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4 **Pre-print version**

5 **ECMO Simulation-Based Training: Methods,**
6 **Drawbacks, and a Novel Solution**

7
8 **Abstract**

9 **Introduction:** Patients under the error-prone and complication-burdened
10 extracorporeal membrane oxygenation (ECMO) are looked after by a highly-
11 trained, multidisciplinary team. Simulation-based training (SBT) affords ECMO
12 centers the opportunity to equip practitioners with the technical dexterity
13 required to manage emergencies. The aim of this article is to review ECMO
14 SBT activities and technology and suggest a novel solution to current
15 challenges.

16 **ECMO Simulation:** The commonly-used simulation approach is easy-to-build as it
17 requires a functioning ECMO machine and an altered circuit. Complications are
18 simulated through manual circuit manipulations. However, scenario diversity is
19 limited and often lacks physiological and/or mechanical authenticity. It is also
20 expensive to continuously operate due to the consumability of highly-
21 specialized equipment.

22 **Technological Aid:** Commercial extensions can be added to enable remote control
23 and automate circuit manipulation but do not improve on the realism or cost
24 effectiveness.

25 **A Modular ECMO Simulator:** To address those drawbacks, we are developing a
26 standalone modular ECMO simulator that employs affordable technology for
27 high-fidelity simulation.

28

29 **Keywords**

30 ECMO, ECLS, medical simulation, medical training, simulation technology.

31

32 **Introduction**

33 Advances in the technology and increasing evidence of the efficacy of
34 extracorporeal membrane oxygenation (ECMO) has skyrocketed its worldwide
35 adoption.¹ ECMO is an intensive care procedure that supports patients'
36 cardiopulmonary functions during their recovery.² There are two basic ECMO
37 configurations: veno-arterial (VA), and veno-venous (VV). VA ECMO supports both
38 cardiac and respiratory functions, where high pressure oxygenated blood is
39 returned to the arterial system for systemic circulation.² VV ECMO provides partial
40 or complete respiratory support, blood is pumped back to the venous system to be
41 circulated through the body via the heart.² Also, an advanced configuration, veno-
42 venous-arterial (VVA), is established by a second cannula for venous blood
43 drainage.³ Patient's vital dependence on the machine makes its uninterrupted and
44 smooth operation of utmost importance.⁴ Unfortunately, the technique is prone to
45 mechanical and patient-related complications that can occur suddenly, have
46 catastrophic consequences, and call for an immediate and quick intervention of a
47 multidisciplinary nature.^{5,6} To provide quality clinical care to ECMO patients, ECMO
48 specialists are expected to master specialized clinical and technical skills, be able

49 to identify problems and intervene quickly, communicate effectively, and develop
50 the confidence necessary to rapidly manage emergencies that may arise.^{7,8}

51 Highly trained and cohesive multidisciplinary teams are generally a by-
52 product of strong theoretical understanding coupled with the experience of
53 interacting with patients and dealing with critical situations.^{9,10} However, ECMO is
54 error-prone, sparsely used, and is **can be** associated with severe complications¹¹.
55 This makes it unlikely for specialists to encounter all types of ECMO emergencies
56 more than once during their career as an ECMO specialist and become proficient
57 at dealing with them solely from real clinical experience.¹²⁻¹⁴ This is especially
58 problematic in low-volume ECMO centers, which have been shown to have higher
59 rates of patient mortality.¹⁵ It can even be difficult for experienced ECMO team
60 members to retain their technical dexterity the less they are exposed to challenging
61 ECMO complications.¹⁶

62 To satisfy the incompatible needs of quality clinical care and of training
63 novice practitioners, educators employ simulation-based training (SBT) to
64 supplement or replace real medical experiences with intensified and immersive
65 simulation-based activities.¹⁷ SBT offers a safe environment where teams and
66 individuals can rapidly understand ECMO-patient interactions, instill technical skills,

67 communicate with members of different clinical professions, and develop crisis
68 resource management skills expected of ECMO practitioners.^{18,19} For instance, a
69 study on junior-level baccalaureate nursing students showed that employing SBT
70 in the curriculum leads to improved skills performance²⁰. For ECMO centers, SBT
71 provides an opportunity to objectively evaluate the performance of clinicians under
72 stress and time pressure, test their readiness for rare complications, and develop
73 improved problem-solving procedures and emergency codes without interfering
74 with the quality of patient care.^{21,22}

75 The majority of ECMO centers affiliated with the extracorporeal life support
76 organization (ELSO) in the United States have an active or are developing a
77 mannequin-based ECMO simulation program.¹³ As the adoption of ECMO grows
78 internationally, so is the incorporation of ECMO SBT. Although still in its infancy,
79 there is a need to identify the best practices of ECMO SBT while keeping costs in
80 check. This article reviews the methods and technologies used to simulate ECMO
81 emergency scenarios and examine the degree of realism, cost-effectiveness, and
82 sustainability they offer to ECMO specialists and teams. We also introduce our
83 solution to ECMO simulation and how it addresses the drawbacks identified in
84 literature. The literature review was performed using an exhaustive screening

85 process of over forty publications on ECMO, SBT, and ECMO SBT using the
86 PubMed database and Google Scholar.

87

88 **ECMO Complications**

89 By studying ECMO complications, their symptoms, and the corresponding required
90 interventions, we emphasize the necessity for ECMO SBT and highlight simulator
91 features that should be ideally present.

92 Usually unpredictable, ECMO complications can be circuit or patient related
93 and their indications come in the form of visual, auditory, or haptic cues. Life-
94 threatening events related to the circuit are oxygenator failure, pump failure, circuit
95 blood clots, air embolism, and cannula issues.^{11,12,23} On the other hand,
96 pathological and cannulation site bleeding are the most common patient-related
97 complications.²⁴ A systematic review of 1,042 adults treated with VV ECMO reports
98 that complications occurred in 25 – 56% of cases and links them with up to 11% of
99 patient mortality.²⁵ Similar complication rates can be observed in different age
100 groups and pathologies, and in special cases such as ECMO patient

101 transportation.^{6,26,27} A compiled summary of cues, corresponding complications,
 102 and possible interventions are presented in Table 1.

103

104 Table 1: Summary of common ECMO cues and their corresponding complications
 105 and interventions.^{12,23,24,27-29}

| Cues | Complications | Interventions |
|---|---|--|
| Low arterial oxygen saturation (SaO ₂) | <ul style="list-style-type: none"> • Inadequate circuit flow • Increased oxygen consumption (VV) - patient • Declining lung function (VV) - • Upper body hypoxia (VA) | <ul style="list-style-type: none"> • Adjust circuit flow • Diagnose/treat underlying causes • Sedate/cool the patient • Switch to VV or VVA ECMO |
| Low drainage limb oxygen saturation | <ul style="list-style-type: none"> • Inadequate circuit flow • Increased oxygen consumption • Increased cardiac output | <ul style="list-style-type: none"> • Adjust circuit flow • Diagnose/treat underlying causes • Sedate/cool the patient |
| High drainage limb oxygen saturation | <ul style="list-style-type: none"> • Recirculation (VV) | <ul style="list-style-type: none"> • Confirm and adjust cannula position • Change cannula type • Perform echocardiogram • Adjust pump flow • Administer fluids • Change to VA ECMO |
| Loss of circuit flow | <ul style="list-style-type: none"> • Pump failure • Circuit airlock • Circuit blood clots • Obstruction in the blood path | <ul style="list-style-type: none"> • Perform CPR with chest compression • Use manual handcrank and replace pump • De-air the circuit • Replace the circuit • Check tubes for kinks |
| Fall in tidal volume and/or a deteriorating chest radiography | <ul style="list-style-type: none"> • Declining lung function • Inflammatory response to ECMO | <ul style="list-style-type: none"> • Increase circuit flow • Restrict fluids and wait for improvements |

| | | |
|---|---|---|
| | <ul style="list-style-type: none"> • Infection • Left ventricular distention (VA) | <ul style="list-style-type: none"> • Diagnose/treat infection • Decompress/vent the left ventricular |
| Low return limb oxygen saturation and no blood color difference between circuit limbs | <ul style="list-style-type: none"> • Disconnected gas supply • Oxygenator capabilities exceeded • Oxygenator failure | <ul style="list-style-type: none"> • Perform CPR with chest compression • Check connections • Add another oxygenator in parallel • Replace oxygenator |
| Low circuit flow, high negative drainage limb pressure, shattering of drainage limb and/or hypotension | <ul style="list-style-type: none"> • Obstruction of the drainage cannula due to position or blood clots • Hypovolemia • Tamponade (VV) • Pneumothorax | <ul style="list-style-type: none"> • Address cannula issues • Check blood volume/administer fluids • Perform pericardiocentesis or pericardial window • Insert thoracostomy or drain tube • Use needle decompression |
| Low circuit flow, high plasma in blood, change in pump sound, visible dark/white spots in pump head/oxygenator/circuit tubes, and/or increasing pressure difference across oxygenator | <ul style="list-style-type: none"> • Blood clots in the circuit | <ul style="list-style-type: none"> • Increase anticoagulation • Change pump/oxygenator or the entire circuit |

106

107 As mentioned earlier, troubleshooting ECMO complications demands well-

108 coordinated teamwork. During SBT activities, an emergency scenario often begins

109 after the bedside clinician notices a particular cue, identifies the potential

110 complication, and calls for help. The interprofessional ECMO team then splits roles

111 between patient stabilization and circuit management. Practitioners responsible for

112 stabilizing the patient are tasked with initiating ventilator support, controlling patient

113 temperature, administering drugs or fluids, adjusting patient position (e.g. the
114 Trendelenburg position), etc. In parallel, other team members are addressing the
115 underlying cause of the complication, which sometimes entails a procedurally
116 complex circuit change or circuit de-airing.²³ Those procedures require all team
117 members to agree on the sequence of events to mitigate errors and optimize for
118 procedural speed.²⁴ If the patient is completely dependent on extracorporeal
119 support, the team have to restore ECMO support within minutes.⁶ In addition to
120 time pressure, the multi-person nature of ECMO interventions coupled with the
121 generally limited space makes performing optimally quite challenging.^{7,30,31} This is
122 not limited to ECMO emergencies, but also includes situations where ECMO is
123 deployed on the spot such as in extracorporeal cardiopulmonary resuscitation
124 (ECPR),³² rewarming of severe or accidental hypothermia,^{33,34} or maintaining
125 organs alive for donation after circulatory death.^{35,36}

126

127 **ECMO Simulation**

128 Thankfully, SBT offers a safe venue to practice those complex interventions. In fact
129 they have been shown to improve participants' knowledge,¹⁶ confidence,³⁷
130 behavioral skills,³¹ and technical dexterity.^{19,38} To simulate ECMO emergencies
131 with high-fidelity, SBT must take place in-situ or in an environment that resembles
132 an intensive care unit (ICU) or an emergency room. This environment should have
133 all the equipment used in real-world ECMO cases. Ideally, an ECMO simulator
134 should be able to present learners with realistic hydraulics (pressures, flow rates,
135 and pump speeds) and blood parameters (oxygen saturations, hemoglobin levels,
136 hematocrit, blood temperature, etc.) typically displayed on the ECMO machine
137 console or inline monitors. To simulate complications, the simulator should be able
138 to generate realistic visual, auditory, and/or haptic cues (e.g. pressure changes
139 corresponding to a failing pump or a deoxygenated blood color due to an
140 oxygenator failure.) Lastly, interactivity is essential to allow learners to diagnose by
141 themselves the problem and perform troubleshooting actions accordingly.

142 Still being in its infancy, ECMO SBT offers a sparse collection of full-fledged
143 simulators. To this day, many teams simulate ECMO using an approach
144 reminiscent of Anderson *et al.* Developed over a decade ago, Anderson et al.'s
145 approach does not require any specialized tools and can be constructed using
146 readily available medical equipment (ECMO machines and circuits, cannula, tube,
147 saline bags, bladders, etc.).^{39,40}

148 Anderson and her colleagues set up their ECMO SBT in a simulation room
149 equipped with functioning ventilators and a radiant warmer, an ECMO code cart, a
150 functional ECMO circuit, and a low-fidelity neonatal mannequin.³⁹ The ECMO
151 circuit consisted of a roller pump, oxygenator, heat exchanger, and a bladder box
152 interconnected using a ¼" Tygon tubes filled with food-colored saline to simulate
153 blood.³⁹ "Blood" circulation was achieved by connecting the venous and arterial
154 cannula, inserted into the mannequin's neck using a tee-connector.³⁹ To increase
155 realism, a balloon was connected to the mannequin's trachea in its chest cavity to
156 simulate lung compliance and an infusion pump was used to simulate fluid delivery
157 to the patient.³⁹ Patient's physiological parameters were displayed on a remotely-
158 controlled bedside monitor and pulse oximeter.³⁹ Complications were simulated by
159 manual manipulations of the circuit and changes to the parameters on the patient

160 monitor. For example, hypovolemia is simulated by withdrawing fluid from the
161 circuit and lowering the blood pressure, and similarly, air embolism is simulated by
162 injection of air into the circuit.³⁹

163 Anderson et al.'s ECMO simulation approach quickly gained in popularity
164 and was gradually adapted by other teams. A common alteration is to complement
165 the ECMO circuit loop with a reservoir (typically a saline bag or a bladder) inside
166 the mannequin's abdominal cavity connected to a syringe. In cases where the
167 mannequin cannot be modified, drilled, or is vulnerable to water damage (e.g. due
168 to electronic components inside the mannequin), the ECMO circuit is connected
169 directly to the reservoir (without cannula) and placed away from mannequin.⁴¹
170 Figure 1 shows a modern ECMO simulation setup. It is currently used with modern
171 centrifugal pump based ECMO circuits such as Maquet Rotaflow pump, Maquet
172 CardioHelp system, Thoratec's CentriMag, and a plethora of basic to advanced
173 mannequins such as the Laerdal's ResuciJunior, SimMan, SimBaby, and Nursing
174 Kelly, CAE's PediaSim, and Gaumard's Hal 3201.^{5,38,41-44}

175

176 [insert Figure 1]

177 Figure 1: A Modern ECMO simulation setup.⁴²

178

179 Manual circuit manipulations are used to generate complications' cues, of
180 which the most basic form is the withdrawal and addition of fluid, or the injection of
181 air. Withdrawing liquid from the circuit, for example, causes the inlet pressure to
182 become more negative and reduces the flow rate regardless of the pump speed.
183 Correspondingly, this triggers the ECMO console's pressure and flow rate alarm,
184 and with the help of the remotely controlled patient monitor, hypovolemia and
185 tamponade can be simulated. Different ECMO centers improvise new circuit
186 manipulations or topologies to create new scenarios or enhance existing scenarios
187 for higher fidelity. For example, from our experience at **Hamad Medical Corporation**
188 **(HMC)**, blood clots in the membrane are simulated by injecting finely shredded
189 animal liver parts into the venous line. Subsequently, this puree gets stuck in the
190 membrane causing the trans-membrane pressure to rise and giving appearance of
191 a dark clots on the membrane. Royal Brompton Hospital simulation team
192 developed a novel circuit topology to simulate open chest cardiac tamponade.¹⁹
193 Attached to a neonatal mannequin's chest is a saline bag (the circuit's reservoir)
194 with a silicone tube loosely wrapped around its center and another saline bag
195 connected to a syringe on top (Figure 2).¹⁹ Both bags are covered with a sheet of

196 mannequin skin with a silicone rubber membrane-window in the middle. During the
197 simulation, the top saline bag is filled with red colored liquid to compress the
198 silicone tube and restrict venous outflow the circuit flow and pressures to drop.
199 The filled saline bag also bulges out of the silicone rubber window, simulating open
200 chest bleeding.¹⁹ Table 2 presents common methods used to simulate ECMO
201 emergency scenarios.

202

203 [insert Figure 2]

204 Figure 2: Royal Brompton Hospital open chest cardiac tamponade simulation
205 method.¹⁹

206

207 Unfortunately, in many scenarios the displayed circuit and blood parameters
208 and simulated complication cues are not realistic in relation to the enacted
209 scenario. As ECMO circuits migrated from roller to centrifugal pumps, ECMO
210 simulation lost its ability to set realistic circuit pressures—prior to the start of the
211 session—using the pump occlusion. Circuit manipulations that affect the circuit
212 (e.g. fluid volume) do not necessarily simulate authentic abnormal pressure values
213 but induce values that are high or low enough to trigger the ECMO console alarm.

214 Moreover, in the case of oxygenator failure, the pressure changes produced (rise
215 in pre- and post-membrane pressures) do not reflect the realistic cue (rise in trans-
216 membrane pressure) of the complication. Other parameters are generally
217 uncontrollable remotely or via circuit manipulations, for example, pump speed and
218 sweep gas flow rate have to be manipulated discretely by a confederate nurse and
219 blood parameters (e.g. blood gases, hematocrit, hemoglobin, and activated clotting
220 time (ACT)) on modern ECMO consoles and inline monitors cannot be controlled.
221 This leaves participants having to imagine and pretend during simulations, not only
222 in scenarios where the generated cues do not match that of the expected
223 complication but also in scenarios where cues are generated by confederate
224 actors. For example, an actor nurse turns off the pump to simulate pump failure
225 and participants have to pretend that the pump has failed.
226

227 Table 2: Simulated ECMO scenarios, methods of simulation, induced cues, and gaps and
 228 drawbacks.^{5,38,39,41–45}

| Scenarios | Methods | Cues | Gaps and drawbacks |
|---|---|---|---|
| Pump or power failure | Confederate nurse turns off the pump. | Loss in circuit flow and pump's rotation per minute. | Checking the status of the pump is a part of troubleshooting pump failure. Participants have to pretend the pump is not turned off. |
| | Confederate nurse turns off the power. | Battery alarm triggers if the battery was drained beforehand. If the battery is completely drained, the pump and console will turn off. | Similar to the above, participants have to pretend the power is not disconnected/turned off. Furthermore, console battery must be drained before simulation and the scenario must begin shortly after to prevent it from charging back up. |
| Oxygenator failure or membrane clots | Adding fluid into the circuit or partially clamp the arterial line. | Rise in pre-and-post membrane pressure and fall in circuit flow rate. | <p><i>Incorrect cues:</i> the emergency is characterized by the rise of trans-membrane pressure.</p> <p><i>Missing cues:</i> visible clots on the membrane, no blood color change representing hypoxemia, unrealistic blood parameters (blood gases, hematocrit, hemoglobin, and activated clotting time) on modern ECMO consoles (e.g. CardioHelp) or inline monitors.</p> <p><i>Contextual authenticity:</i> rapid oxygenator failure is extremely rare.⁴⁶ Clots typically build up, and hence, a more realistic scenario would start with indicators of oxygenator failure such as low oxygenation efficiency and high trans-membrane pressure that are not</p> |

| | | | |
|---|---|--|---|
| | | | sufficient to trigger alarms but still indicate potential failure. Additionally, it is difficult to discretely clamp the circuit lines. |
| | Injection of animal liver puree into the venous line of the circuit. | Rise in trans-membrane pressure (rise in pre- and fall in post-membrane pressure), fall in circuit flow rate, and the appearance of dark spots on the membrane. | Address the incorrect pressure cues and missing visible clots in the method above. However, it can be performed only once per oxygenator as the liver cannot be removed afterwards. It is inconvenient and expensive to replicate. |
| Hypovolemia, cardiac tamponade, access insufficiency, or hypotension | Withdrawing fluid from the circuit. Optional: (a) partial clamp near the pump inlet or a confederate nurse discretely shaking the venous line. (b) pushing blood colored liquid to a chest drain set near the mannequin using a syringe. | Fall in pre-and-post membrane pressure and circuit flow rate. Optional: (a) Line shattering of the venous line. (b) Appearance of blood colored liquid in the chest drain, simulating bleeding. | <i>Missing cues:</i> line shattering and visible bleeding (depending on the simulated scenario) unless options (a) and (b) are used, providing additional cues but increasing scenario operation and coordination complexity. |
| | Partial clamp of the venous line or Royal Brompton Hospital's double saline bag method. | Fall in pre-and-post membrane pressure and circuit flow rate and shatters in the drainage line. | Address the missing line shatters but still misses the visible bleeding unless option (b) of the first method is used. It is also difficult to discretely clamp the circuit lines. Royal Brompton Hospital's method adds complexity. |
| Hypertension or volume overload | Adding fluid into the circuit or partial clamp of the arterial line. | Rise in pre- and post-membrane pressure and fall in circuit flow rate. | It is difficult to discretely clamp the circuit lines. |
| Kink in circuit | During a | Depending on the | It is difficult to discretely kink the |

| | | | |
|------------------------|--|---|----------------|
| lines | transportation/bed transition scenario a confederate nurse kinks the venous or return lines under the mannequin's legs or back | kink location pre-and-post membrane pressures will fall (venous line kink) or rise (arterial line kink). | circuit lines. |
| Air entrainment | Injection of air into the circuit. | Noise of air in the pump head and triggering of the bubble sensor or a complete airlock and loss of circuit flow depending on the volume of air injected. | None. |

229

230 Advantages of this medium fidelity method is its simple construction, non-
231 complex operation, and physical realism. Any ECMO center with a vacant room
232 and a mannequin can assemble and operate this ECMO simulator. Moreover,
233 novice practitioners can interact with the real circuit and improve their psychomotor
234 or technical skills during simulations. However, the approach suffers from many
235 drawbacks. As mentioned earlier, the authenticity of simulated scenarios is weak
236 and are detached from reality. This means that it is difficult for learners to suspend
237 their disbelief and fully immerse in simulations. Due to the limited and binary (e.g.
238 high or low pressure) control over the simulator, instructors are forced to simulate
239 emergencies with pressure changes as the primary cue. Hence, simulated

240 emergencies are not diverse in their difficulties and underlying causes limiting the
241 amount of critical thinking required to identify the simulated problem. For example,
242 the failure of the blood oxygenation is almost always simulated as clots in the
243 membrane with an incorrect pressure cue and no visible clots. Learners who have
244 experienced the scenario before can identify the simulated scenario without
245 engaging their full critical thinking abilities. SBT in general is very costly to facilitate
246 even with a low-fidelity setup.⁴⁷ The cost aspect is exacerbated in ECMO SBT as
247 the setup relies on an ECMO machine and expensive consumable circuit
248 components. Ng *et al.* reported the replacement of twenty-six ECMO circuits, forty-
249 six cannula, and other consumables over the span of two years in the context of
250 SBT activities.⁴² Furthermore, due to the nature of how simulations are operated
251 (by manual manipulations and confederates, ECMO simulations have to be
252 operated by a well-briefed and coordinated team of clinicians or **simulation**
253 **specialists**, increasing the cost of human resources. Subsequently, the cost of
254 ECMO simulations is very high, hence limiting or prohibiting opportunities for
255 training, reducing the frequency of simulations, and prohibiting its use for mastery
256 or deliberate practice.

257 **Technological Aid**

258 In recent years, technology has been used in ECMO SBT to elevate some of its
259 limitations and drawbacks. This includes setting specific pressure and blood flow
260 values, automating some manual and laborious tasks performed by confederates,
261 and enabling remote control of the simulator.

262 We have observed at HMC the use of the built-in audio-visual (AV)
263 capabilities of simulation rooms to visualize the pressure changes induced by
264 volume adjustments done from the control room. This was achieved by focusing a
265 camera on the ECMO machine console and accessing its video via a computer
266 linked on the networked AV system, and so it could also be viewed from the
267 observation room. In the in-situ or ECMO transport contexts, they also use a mini-
268 camera with Wi-Fi connectivity (e.g. GoPro) positioned directly on the ECMO
269 machine console and view the live video stream on a tablet or smartphone in the
270 control room. The device screen was itself shared via their integrated AV system
271 so it could be displayed into the observation room.

272 Lansdowne *et al.* incorporated the Orpheus Perfusion Simulator, a device
273 originally designed for use with a heart-lung machine, into ECMO circuits
274 (Figure 3).⁵ Currently produced by Terumo, the Orpheus has an hydraulic model

275 which replicates the behavior of patient circulation using venous and arterial
276 capacitance, native heart, venous and arterial valves, and also based on the
277 Frank-Starlin model.^{48,49} It also comes with a perfusionist touchscreen interface to
278 display blood gases, blood pH, ACT, and allow learners to administer drugs (e.g.
279 anticoagulants) digitally.⁴⁸ Parameters displayed on the screen react to changes in
280 the circuit hydraulics and digitally administer drugs using computerized models.⁴⁸
281 In ECMO SBT, the Orpheus connects to an ECMO circuit in series (i.e. between
282 the arterial and venous lines).⁵ In Lansdowne's implementation, the circuit lines
283 were passed to the Orpheus through drilled holes in the backside of a basic
284 mannequin. Complications are simulated using the same methods listed in Table 2.
285 Oxygenator failure, for example, is simulated using the Orpheus's ability to obstruct
286 the arterial line which in addition to pressure changes, produces realistic blood gas
287 changes on the learner's interface.⁵

288

289 [insert Figure 3]

290 Figure 3: Orpheus Perfusion Simulator in ECMO SBT (modified with
291 permission).⁵

292

293

294 Advantages of using the Orpheus are the more realistic circuit hydraulics
295 and the automation it provides. Hence, scenario management is more convenient
296 and requires lower number of personnel. However, it does not address the realism
297 gaps in simulation scenarios and the costs associated with the ECMO console and
298 consumable circuit components, or provide unique mechanics to simulate missing
299 visual or auditory cues (e.g. blood hypoxemic color, blood clots, or clotted pump
300 head noise). Blood parameters are displayed on a separate screen instead of
301 existing ECMO console/inline monitors, which creates a contextual disconnect
302 between real ECMO and simulated ECMO. Furthermore, instructors cannot directly
303 control blood parameters and the used computerized model only reacts to
304 hydraulic changes and administered drugs, and hence, realistic blood parameters
305 corresponding to complications with no hydraulic cues (e.g. recirculation or low
306 oxygen saturation due increased metabolic activity) cannot be simulated. It also
307 reinforces trainee's reliance on obtaining information from displayed data rather
308 than cues from the patient or the circuit; a problem that also exists in standard
309 ECMO simulation.

310 In addition to the Orpheus, there are other commercially available ECMO
311 simulators such as the Curtis Life Research's EigenFlow and the Chalice Medical's
312 Parallel Simulator.^{50,51} Both devices enable remote venous and arterial line
313 obstruction, circuit volume removal, and injection of air. Their obstruction of the
314 circuit line is variable (using variable valves) which theoretically allows any
315 pressure or circuit flow value to be obtained. However, to obtain specific values,
316 instructors must be able to obtain feedback from the ECMO console by manually
317 calibrating the corresponding pressure and flow values per level obstruction. The
318 EigenFlow is controlled using an iPhone application and comes with a 10" LCD
319 screen displaying blood parameters. Meanwhile, the Parallel simulator comes with
320 two tablet computers, one given to instructors for control and the other displaying
321 both patient vitals and blood parameters. The Parallel's control software gives
322 instructors the option to pre-program scenarios (e.g. parameter or circuit changes
323 in a particular sequence) and execute them when needed. This can be beneficial
324 for standardization purposes, however, it can make scenarios feel more staged
325 and unnatural as the pre-programmed scenario can proceed without consideration
326 of the trainee's actions. Unlike the Orpheus, those simulators do not possess
327 hydraulic or blood parameter models, and hence, the parameters displayed are not

328 dynamic and need to be changed at the instructor's discretion. On top of that, since
329 simulated ECMO emergencies are preplanned and those interfaces feature no
330 computerized models but are simply screens with numbers on them, this
331 functionality could more cost-effectively be replaced by a computer, PowerPoint
332 slides, and a clicker.

333 Table 3 summarizes the advantages and disadvantages of aforementioned
334 ECMO simulation devices.

335 In a collaborative effort, HMC and Qatar University are working towards a
336 more realistic, cost-effective, and user-friendly ECMO SBT that addresses the
337 aforementioned gaps and drawbacks. We started developing a simulator that
338 behaves, looks, and feels realistic, but does not rely on a real ECMO machine and
339 oxygenator. This was done through the design of independent modules, each
340 responsible for producing a particular ECMO visual, audio, or haptic cue.^{52,53}
341 Those modules are then interconnected using a local wireless network and can be
342 fully controlled remotely using a tablet instructor application.⁵⁴ The simulator is
343 centered around an "ECMO circuit" module which relies on a thermochromic fluid
344 and continuous temperature adjustment to simulate blood oxygenation and
345 deoxygenation (Figure 4A).⁵⁵ Instead of a real oxygenator and pump head, 3D

346 printing was utilized to replicate circuit components used to circulate the
347 thermochromic fluid to maintain circuit continuity (Figure 4C). A line shattering
348 module is hidden under the bedding and connects to the circuit generating shatters
349 in the drainage (Figure 4D). The system provides bleeding on-demand from a
350 separate tank and a pump (Figure 4E). We have also replicated the ECMO console
351 interface used at HMC which learners can interact with (Figure 4F). Modules and
352 the interface are remotely controllable via a tablet application that features a live
353 control panel (Figure 4G) from which commands are sent in real-time. In addition, it
354 includes a sequence manager so scenarios can be pre-programmed and executed
355 during simulations (Figure 4B).⁴⁵ Despite the high research and development
356 costs, the modules themselves are cost-effective. The ECMO circuit module
357 hardware costs 300 USD and is reusable, which could result in an increased
358 frequency of SBT opportunities. Instructors have complete control over the system.
359 The main disadvantages of our system are the slight loss of physical (i.e. weight,
360 size, texture) realism as it is difficult to 3D print components and cases that are
361 exact replicates of the real-ones.
362

Table 3: Advantages and disadvantages of commercial ECMO simulators.^{5,48-51}

| Device | Advantages | Disadvantages |
|------------------------------------|---|---|
| Terumo Orpheus Perfusion Simulator | <ul style="list-style-type: none"> • Simulates patient circulatory behavior and allows ECMO consoles to display realistic and age-specific hydraulic parameters. • Enables remote obstruction of arterial and venous lines, draining of circuit volume, and injection of air into the circuit. • Provides an interactive learner interface displaying blood parameters based on a computerized model with the ability to administer drugs. • Reduced manpower costs associated with operating ECMO SBT. | <ul style="list-style-type: none"> • Simulates patients above 25kg and works best with 3/8" tubes, which limits simulating neonatal scenarios. • Hydraulic parameters are only realistic under normal conditions (i.e. no complications simulated), abnormal hydraulic parameters (required to simulate complications) can be unrealistic. • Does not provide any additional or more emergency cues, simulated emergencies inherent drawbacks from manual methods. • Disconnect between parameters displayed on real devices and inline monitors and ones simulated on the learner's interface. • Reinforces learner reliance on displayed parameters. • Modeled blood parameters are not always realistic with respect to the enacted scenarios and instructors do not have the option to change parameters manually during a scenario. • Control is performed using a laptop mounted on top of an electronic control unit, which is less mobile in comparison to the tablet/phone applications used with the other solutions. • Increased equipment and maintenance costs. • Does not resolve costs related to use of real ECMO circuit and their consumables. |
| EigenFlow and | <ul style="list-style-type: none"> • Enables remote | <ul style="list-style-type: none"> • Does not generate realistic circuit |

| | | |
|----------------------------|--|---|
| <p>Parallel Simulators</p> | <p>obstruction of arterial and venous lines, draining of circuit volume, and injection of air into the circuit.</p> <ul style="list-style-type: none"> • Specific pressure and flow values can be obtained by variable obstruction. • Provides a learner interface displaying blood (EigenFlow and Parallel) and patient (Parallel) parameters. • Displayed parameters are selected manually, removing restrictions of Orpheus' model based approach. • System is remotely controlled through tablet (Parallel) and mobile (EigenFlow) applications, improving mobility and convenience. • Parallel: remote control application allows for a sequence of commands and parameter changes to be pre-programmed, saved, and retrieved. • Reduced manpower costs associated with operating ECMO SBT. | <p>hydraulics.</p> <ul style="list-style-type: none"> • Does not provide any additional or more emergency cues, simulated emergencies inherent drawbacks from manual methods. • Setting realistic circuit hydraulic through the simulator variable venous and arterial obstruction requires instructors to visualize the ECMO console to obtain feedback on pressure and flow changes. • Disconnect between parameters displayed on real devices and inline monitors and the ones simulated on the learner's interface. • Learner interface is not interactive and is simply a tablet that displays values adjusted remotely by instructors. This function can be cost-effectively replicated in-house. • Reinforces trainee reliance on displayed parameters. • Parallel: Pre-programmed scenarios can feel staged and unnatural. • Increased equipment and maintenance costs. • Does not resolve costs related to the use of real ECMO circuit and consumables. |
|----------------------------|--|---|

364

365

[insert Figure 4]

366

Figure 4: Components of the modular ECMO simulator.

367 **Conclusions**

368 Existing ECMO simulation solutions are all based on a functioning ECMO machine
369 to ensure a high level of realism yet rely on an altered circuit requiring operator
370 manipulations in order to create or simulate complications. Although this approach
371 offers a quick and generally accessible simulation solution, it is unable to recreate
372 all possible ECMO complications with high-fidelity, cannot be remotely controlled,
373 and most importantly, is linked to a high equipment setup and maintenance costs.
374 Commercial simulation products provide the missing remote control capabilities
375 and automate circuit manipulations although inherits much of the realism gaps from
376 the aforementioned approach and do not mitigate the costs associated with ECMO
377 machine and consumables. Hence, ECMO still necessitates a cost-effective, yet
378 high-fidelity simulation solution that does not rely on the use of real equipment but
379 also do not present of risk of confusing learners due to unusual circuit alterations.
380 These factors motivated the development of our own modular and standalone
381 simulator that will offer a comprehensive, realistic, cost-effective, and user-friendly
382 solution for ECMO SBT.

383

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403

404 **Declaration of Conflicting Interests**

405 The Authors declare that there is no conflict of interest.

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