (MIS-C), a few additional data elements were added to the original COVID-19 Addenda and the Addenda was renamed SARS-CoV-2 Addenda.

Data elements added to the renamed SARS-CoV-2 Addenda in June 2020 included:

1. **Identification of any Patient < 21 Years Old with Suspected MIS-C**
2. **Diagnostic Testing (only applicable for MIS-C patients)** (Active SARS-CoV-2 infection by PCR, prior SARS CoV-2 infection confirmed by IgG / IgM serology testing, or MIS-C suspicion without positive laboratory testing)
3. **Organ System Involvement (only applicable for MIS-C patients)** (cardiovascular*, renal respiratory, hematological, gastrointestinal, dermatological or neurological)
4. **Addition of Aspirin as a Therapy (all SARS-CoV-2 patients)**
5. **Pre-ECLS Anticoagulation (all SARS-CoV-2 patients)** (none, prophylactic anticoagulation# or targeted treatment anticoagulation)

*Cardiovascular organ involvement is further specified as (all that apply):
- Systolic ventricular dysfunction
- Hemodynamically significant arrhythmias
- Vasomotor dysfunction / vasoplegia
- Coronary artery ectasia or aneurysm.

# Prophylactic or therapeutic anticoagulation is further specified as (all that apply):
- Heparin (continuous infusion)
- Low-Molecular-Weight Heparin
- Direct Thrombin Inhibitor
- Novel Oral Anticoagulants (NOAC)
- Other

With thanks to the consultation group:

Peta Alexander (Boston, MA)
Katherine Cashen (Detroit, MI)
Ryan Coleman (Houston, TX)
Karen Fauman (Chicago, IL)
Matt Paden (Atlanta, GA)
2020 ELSO Registry ECPR Addenda
January 21, 2020

PROPOSED vs ORIGINAL ECPR ADDENDA
Peta Alexander, Ryan Barbaro, Ravi Thiagarajan

Development Process for Revised ECPR Addenda

As the Database Definitions project was approaching finalization, it was clear that the ECPR Addenda required updating and defining in an equivalent way. Representatives of the ELSO Registry Committees and experts in the field were convened to an ECPR Addenda Working Group. The new addenda were developed iteratively by small group teleconferences and wider group survey at multiple stages between February 2018 and January 2019. The process included audit of the existing ECPR Addenda for relevance, and rebuilding in line with current clinical practice and best available evidence. As the document was being finalized, targeted expert opinion was sought to optimize elements (with thanks to Dr Frank Moler, Professor of Pediatrics, Michigan Medicine, University of Michigan and Dr Monika Kleinman, Associate Professor of Anesthesia, Harvard Medical School). The current document (Proposed ECPR Addenda 7 January 2019.xls) is the result of the consultative process and is our recommendation for inclusion into the ELSO Registry to replace the current ECPR Addenda.

Data elements were grouped by Pre-Cardiac Arrest, Cardiac Arrest, Management of the Cardiac Arrest (‘Code’), Circulation, Cannulation and Circuit Details and Post ECPR Management. Elements were classified as Mandatory or Non-Mandatory in keeping with the style of the revised ELSO Registry Database Definitions, but it should be noted that the entire ECPR Addenda represents a non-core dataset within the Registry (ie the addenda itself is non-mandatory, but if it is to be completed, there are fields within it which are core/mandatory elements). In addition, some elements of the ELSO Registry with particular relevance to ECPR are included in the document for illustration only. These will not be recollected in the ECPR Addenda.

In addition to a more global focus including adult ECPR care, one of the important changes to the ECPR Addenda is determining whether a cardiac or non-cardiac pathology precipitated the cardiac arrest. There are a couple of outstanding issues:
1. We have included some Process Quality Metrics in the ECPR Addenda (+/- for migration to ELSO main Registry)

2. This development process identified at least 1 additional cluster of data points which are relevant to the entire ELSO Registry, rather than just the ECPR Addenda – we suggest that these should be considered for inclusion in the main Registry.

3. If elements of the ECPR Addenda can be meaningfully incorporated into a predictive model for outcome of in-hospital mortality, then we propose that these elements should be migrated into the ELSO (main) Registry as MANDATORY fields. The rest of the ECPR Addenda should remain as an optional form for completion for relevant patients.

Process Metrics for Consideration

We propose inclusion of some features related to Quality of CPR – for example, end-tidal CO2, the use of CPR feedback device and collection of NIRS if it is utilized during CPR.

The working group suggested collecting data on the neurological investigations used by centers in the first 24-hours after ECPR. These would serve to identify a ‘denominator’ for analyses of neurological injury. An example of potential process is included in Figure 1. Further discussion re: location of these fields in ECPR Addenda alone, or more relevant to the ELSO Registry may be warranted.

FIGURE 1
In addition, it is established that team dynamics are an important component of ECPR success. We have included a field requesting information about inter-disciplinary team debriefing associated with the ECPR events reported to the registry (Figure 2).

FIGURE 2

Monthly review of CPR cases has been associated with improved survival post CPR. Choose YES for this field if your inter-disciplinary team discussed the resuscitation event and ECPR process in the period following ECPR (Chan PS, JAMA Cardiology 2016). IF YES - did this occur within 24 hours? If >24 hours, did this occur within 1 month; if >1 month, did this occur within 3 months.
**Data Points for Main Registry Consideration**

There was meaningful interest from the working group to include medications which impact bleeding and clotting. Our suggested strategy for inclusion is shown in Figure 3. We would advocate that if these datapoints are included, it should be as additional ELSO Registry elements, rather than as part of the ECPR Addenda.

**FIGURE 3**

In addition, the working group noted that some estimate of neurological outcome has increasingly been incorporated into reported clinical outcomes of studies. While especially relevant for patients undergoing ECPR, some assessment of neurological outcome could be incorporated into the ELSO Registry (Figure 4).

**FIGURE 4**
**E-CPR Prediction Modelling**

This project out of the ECPR Addenda working group, has been approved to proceed and we will anticipate sharing results in 2019.

### DIRECT COMPARISON PROPOSED vs PRIOR ECPR ADDENDA

<table>
<thead>
<tr>
<th>ELEMENT</th>
<th>PRIOR</th>
<th>PROPOSED</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRE-ECPR</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precipitating Event</td>
<td>Not an element of the Addenda</td>
<td>Cardiac vs Non-cardiac</td>
</tr>
<tr>
<td>Antecedent Event</td>
<td>Choose from menu of conditions in the 4 hours prior to ECPR</td>
<td></td>
</tr>
<tr>
<td>Comorbid Conditions</td>
<td>Choose from menu of conditions present in the 24 hours before</td>
<td></td>
</tr>
<tr>
<td>Pre-existing Interventions</td>
<td>Collected as part of ELSO Registry</td>
<td>No change</td>
</tr>
<tr>
<td><strong>CARDIAC ARREST</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Witnessed event and time</td>
<td>Question in Preliminary Information</td>
<td>Question in CARDIAC ARREST With follow-on question for time etc</td>
</tr>
<tr>
<td>Location of arrest</td>
<td>Separate request for time of CODE Options included only inpatient, mainly pediatric settings</td>
<td>Choose from locations which also include outpatient and adult alternatives</td>
</tr>
<tr>
<td>Outpatient specific questions</td>
<td>Not previously an element</td>
<td>Triggered if outpatient setting listed</td>
</tr>
<tr>
<td>CODE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Time CPR commenced</td>
<td>Collected in CODE table</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Total CPR time to ECMO flow</td>
<td>Collected in CODE table</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Multiple CPR in 24 hours?</td>
<td>Collected in CIRCULATION</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Pulse at time of cannulation</td>
<td>Collected in CODE table</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Compression method</td>
<td>In PRELIMINARY INFORMATION</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Initial documented rhythm</td>
<td>In PRELIMINARY INFORMATION</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Cardioversion or defibrillation</td>
<td>Not previously an element</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Rhythm at cannulation</td>
<td>Collected in MEDICATIONS</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Medications administered</td>
<td>Not previously an element</td>
<td>Question in CODE</td>
</tr>
<tr>
<td>Other interventions during CPR</td>
<td>Not previously an element</td>
<td>Question in CODE targeting pacing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIRCULATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPR quality – ETCO2</td>
<td>Not previously an element</td>
<td>Question in CIRCULATION</td>
</tr>
<tr>
<td>CPR quality – Arterial BP</td>
<td>Collected Best/Worse + SBP/MBP</td>
<td>DBP prior to ECMO only</td>
</tr>
<tr>
<td>CPR quality – feedback device</td>
<td>Not previously an element</td>
<td>Question in CIRCULATION</td>
</tr>
<tr>
<td>CPR quality – NIRS</td>
<td>Not previously an element</td>
<td>Question in CIRCULATION</td>
</tr>
<tr>
<td>CPR quality – signs of life</td>
<td>Not previously an element</td>
<td>Question in CIRCULATION</td>
</tr>
<tr>
<td>CANNULATION AND CIRCUIT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cannulation location</td>
<td>In PRELIMINARY INFORMATION</td>
<td>In CANNULATION AND CIRCUIT</td>
</tr>
<tr>
<td>Circuit pre-primed</td>
<td>In PRELIMINARY INFORMATION</td>
<td>In CANNULATION AND CIRCUIT</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Priming solution</td>
<td>In PRIME</td>
<td>In CANNULATION AND CIRCUIT</td>
</tr>
<tr>
<td><strong>POST-ECPRE CARE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>Not previously an element</td>
<td>LV decompression question</td>
</tr>
<tr>
<td>Neurology</td>
<td>Not previously an element</td>
<td>EEG and Imaging questions</td>
</tr>
<tr>
<td>Temperature management</td>
<td>Extensive questions about exact temperature management</td>
<td>Question re: intent of therapeutic strategy</td>
</tr>
<tr>
<td>Temperature achieved</td>
<td>Extensive questions about exact temperature management</td>
<td>Question re: max temp</td>
</tr>
<tr>
<td>Blood gas – first within 4 hours</td>
<td>Previously an element of the main registry</td>
<td>Question in POST-ECPRE CARE</td>
</tr>
</tbody>
</table>

**REMOVED ELEMENTS**

- Exact code times and timing of CPR during a multi-rhythm code
- Exact time of ROSC – we just ask for total CPR
- Best/worst pH and BPs during CPR
- Volume management
  - First temperature
  - Hours <32 degrees
  - Hours 32-34 degrees
  - Hours 34-35 degrees
  - Hours 35-36 degrees
  - Hours over 36 degrees
**Type of cooling system used**

Heparin Bolus
With thanks to the ECPR Addenda Working Group

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Equipment and Cannula Data Entry Upgrade
January 21, 2020

Background:
Continued evolution in ECLS support necessitates upgrades to the ELSO Registry involving the ability to report equipment and cannula usage. Currently, the Registry asks for starting equipment and cannulas at the onset of an ECLS run and allows for the reporting of equipment exchanges or changes to cannulation strategies only with subsequent ECLS runs or modes. To date, reporting changes in cannulation strategy within the same ECLS mode (for example, change from thoracic to neck cannulation during the same V-A run) or equipment exchanges during a single ECLS run and mode has been limited by these restrictions.

When implementing any upgrade to Registry data entry, ELSO prioritizes improved flexibility in reporting options while not increasing the burden of data entry for the majority of unaffected ECLS runs. Upgrades to the Mode and Equipment tab (now Modes and Cannulations) and the addition of an Equipment tab adds functionality in the following ways:

- Allows for the removal or addition of cannulas with date stamps in event of a change in cannulation strategy
- Allows for the exchange or addition of blood pumps or oxygenators within a single ECLS run and mode
- Allows for the entry of simultaneous use of more than one piece of equipment within a single category (i.e. simultaneous utilization of more than one blood pump or oxygenator)
- Identifies reasons for changes in equipment or cannulation strategy

Additional information and guidance can be found below or on pages 80-94 of the ELSO Registry Database Definitions document, pages 3 and 4 of the ELSO ECLS Registry Form or the ELSO Registry 2020 Instructions document.

**EQUIPMENT AND CANNULA DATA ENTRY UPGRADE**

**DIRECT COMPARISON**

**PRIOR VS. FOLLOWING UPGRADE**

**Modes & Cannulations:**

**ECLS Mode:**

*ECLS Mode Data Entry Location Prior to Upgrade:* Mode and Equipment tab
ECLS Mode Data Entry Location After Upgrade: Modes & Cannulations tab

ECLS Mode Data Entry: No change to ECLS Mode data entry within appropriate tab

EXTRACORPOREAL LIFE SUPPORT ORGANIZATION

Phone: (734) 998-6600
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ECLS Cannulations:

New Cannula Addition Location Prior to Upgrade: Mode and Equipment tab (see above)
New Cannula Addition Location After Upgrade: Modes & Cannulations tab (see above)

New Cannula Data Entry Comparison of Prior vs. After Upgrade:

- Add a new cannula in the same way as prior:

  ECLS Mode: V-V
  Add New Cannula

- Prior to upgrade, no opportunity existed to clarify a start or end time for specific cannula use. Prior to upgrade, within a single mode of ECLS, data was not collected regarding time of cannula addition nor identification of cannula exchange or removal:

- Following upgrade, if cannula(s) are in place for the entire ECLS mode, check the box confirming that the start and end times for that cannula are the same as the time on and time off ECLS:

- Following upgrade, once a cannula has been entered, your center will have the opportunity to replace the cannula (for example with a change in cannulation strategy from thoracic cannulation to neck cannulation).
Following upgrade, if you choose to replace a cannula, you will be required to supply a reason for replacement:

Following upgrade, if you add or remove a cannula, you will be given the opportunity to enter start and end times for cannula use if different from start and end times for ECLS support for that run:
The end time of the old device is the same as the start time for the new device:

☐

The start time and end time of the new device is the same as the time on and time off of the run:

☐

**New Device Start Time:**

Month / Day / Year

Hour : Minute

**New Device Start Time is required**

**New Device End Time:**

Month / Day / Year

Hour : Minute
**Equipment**:

**Equipment Data Entry Location:**

*Equipment Data Entry Location Prior to Upgrade: Mode and Equipment tab*

<table>
<thead>
<tr>
<th>Mode and Equipment</th>
<th>Diagnoses</th>
<th>Procedures</th>
<th>Complications</th>
<th>Infections</th>
<th>Outcome</th>
<th>Addenda</th>
<th>Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run Info</td>
<td>Pre ECLS Assessment</td>
<td>Pre ECLS Support</td>
<td>ECLS Assessment</td>
<td>Mode and Equipment</td>
<td>Diagnoses</td>
<td>Procedures</td>
<td>Complications</td>
</tr>
</tbody>
</table>

*Equipment Data Entry Location After Upgrade: Equipment tab*

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Diagnoses</th>
<th>Procedures</th>
<th>Complications</th>
<th>Infections</th>
<th>Outcome</th>
<th>Addenda</th>
<th>Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registry</td>
<td>Pre ECLS Assessment</td>
<td>Pre ECLS Support</td>
<td>ECLS Assessment</td>
<td>Equipment</td>
<td>Diagnoses</td>
<td>Procedures</td>
<td>Complications</td>
</tr>
</tbody>
</table>

**Equipment Replacements or Additions:**

- **Prior to upgrade**, your center only had opportunity to enter a single equipment option for each type of equipment (i.e. membrane lung, blood pump, heat exchanger, hemofilter or temperature regulation) per ECLS mode:

  ![Membrane Lung](image)

  - Manufacturer: [Select]
  - Device: [Select]
  - Center Specific Device: [Select]

- **Following upgrade**, your center will have opportunity to either replace or add an additional membrane lung or blood pump:

  ![Membrane Lung](image)

  - Manufacturer: [Select]
  - Device: [Select]

  - This Membrane Lung was replaced during this Run
  - Another Membrane Lung was added during this Run

- **Following upgrade**, if you **replace a membrane lung**, your center will have opportunity to identify replacement with the same device or a new device, and enter appropriate start and end times of use for that device:
• **Following upgrade**, if you identify replacement of a **membrane lung**, you will be required to identify a **primary** reason for device replacement from a list of reasons specific to membrane lung replacement:

- Please add the new equipment below that replaced the Membrane Lung

<table>
<thead>
<tr>
<th>Center Specific Device:</th>
<th>Device</th>
<th>Device Replacement Reason:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Please Select -</td>
<td>- Please Select -</td>
<td>- Please Select -</td>
</tr>
<tr>
<td>Manufacturer:</td>
<td>Device is required</td>
<td></td>
</tr>
</tbody>
</table>

When did this Membrane Lung replace previous Membrane Lung

- New Device Start Time:
  - Month / Day / Year Hour : Minute
  - New Device Start Time is required
  - New Device End Time:

<table>
<thead>
<tr>
<th>Device Replacement Reason:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Please Select - Structural integrity</td>
</tr>
<tr>
<td>Decreased efficiency of gas exchange</td>
</tr>
<tr>
<td>Acute obstruction to blood flow</td>
</tr>
<tr>
<td>Increasing resistance to blood flow</td>
</tr>
<tr>
<td>Thrombosis / coagulopathy</td>
</tr>
<tr>
<td>Hypothermia</td>
</tr>
<tr>
<td>Equipment longevity / center protocol</td>
</tr>
<tr>
<td>Entire circuit replaced due to indicated component(s) change</td>
</tr>
<tr>
<td>Entire circuit replaced following temporary transition to bypass</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

• **Following upgrade**, if you identify replacement of a **blood pump**, you will be required to identify a **primary** reason for device replacement from a list of reasons specific to blood pump replacement:
Following upgrade, if you identify addition of a membrane lung or blood pump your center will have opportunity to identify replacement with the same device or a new device, and enter appropriate start and end times of use for that device:
With thanks for input from the following ELSO Technologies Committee members:

Jonathan Haft (Ann Arbor, MI)
Tim Maul (Orlando, FL)
John Toomasian (Ann Arbor, MI)
Allison Weinberg (Ann Arbor, MI)
Miscellaneous January 2020 Registry Updates

January 21, 2020

Infectious Organisms Added:

1. Herpes Virus 6, Organism ID: 224, Viruses and prions
2. Parvo Virus B19, Organism ID: 225, Viruses and prions
3. Mycobacterium chimera, Organism ID: 226, Mycobacterium