The process, logistics and governance behind a high-stakes novel intervention: the use of extracorporeal membrane oxygenation (ECMO) in the hyperbaric chamber

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Abstract
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Introduction: A multi-trauma patient receiving extracorporeal membrane oxygenation (ECMO) developed severe disseminated vaso-invasive fungal disease. In the absence of any remaining treatment escalation options, hyperbaric oxygen treatment (HBOT) was considered as a last effort at gaining disease control. Previously, the use of modern ECMO devices had not been validated for hyperbaric use at our centre or, to the best of our knowledge, at any other centre around the world. We had, however, identified a potentially hyperbaric compatible ECMO device and had commenced a validation process. The aim of this report is to highlight the practical, operational and governance processes undertaken to safely provide HBOT utilising ECMO at short notice.
Methods: A detailed risk assessment, development of risk reduction strategies and workflows, emergency out-of-session ethics review, clinical innovations committee review, legal advice, executive approvals and informed consent were undertaken over a 32-hour period prior to commencing HBOT.
Results: We present the identified risks, governance approvals, workflow, staffing model, chamber layout and safety checklist utilised to successfully deliver thirteen HBOT sessions to a patient on venovenous (VV) ECMO.
Conclusions: Through an extensive and coordinated effort involving multiple specialties and disciplines at our service, we were able to safely deliver HBOT to a patient supported by VV ECMO.

Introduction

A 20-year-old male was involved in a Class A aviation incident in dense tropical bushland and sustained major traumatic injuries. Following a damage-control pneumonectomy he was unable to be adequately ventilated and was commenced on venovenous extracorporeal membrane oxygenation (VV ECMO) prior to transfer to our centre. Several weeks into his hospital stay he developed disseminated vaso-invasive fungal disease which failed to respond to maximal medical therapy and repeated, extensive, debridement. In the absence of any remaining treatment escalation options hyperbaric oxygen treatment (HBOT) was considered in a critical-care capable hyperbaric facility, as an essentially experimental treatment. The rationale included attractive patho-physiological mechanisms, and previous published and unpublished reports suggesting a potential benefit of HBOT in the treatment of vaso-invasive fungal disease.[1–5] At this time ECMO had not been validated for in-chamber use in our centre or to the best of our knowledge in any other centre worldwide, however a validation process was underway at our centre.[6]

The aim of this report is to highlight the practical, operational and governance processes that were undertaken to safely provide HBOT as a last effort to a patient dependent on VV ECMO using the Maquet (Getinge) original series Rotaflow (Rotaflow 1) at short notice. The technical report and clinical components of the case are beyond the scope of this report and are detailed elsewhere.[6,7]

Methods

A series of inter-dependent working groups were urgently convened to work together and in parallel to navigate the complexities of safely delivering ECMO in the hyperbaric environment. The aims of the working groups were to: i) configure and perform additional testing of the Rotaflow 1; ii) establish workflows, logistics, staffing and contingency plans; iii) identify risks and risk reduction measures; and iv) navigate the clinical governance and consent requirements for a novel and experimental intervention.

The working groups consisted of senior hyperbaric, intensive care and ECMO clinicians (medical and nursing), and biomedical engineers. A scribe role was allocated.

RISK ASSESSMENT

Equipment safety

As part of a longer-term project to develop ECMO capability in the hyperbaric chamber, a Rotaflow 1 console had previously been reconfigured to run without a battery on a dedicated and highly redundant medical power supply installed in the hyperbaric chamber, with preliminary testing performed on a circuit primed with saline.[6] However, at the time this patient was considered for HBOT we had not yet validated the use of ECMO with a circuit primed with blood or applied *in vivo* conditions. An assessment of risks was undertaken (Table 1), and risk reduction strategies are described in Results.

Table 1
Summary of key risks assessed prior to delivery of ECMO in the hyperbaric environment

Equipment
Fire safety
Device integrity under pressure
Device performance under pressure
Patient
Injury or death relating to equipment failure or malfunction
Oxygen toxicity
Barotrauma
Staff
Staff decompression injury in event of an emergency decompression procedure
Well-being
Reputational
Legal
Organisation
Organisational risk
Opportunity cost impact

Staff and patient safety

A customised HBOT treatment table was developed to maximise potential therapeutic benefit whilst ensuring that the inside attendants did not acquire a decompression obligation. Attendants could therefore be rapidly decompressed at any point in an emergency. Consideration was given to the unknowns around oxygen toxicity in the setting of oxygen delivery via both a ventilator and the ECMO circuit.

Emergency scenarios

Emergency management plans specific to this patient on VV ECMO in the hyperbaric chamber were developed for the following scenarios: pulmonary barotrauma, air embolism, loss of primary and secondary gas supply, cardiac arrest, ECMO pump or circuit failure.

CLINICAL GOVERNANCE APPROVALS

Given the novel and untested nature of delivering HBOT to a patient on ECMO, it was considered that ethics committee review, clinical innovations committee review and executive approvals were required. At our centre, the ethics committee is primarily responsible for research governance but also can be called to provide advice to management on case specific dilemmas. The clinical innovations committee includes a wide range of senior clinicians, technical and management personnel who normally conduct scheduled considerations of the appropriateness of technical, equipment and process innovations proposed for introduction at our centre. A briefing document was prepared for these committees and emergency 'out of session' meetings were scheduled with hyperbaric and intensive care leadership input. Approvals and consent were sought on the proviso that all parties were willing to accept that in addition to identified risks, there were potentially unidentified and unquantifiable risks to the patient.

NEXT OF KIN CONSENT

The patient was unconscious throughout the planning, discussions and approvals processes, and therefore unable to provide consent. When a clear strategy was established to deliver treatment in the safest possible fashion and organisational approvals had been granted, a discussion was held with his next of kin. The medical treatment decision maker was provided with written information about the proposed treatment and a comprehensive informed consent process was undertaken.

LOGISTICS

Staffing

A staffing model was developed to ensure maximal safety during this novel intervention, with specific consideration to the skill-mix and roles of staff inside and outside of the chamber.

Workflow

A workflow plan was established by the working group prior to initiation of HBOT. A specific hyperbaric-ECMO chamber checklist was developed for use alongside pre-existing hyperbaric checklists.

Patient and equipment positioning

Planning of patient and equipment positioning in the chamber was performed by hyperbaric nursing staff.

Briefing document

A team briefing document was prepared which detailed the clinical situation, planned intervention, workflows, emergency procedures, administrative tasks, roles and responsibilities.

Results

ADDRESSING THE IDENTIFIED RISKS

Equipment safety

The Rotaflow 1 was deemed safe from a fire-safety perspective in the hyperbaric environment and had performed consistently with a circuit primed with saline during preliminary testing.[6] Additional technical tests did not demonstrate any macroscopic bubbles visually, microscopic bubbles via ultrasonic detection methods, or any leaks in the system.[6]

ECMO components used at our centre include a console, pump, patient circuit with oxygenator, gas supply, blender and blood warmer. During HBOT, the blood warmer and gas blender were excluded from the setup as they had not undergone testing. Traditional temperature management techniques were utilised including hyperbaric chamber heating and blankets. Oxygen was supplied directly to the oxygenator via flexible oxygen tubing from a standard oxygen flow meter connected to a medical oxygen outlet in the chamber, in line with ECMO transport practice at our institution.

Staff and patient safety

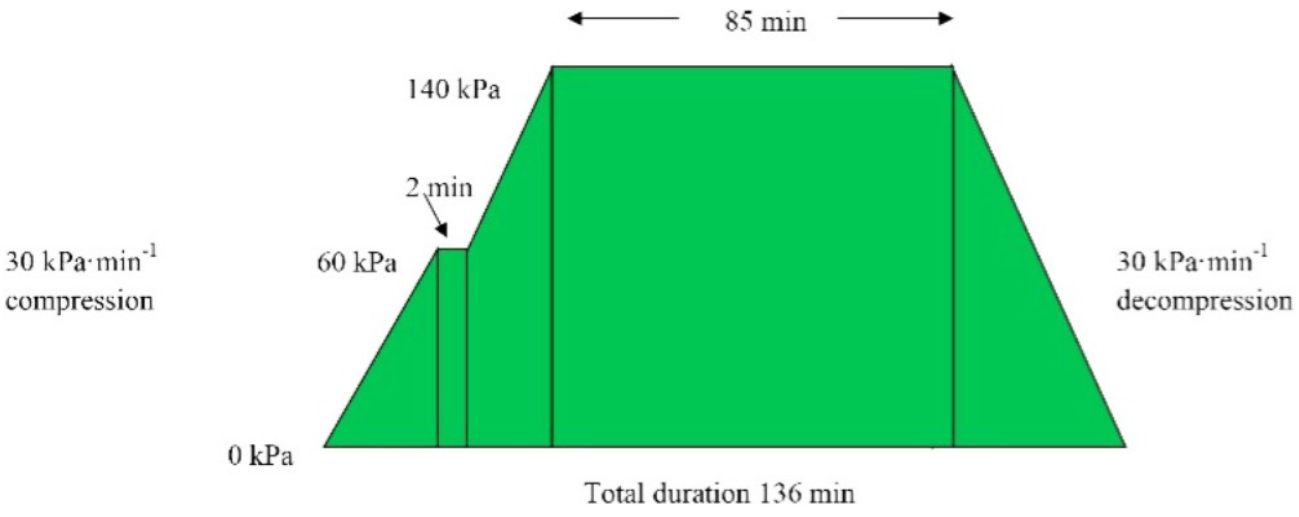
The HBOT treatment table (Figure 1) involved a pressurisation rate of 30 kPa·min^{-1} to a maximum pressure of 140 kPa (gauge pressure) (2.4 atmospheres absolute [atm abs]). A two-minute hold was introduced on reaching 60 kPa to allow for equipment checks and examine for bubbles in the circuit, and also for personnel checks and to ensure all key clinical parties inside and outside of the chamber, were comfortable and willing to proceed. The total hyperbaric oxygen delivery time at 140 kPa was 85 minutes. There were no air breaks and the patient remained on 100% FiO_2 via the ventilator (and ECMO oxygenator) for the duration of the treatment table. Attendants breathed 100% oxygen from five minutes prior to commencing decompression until completion of the treatment table. The chamber was decompressed at a rate of 30 kPa·min^{-1}.

Emergency scenarios

In addition to close observation for known complications of HBOT including hypercapnia, oxygen toxicity and hypoglycaemia, particular consideration was given to the critical scenarios and contingency plans described below.

Pulmonary barotrauma is a rare complication of exposure to the hyperbaric environment. The patient treated was at increased risk due to single lung ventilation complicated by acute respiratory distress syndrome and a friable bronchial

Figure 1
Hyperbaric ECMO treatment table; note that treatment pressures are gauge pressure



stump post-pneumonectomy.[8,9] The patient had mixed restrictive and obstructive ventilatory challenges, and a mixed ventilation strategy was employed using the Getinge Servo-i HBO Ventilator. Medical staff were equipped with a needle and finger thoracostomy kit inside the chamber for chest decompression if required.

In the event an air embolism was detected in the ECMO circuit, the circuit was to be immediately clamped and emergency decompression procedure commenced to facilitate a circuit change. The patient's intensive care unit (ICU) ECMO console was a Getinge Rotaflow II (Rotaflow 2); this remained on charge at all times with a spare primed permanent life support (PLS) circuit, immediately outside the hyperbaric chamber.

In the unlikely event of interruption to both primary and back-up oxygen supply systems, rapid decompression would occur and cylinder oxygen would be utilised.

Given the patient was supported with a VV ECMO configuration, there was no circulatory support in the event of a cardiac arrest. In this instance, the in-chamber nursing attendant would commence chest compressions and the hyperbaric team lead would coordinate a rapid decompression and initiate an emergency (Code Blue) response. After chamber decompression, the patient would be transported down to a resuscitation area outside the chamber for ongoing advanced life support and defibrillation if required, with ECMO blood flow maintained by utilising the hand-crank.

In the event of an ECMO pump failure, the inside hyperbaric ECMO clinician would transfer the pump-head onto the back-up hand crank and restore flow, the technicians would commence an emergency decompression and on return to 1 atm abs the extracorporeal life support (ECLS) team would exchange the console.

In the event of circuit failure, the circuit would be clamped, emergency chamber decompression would occur, followed by a rapid assessment and circuit change by the two ECMO clinicians in the hyperbaric resuscitation area.

GOVERNANCE APPROVALS

The final consensus from both the ethics and the clinical innovations committees was to endorse the recommendation to conduct hyperbaric oxygen treatment on this patient. Given the unique situation, the hospital legal team confirmed indemnity from the hospital's insurance provider relating to the provision of HBOT for this patient on ECMO. Hospital executive provided approval to proceed.

MEDICAL TREATMENT DECISION MAKER CONSENT

The medical treatment decision maker provided informed consent amidst the uncertainty of this novel delivery of HBOT. This decision was made in the interest of the patient, who, it was felt, would have wanted to proceed with HBOT despite the uncertainty. It was also believed that he would have liked to be a part of validating the safe delivery of HBOT with ECMO for the benefit of other patients in the future.

STAFFING

The provision of hyperbaric treatment to a patient on ECMO required a large collaborative effort among senior ECMO and hyperbaric physicians, clinical nurse specialists and biomedical engineers.

Inside the chamber two models of staffing were utilised:
1) a critical care nurse qualified in both ECMO and hyperbaric nursing, and a senior critical care physician with both hyperbaric and ECMO credentialing; or
2) two critical care nurses qualified in both ECMO and hyperbaric nursing and a critical care hyperbaric physician.

All staff working inside the chamber were required to have current certificates of fitness to work in a compressed air environment.

Outside the chamber, the team consisted of a dedicated team leader, the chamber operator, a hyperbaric nurse, an ECMO clinical nurse consultant, two ECMO physicians, the ICU bedside nurse, and the operations manager.

A dedicated team leader role was seen as critical to manage any interactions between the clinical team and external parties and to provide overall coordination and monitoring of clinical processes and leadership of emergency response should that have been needed, noting the large number of personnel and roles involved. This role was fulfilled by the (outside) senior hyperbaric physician.

WORKFLOW

Preparation to commence HBOT

The first treatment session commenced 32 hours after the initial clinical determination to pursue HBOT. The patient had middle ear tympanostomy tubes inserted to reduce the risk of barotrauma. Prior to the first HBOT, the HLS ECMO circuit was changed to a PLS circuit compatible with the Rotaflow 1 and Rotaflow 2 consoles and the Quadrox i-adult HMO 70000 (Quadrox) oxygenator. There was a right femoral multi-stage 25 Fr access cannula and a left femoral single-stage 21 Fr return cannula.

Pre-treatment

In ICU before each transfer to the hyperbaric chamber, the patient was prepared using a standardised intra-hospital transport checklist.

All involved teams (Hyperbaric, ECMO & ICU) gathered for a briefing one hour prior to each planned HBOT session. The structured brief prepared in the planning phase was used to ensure consistent delivery of all important information.

Prior to each treatment session, sedation was deepened to reduce the risk of awareness, and for the early treatments a continuous infusion of muscle relaxant was given to prevent ventilator desynchrony and ECMO access insufficiency (a state where the suction pressure at the access cannula is excessive in relation to the venous return). The patient's ECMO flow requirements and fluid state were also optimised to prevent access insufficiency.

Transport and arrival at chamber

The patient was transported on the Rotaflow 2 by the ECMO and ICU teams to the hyperbaric chamber, where a primary survey was completed upon arrival. Hyperbaric nurses performed a sequential changeover of ICU equipment in communication with the ECMO team and critical care hyperbaric physician team leader – the oxygenator to the chamber/wall source of oxygen, monitoring cables to the chamber monitor and endotracheal tube to the hyperbaric ventilator. Ventilator settings were confirmed, and the endotracheal tube cuff inflator was connected to the pilot balloon of the endotracheal tube.

Standard pre-treatment chamber checklists were completed, which include in-chamber safety equipment checks, attendants' oxygen mask checks, confirmation of the pressure fitness of attendants and medical emergency plans, a safety time-out, and patient safety checks.

Once standard intensive care hyperbaric checks were completed, the ECMO team commenced a swap of consoles onto the hyperbaric-modified Rotaflow 1 and the flow was zeroed. Patient vital signs were closely observed during this period. Once the console swap was complete, final pre-treatment attendant checks were completed and chamber pressurisation (HBOT) commenced.

During treatment

Once pressurisation began, the hyperbaric ECMO physician monitored the circuit both visually and using Doppler ultrasound for air bubbles. The hyperbaric nurse monitored the patient's ventilation and haemodynamic parameters. During pressurisation, the chamber fan and chiller were left off for noise reduction and heat conservation. When the chamber reached the target pressure of 140 kPa (2.4 atm abs), the first arterial blood gas (ABG) was taken to assess the adequacy of patient ventilation, blood flow and fresh gas flow (FGF) to the oxygenator. Adjustments were made as required. The first of two samples were then taken for pre- and post-oxygenator blood gas analysis. A second arterial blood gas was taken later in the treatment.

Throughout the treatment, the patient was monitored with continuous five lead ECG, arterial blood pressure, oxygen saturation, waveform capnography and nasopharyngeal temperature monitoring. Pre- and post-oxygenator pressure transducers were not connected during treatment, as is standard practice during transport.

The inside attendants reassessed the patient prior to donning their own oxygen masks for decompression. Particular consideration was given to vasoactive medication adjustments that had occurred during the treatment, and a reduction in hyperbaric oxygen-mediated vasoconstriction during decompression was anticipated. The patient's ventilation status was monitored closely on decompression for signs of pneumothorax. Pressure bags were adjusted to avoid rupture of the normal saline fluid bag within.

Post-treatment

Once the treatment had concluded, a staged process was undertaken in the chamber to transfer the patient back onto ICU transport equipment and the Rotaflow 2 console. After a final patient assessment and a pre-return transport checklist were performed, handover of patient care was given and the ICU/ECLS teams transported the patient back to ICU. It was recommended to slowly wean the patient's FiO_2 via the ventilator (not via the ECMO blender) over 60 minutes after return to ICU, as per standard practice.

ECMO chamber checklist

Consistent with standard procedures for both hyperbaric and ECMO operations in our organisation, a hyperbaric ECMO checklist was developed (Table 2).[10] This checklist was further refined as experience was gained during the course of treatment. The checklist was deemed an important safeguard to mitigate human factor elements in a dynamic clinical environment supported by a large multidisciplinary team.

CHAMBER LAYOUT AND PATIENT POSITIONING

We elected not to alter the positioning of the ventilator, equipment trolley, or IV pole and medication infusion pumps from our standard critical care practice. The patient's bed was centrally located within the main lock (feet toward exit), and the ventilator was placed at the patient's left shoulder connected to oxygen, air, nitrogen and power outlets at a central utility station. The IV pole and infusion pumps were placed to the right side of the head of the bed, in proximity to the patient's central venous access device (Figure 2). The Rotaflow 1 console was placed in close proximity to the foot end of the bed and the power cable, fresh gas flow and nitrogen purge tubing were routed together via the chamber ceiling to maintain clear access to vital circuit components.

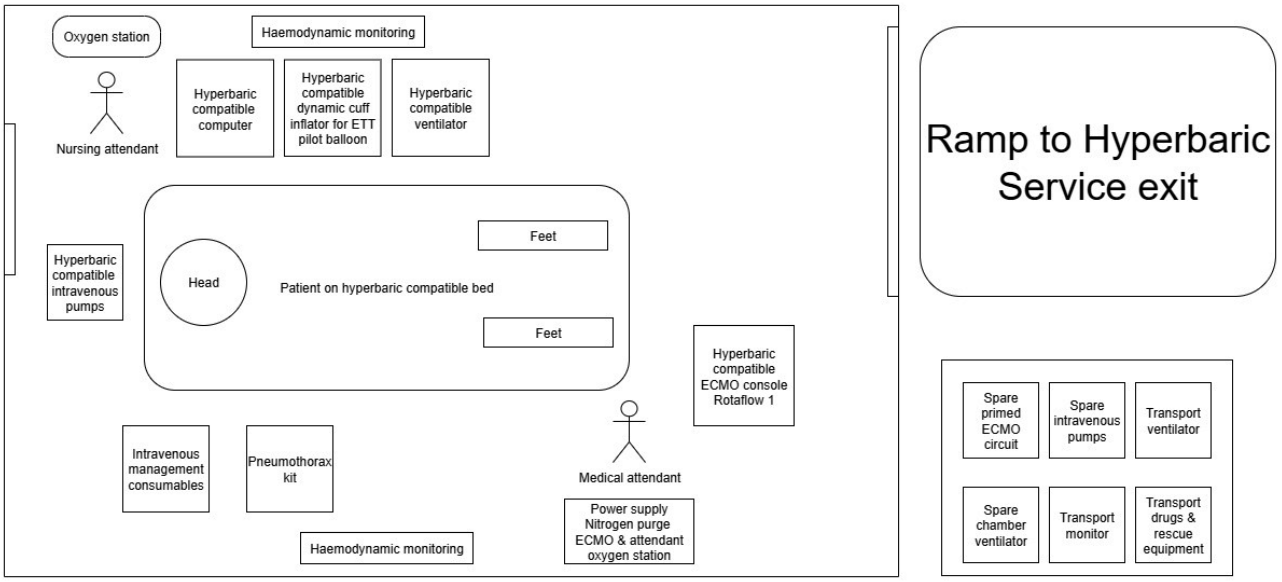
Table 2

Hyperbaric ECMO checklist; ECMO – extracorporeal membrane oxygenation; HBS – hyperbaric service; ICU – intensive care unit

Start-up procedure for hyperbaric ECMO device (device will not start unless connected to in-chamber power)
Confirm ECMO oxygenator connected to oxygen flowmeter and confirm oxygen set to fresh gas flow required – pre-pressurisation □ – at pressure □ – post decompression □
Confirm nitrogen purge is connected and ON (check with Technician)
Confirm compatible ECMO console and primed circuit are plugged in and available at bottom of chamber ramp
Measure ECMO cannula insertion length to ensure unchanged since leaving ICU
Confirm ECMO circuit and cannula secured with no visible bleeding
Confirm four ECMO clamps present
Confirm the following HAVE BEEN REMOVED from the ECMO trolley and chamber: – blood warmer – blender – all oxygen cylinders – all alcohol and skin adhesives
Visualise yellow cap is in-situ on ECMO oxygenator
Confirm hyperbaric ambient cooler is off and patient temperature probe is in-situ
Check ECMO console alarms are set

Figure 2

Layout of equipment in the main lock of the multiplace chamber for hyperbaric ECMO



Discussion

Prior to the development of cardiopulmonary bypass equipment suitable for small infants, cases of paediatric congenital heart disease underwent cardiothoracic surgery in the hyperbaric chamber and there are reports of early work in the 1960s to 1980s involving animals or patients undergoing HBOT whilst on cardiopulmonary bypass or ECMO.[11,12] A conference abstract describes a series from China including 48 children and adults who underwent cardiothoracic surgery

with extracorporeal circulation under hyperbaric conditions in 1984.[13] However, to the best of our knowledge, this case represents the first time that a patient has received HBOT whilst on ECMO, and the first documented use of the Rotaflow 1 console and Quadrox-i oxygenator under hyperbaric conditions. This paper is also the first instance where processes and workflow for safe delivery of HBOT with ECMO have been documented.

The patient had previously been on an ECMO console which was assessed as not suitable for hyperbaric use, and an initial circuit change was therefore required to facilitate HBOT. He was then transported each day from ICU on the Rotaflow 2 (of which the circuit is compatible with the original series Rotaflow), switched to the Rotaflow 1 on arrival in the hyperbaric unit, and back to Rotaflow 2 after hyperbaric treatment for transfer back to ICU. This was required because preliminary testing and power modifications had been made on the Rotaflow 1 device, and without battery power it was not suitable for use in transport.

Thirteen HBOT sessions were delivered for this patient over fifteen days, with a pause over the second weekend.

Skill-mix and inter-operability between hyperbaric, ECMO and intensive care teams were critical in ensuring the clinical capacity to deliver ECMO safely in the hyperbaric environment. Critically, the preliminary testing and modifications of the device would not have been achieved without dedicated hyperbaric biomedical engineers employed within our service. Technical details of this work are outside the scope of this manuscript and can be found in a corresponding technical paper.[6]

Strategic actions to mitigate risks and harm reduction in a realm of uncertainty were also key to delivering ECMO in the hyperbaric chamber. Non-technical skills were emphasised in the planning sessions and utilised throughout, including shared mental models, closed loop communication, clear task delineation and anticipation of problems in advance. A process-focused approach was used, with repeated evaluation of impacts and outcomes being identified through discussion and feedback. Consideration was given to the psychological safety of staff, and to the potential impact of an adverse event or adverse patient outcome. Risk of moral injury in such a scenario was considered and staff were given the opportunity to voice any concerns they had about the safety or appropriateness of proceeding with treatment.

Given this is a first-of-a-kind experience, in the world to our knowledge, we hope that these documented processes will help organisations worldwide develop the capability to safely deliver HBOT to a patient supported with ECMO. On a local level, these processes will be consolidated into a guideline should the need arise to provide HBOT to a patient on ECMO in the future.

Conclusions

The novel approach of providing HBOT to a patient supported with VV ECMO was complex and required a whole-of-system approach with meticulous planning. A collaborative approach in our organisation allowed the delivery of a considered plan incorporating risk assessments, mitigation strategies, workflows and checklists. Together with expedited organisational safeguards through the clinical innovations, ethics and executive committees, we delivered the world-first in-vivo HBOT course to a patient supported on VV ECMO. Having demonstrated the safe and successful use of the Rotaflow 1, we envisage developing the capacity to treat patients supported with ECMO with a round-the-clock service in the future. We hope the experience shared here will encourage the development of similar capabilities in other health services worldwide.

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