Setup and Maintenance of Extracorporeal Life Support Programs

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Abstract: Setting up an extracorporeal life support program requires motivated experts, institutional commitment, and an interprofessional team of healthcare providers with dedicated time, space, and resources. This article provides guidance on the key steps involved in the process of developing a sustainable extracorporeal membrane oxygenation program, based on guidelines from the Extracorporeal Life Support Organization and from an international perspective. (*Pediatr Crit Care Med* 2013; 14:S84–S93)

Key Words: extracorporeal membrane oxygenation; pediatrics; program development

In this review, we provide guidance on setting up an extracorporeal membrane oxygenation (ECMO) program to support pediatric patients. This article is intended for physicians and healthcare professionals who are already experts (i.e., professionals formally credentialed or board certified by their national organization) in the field of pediatric or neonatal intensive care and for individuals who will be responsible for building a *new* ECMO program.

By the end of the article, the reader should have an understanding of the six steps involved in the development of an ECMO program: *planning, developing, implementing, sustaining, evaluating,* and *moving forward* (**Fig. 1**). The approach is based on published recommendations from the international Extracorporeal Life Support Organization (ELSO) (1) and published literature from groups that report the experience of building programs for pediatrics or adults in North America (2, 3), Europe (4), or Australasia (5). This information is intended to complement ELSO documents and texts that are already available (1, 6).

We direct the reader to additional references for guidelines that are beyond the scope of this review. These include extracorporeal life support (ECLS) certification (7), the development of a simulation program for ECLS (8), the development of ECLS programs for adults (9–11), the development of an ECLS program for the sole purpose of donor organ support (12–15), and the development of ventricular assist device (VAD) programs as a bridge to transplantation (16).

SETTING UP A PEDIATRIC ECMO PROGRAM

Step 1–Planning

When considering starting up an ECMO program, there are three important components of the planning phase: the identification of key personnel, a needs assessment, and development of a strategic plan.

Selecting a Steering Group. The steering group will take on the early responsibility of scoping an ECMO program, setting realistic, achievable goals, ensuring successful and efficient implementation, and includes clinicians and administrators who are all invested in the success of the service. The key personnel in the steering group should involve clinicians and administrators who are all invested in the success of the service; these include physicians (and physician extenders where appropriate) and health care providers (nurse, or respiratory therapist, or perfusion specialist) from critical care, neonatology, cardiovascular surgery, and general surgery. Hospital administration must also support the ECMO program, ideally with an executive sponsor who actively participates in planning and implementation. Although the majority of established ECMO programs have a medical director and one or more coordinators (discussed later), at the earliest stage of planning a new program these posts may not yet exist. In any case, it is essential that the personnel involved in the program development have the appropriate expertise in the field, are invested in this

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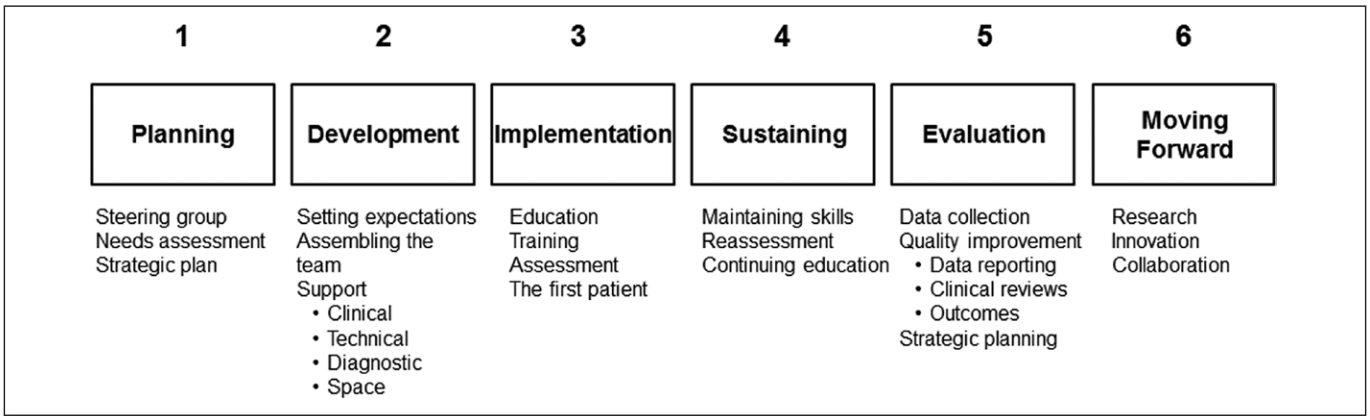

Figure 1. Six steps suggested to undertake when setting up an extracorporeal membrane oxygenation (ECMO) program.

process, and ideally have good relationships with internal and external stakeholders.

The Needs Assessment. The limits and boundaries of highly complex therapies are key determinants of their success and need to be clearly defined at the outset. The needs assessment will define the scope and role of the program in the institution and within the local medical community, as well as defining the patient population and the demand for the service, both at the outset and in the future. In order for a program to be viable, it first requires the appropriate patient population, identifiable both clinically and geographically. Some of these patients may already be within the existing patient demographic but either cannot be offered ECMO at all or must be transferred elsewhere for this; others may represent an entirely new patient population. Assessing the local or regional needs is essential, and clearly this will vary according to the existing components of the clinical service and with the location of existing ECMO centers. Although there is no clearly established minimum annual volume for an ECMO program, hospital volume is a variable associated with improved outcomes in some patient groups (17–19).

An accurate needs assessment requires the early engagement of key clinical personnel who are experts in their respective clinical fields—for example, cardiac surgeons, general or thoracic surgeons, pediatric intensivists, and neonatologists—who together would clarify and define the local scope of the ECMO program determined by current and future indications for ECMO, as well as contraindications. Early engagement of those clinical services whose patients may be supported with ECMO therapy may be beneficial to avoid potential conflict or skepticism later. Such groups may include hematology/oncology, pulmonary medicine, cardiology, emergency medicine, trauma, or lung/liver/bone marrow/cardiac transplant. Involving perfusion personnel, nursing staff, respiratory therapists (if they are anticipated to be an active part of the program), and ancillary support staff will be vital. This needs assessment will ultimately provide an estimated anticipated annual volume. The patient-specific indications can be translated into programmatic objectives and performance endpoints.

A highly complex and advanced therapy, such as ECMO, should be highly centralized to ensure an adequate referral base and patient volume to provide the best possible outcomes. Although ECMO in children is typically separated into neonatal, pediatric, and cardiac support, it is not a requirement that a new ECMO center should support all three patient groups. For example, the absence of a neonatal ICU (NICU) or robust neonatal referral base should not preclude the development of pediatric and cardiac ECMO services if these other patient populations exist. Similarly, a stand-alone cardiothoracic hospital may only be required to develop cardiac ECMO services.

Measuring the demand for a new service—the needs assessment is a complex process, as there are two components to this: the existing unmet need as well as the potential demand, which may be unknown at the outset.

The existing unmet need. This is an estimate of the number of children already being admitted to the institution who may benefit from ECMO if this were available. In addition to using known data relating to patients "transferred out" to other ECMO centers for support, specific diagnosis-related and disease severity-related search criteria can be applied to institutional databases to gauge this. Examples of such criteria include cardiac, respiratory, or cardiorespiratory failure as starting points, with interrogation of disease severity and other clinical variables as further identifiers.

The potential or future need. This is more difficult to gauge and includes two key factors. First, and easiest, will relate to a new service developing within the institution that may require the support of ECMO. The best example of this would be the introduction of a cardiac surgical service, which naturally lends itself to the development of cardiac ECMO. The volume of cardiac ECMO in cardiac surgical centers is highly variable but would typically range from 1% to 5% of the total annual pediatric cardiac surgical volume (20). The second factor is less clear and relates to defining a new patient population from outside stakeholders who would either have referred their patients elsewhere for ECMO or who have not previously had access to ECMO. Typically this patient population would be small at the outset but would increase over time if a program is seen to be successful. A sensible approach is to begin by selecting patient populations with more predictable prognoses (e.g., meconium aspiration syndrome with neonatal persistent pulmonary hypertension syndrome) and expanding later to

include patient indications with higher risk of complications or with more uncertain prognoses (e.g., sepsis) (21–25).

The needs assessment can be further supported by data from existing ECMO centers that serve similar populations. For example, recent European groups have gone through this exercise as it relates to neonatal ECMO (4), and others have grown somewhat unexpectedly due to an acute sudden demand—for example, as a result of the H1N1 influenza pandemic, where many new pediatric ECMO centers were "born" and subsequently have sustained their programs (26–28). Identifying an ECMO "twin program or mentoring program" is a useful way of assessing programmatic growth and benchmarking. The development of a program is well suited to be the responsibility of an ECMO medical director, who can be a physician or a surgeon.

Developing a Strategic Plan. A successful ECMO program requires buy-in from the highest levels of leadership within an organization and needs a strategic plan. The work put into the earliest phase of planning the ECMO program will serve easily to draft a strategic plan designed to fulfill a mission and purpose. This strategic plan is helpful not only for the core ECMO team but also very important for the institution in terms of engaging administrative support and institutional stakeholders in enabling the development of the program.

A well-defined patient population and volume, a realistic estimate of patient outcomes, together with the ability to benchmark against "similar" centers provides administrators with a reasonable indicator of resource needs. Although survival is clearly an important outcome for an ECMO program, other performance indicators should be defined early in its evolution. These could, for example, include quality indicators, complications, or educational objectives. Endpoints can be divided into usual academic healthcare domains: care practices and delivery, equipment, education, and research. Financial and infrastructure resources should be anticipated to achieve excellence in each of the domains. Given the magnitude of the investment required up front and the impact on resources, it is key to ensure that institutional support is secured early in the planning phase, ideally with an executive sponsor who is a senior administrator in the organization. Working with an administrator will be important to develop a business plan that should estimate direct and indirect expenses and potential revenues, in addition to operating expenses. The minimal start-up budget for a new program will be significant. Although it may be tempting to start an ECMO program by only anticipating the equipment costs or "on a shoestring," i.e., without adequate infrastructure, training, and resources, it is important to resist this where possible until a minimum requirement has been met for the service. Without applying this principle, the organization will be exposing themselves to avoidable risk and potentially setting themselves up for poor outcomes.

At completion of the planning phase, the ECMO steering group should be able to define the scope of the service—in other words, what indications the program will accept as valid for their institution, such as any or all of the ECMO indications, including offering ECMO as a bridge to organ recovery and/or as a bridge to transplantation. There should be a clear written strategic plan with objectives to be achieved quarterly over the next 12 months. ELSO has set criteria for centers of excellence, which can provide a useful template in terms of setting early goals (29).

Step 2–Developing the Service

When setting up an ECMO program, the resources required to support the service must be identified early and should be projected over the first 3–5 years. The components of these resources fall into three categories: organizational, human expertise, and equipment.

ECMO falls within a broad spectrum of organ-assistive technologies. The extent of new resources and infrastructure needed for an ECMO program is in part determined by what, if any, of these other technologies already exist in the new ECMO center. Examples include cardiopulmonary bypass (CPB) support within the context of cardiac surgery, as well as a wide range of extracorporeal technologies used in the ICU setting, including hemodialysis, plasmapheresis and continuous renal replacement therapies, long-term VADs (16), and extracorporeal carbon dioxide removal (30). For ECMO programs being developed in institutions already providing other extracorporeal support, some of the expertise and infrastructure necessary to build an ECMO program may already exist. For others, there may be little or no existing infrastructure to act as a platform for a new ECMO program. Combining similar extracorporeal support systems into a single program has worked well in some centers.

Setting Expectations. An important early guiding principle is that a new ECMO center should not be expected to provide the full scope of ECMO at the outset (**Table 1**). This applies particularly to aspects of ECMO that require additional infrastructure, expertise, and staffing; examples include the ability to offer effective extracorporeal cardiopulmonary resuscitation (ECPR), interhospital ECMO transport, or VAD support as a bridge to organ transplantation. These services should be introduced once the foundation for in-house ECMO has been in place for a period of time, which at a minimum requires 24-hour specialist coverage of ECLS patients and appropriate allied support (laboratory, blood bank, surgical, and perfusion as appropriate).

The ECMO Team. The principal personnel required to staff an ECMO program are a medical director, a coordinator, and a team of ECMO specialists, as well as a team of experienced surgeons who will readily perform cannulation. Many institutions include cardiovascular perfusionists within the ECMO team. Some of the personnel may already be employed within the organization, though a new program may require additional recruitment from outside. At the very least, a new program will require significant training of the ECMO team. The personnel requirement will be driven by the needs assessment that will provide an estimate of volume and patient case-mix and would typically be projected to increase over time as the size of the program increases. Specific training for ECMO specialists will be discussed elsewhere.

TABLE 1. Examples of Scope of Care Provided by Extracorporeal Life Support Programs

Scope of Care
1. Intensive care ECMO program with urgent elective cannulation
2. Intensive care ECMO program with urgent elective cannulation and extracorporeal cardiopulmonary resuscitation cannulation when human resources available only or 24 hr each day/7 days each week
3. Intensive care ECMO program with support for organ failure as bridge to recovery for respiratory failure, cardiopulmonary failure, and cardiac failure (including for failure of coming off cardiopulmonary bypass)
4. Intensive care ECLS program with support for organ failure as bridge to decision making and organ transplantation, including bridge to more long-term organ support devices (e.g., ventricular assist device)
5. Intensive care ECLS program with support for the procurement of organs in a donor
6. Intensive care ECMO program with goal to cannulate and maintain temporarily until transfer to ECLS regional center
7. Intensive care and interhospital ECMO program with goals to cannulate, retrieve (transport), and maintain until either recovery or transplantation
8. Ambulance and out-of-hospital ECMO retrieval service
9. Intensive care ECLS program for ex vivo organ rehabilitation

ECMO = extracorporeal membrane oxygenation, ECLS = extracorporeal life support.

The physician team. An ECMO program requires a core group of ECMO-trained physicians and surgeons. The bedside treating team of intensive care physicians (neonatal, general pediatric, or cardiac) must have a working knowledge and understanding of ECMO support and the technical ability for emergency troubleshooting and circuit intervention. Furthermore, it is within their domain to manage advanced respiratory or multiple organ support and have the necessary expertise to recognize indications for and to apply (or have access to experts in the use of) acute renal replacement, plasma exchange, or similar therapies.

A tertiary ECMO center (or referral center) should include the expertise and skill mix to cannulate and support a patient throughout the ECMO run, during weaning and decannulation, and continue to provide intensive care support thereafter. Cannulation may be performed by cardiac or general pediatric surgeons, and in some cases, particularly when supporting older children and adolescents on peripheral ECMO, by the ICU team. In centers where ECMO is decentralized to more than one ICU area and cardiovascular services are not directly involved in the bedside ECMO support of individual patients (e.g., general ICU patients in many American centers), the cardiovascular surgical team, including perfusionists, typically serve as valuable resources, particularly early in the development of in-house ECMO and education of the new ECMO team.

The ECMO coordinator. The ECMO coordinator is arguably the most important member of the ECMO team. A successful ECMO program requires at least one full-time dedicated ECMO coordinator depending on the volume of the program and institutional resources. The role of the ECMO coordinator is to oversee training, equipment deployment and maintenance of a highly reliable program, and daily operational activities. Additional responsibilities relate to data management and interplay with ELSO and research. ECMO coordinators may come from a professional background in cardiovascular perfusion, respiratory care, or nursing, but regardless of craft group they must have substantial experience in the deployment and management of ECMO (31).

The ECMO specialists. The quality of care provided by an ECMO program is critically dependent on a team of ECMO specialists, who can be certified cardiovascular perfusionists, registered nurses, respiratory therapists, or a combination of these. Mixed care models within units—bringing together more than one craft group—have been very successful. The ECMO specialists primarily manage the ECMO circuit and ECMO-related patient care, though in some jurisdictions, where the specialists are critical care nurses with additional certification, they may also be involved in the non-ECMO care of the patient. The exact model of care is driven by the organizational as well as financial considerations. For example, in Europe and Australia—where there are no respiratory therapists—the majority of, if not all, ECMO specialists are critical care nurses. Some of these jurisdictions (e.g., Royal Children's Hospital, Melbourne, Australia) have a single provider model, with additional backup if there are multiple ECMO patients or if an individual patient's needs surge during, for example, acute deterioration, surgical procedures, or in-hospital transport. Others have dual provider models with a critical care nurse managing the patient and the ECMO specialist managing the circuit. There are no data to compare single provider models undertaking all bedside care responsibilities with multiple provider models where responsibilities are shared among more than one role. As ECMO technology becomes more miniaturized and servo regulation improves, the one-caregiver model may expand in popularity. This may reduce the resources required for ECMO support and lower costs.

Cardiac backup. The absence of cardiovascular surgical backup does not preclude the development of an ECMO service (32–36). However, the institution must have the ability to immediately and comprehensively address all major complications of ECMO, vascular and hemorrhagic, requiring expert surgical explorations and reconstructions. In environments where peripheral and particularly percutaneous cannulations are used, access to ultrasound, echocardiography, or fluoroscopic guidance is strongly recommended, and thus requires access to additional expertise and related equipment.

The success of an ECLS program is built on the expertise of the ECLS clinicians; therefore, identifying necessary expertise among available clinicians should be identified across the organization, with consideration of additional recruitment when necessary. It is essential that expertise and personnel be identified before investing in equipment.

Technical Backup, Storage, and Space

Equipment, safety, and monitoring. ECMO centers must create an environment for the safe delivery of comprehensive ECMO services, particularly based on operational considerations, such as minimum caseload, communication channels, policies, and procedures, as well as physical facilities and equipment. ECMO is a rapidly developing area, with the advent of simplified and miniaturized circuits replacing larger and more complex circuitry. Equipment selection, which is a function of the clinician providers, and based upon the patient population as well as benchmarking alongside other institutions, will in part define the success of a program in terms of its clinical efficiency, quality and safety, and financial viability. The investment in soon-to-be outdated equipment, which may superficially represent a cost saving to the institutions, may in the longer term represent additional expense and may compromise institutional outcomes.

Integral to the maintenance of a high quality and reliable service is the principle of avoiding unnecessary variation, in order to achieve the best possible patient outcomes. ECMO represents a highly complex and relatively "rare" therapy, and it is essential to maintain consistency in equipment selection as well as policies and procedures wherever possible. This maximizes the ECMO team's familiarity with the technology and minimizes the risk of error. This principle should apply where possible across patient populations (e.g., neonatal vs pediatric) and even between ICU areas in a single institution where ECMO services are decentralized. For example, there is little logic in investing in roller-pump technology in the NICU and centrifugal pumps in other areas. Similar principles apply when selecting an oxygenator, tubing, and monitoring technology. A uniform approach simplifies staff training and, in turn, minimizes error as familiarity is improved. Furthermore, this is fiscally appealing and represents a significant cost saving to the institution, given that backup circuitry is always required for patients on ECMO.

Facilities considerations. Part of the planning process for any new service must include consideration of equipment availability, supplies, and storage. Robust methods of ensuring adequate supplies while avoiding expiration of infrequently used items should also be developed and followed. Equipment malfunction or failure is not acceptable in such a high-risk and time-critical therapy. Institutions may choose to store essential equipment in multiple sites, such as the operating room area, within the ICU, or in combination. Most ECMO centers have a dry or wet-primed circuit to be rapidly available for use around the clock. Although there is no absolute consensus as to the shelf-life of a circuit that has been primed under sterile conditions, there is good evidence that an assembled circuit can be stored for up to 1 month without presenting an additional risk of infection (37).

Non-ICU Support Services

Diagnostic and laboratory support services. When developing an ECMO service, it is important to recognize the expertise necessary from outside the ICU environment and engage the support of these services ahead of implementation, bearing in mind that this may require additional infrastructure from the organization. The executive sponsor should be engaged in assisting with this aspect of developing an ECMO service. The key support services relate to laboratory services, transfusion and blood bank services, and diagnostic imaging, all of which require 24/7 active operations. Laboratory services will need to be prepared to process larger numbers of routine and urgent samples, as well as the maintenance and upkeep of point-of-care devices. The blood bank will be required to have a minimum supply of blood products to be immediately available for ECMO patients at all times. Diagnostic imaging services will be required to provide radiography and rapid interpretation of standard imaging as well as urgent CT and portable ultrasonography. Again, the success of an ECMO program may depend on phasing in aspects of a service which may place excessive additional demands on these support services.

Technological support. ECMO technology itself demands specialized technical support from the hospital's equipment specialists. It may be housed within the perfusion services, within the biomedical engineering departments, within the critical care units, or a combination of these depending on the institutional setup. Equipment selection may in part be guided by maintenance, upkeep, and replacement agreements, and it is therefore essential to engage these services early in the selection process.

Clinical support services. ECMO is a complex therapy that places significant specific medical needs on the patient as well as major emotional, psychological, and financial pressure on the family. Patients supported on ECMO will require adequate assessment and therapy during their ECMO care, after ICU discharge, and in the years following. Allied health services, including physiotherapy, occupational therapy, language services, spiritual support, and social work, are all integral to the planning of an ECMO program. In addition, clinical support services, including nutrition support, respiratory medicine, cardiology, nephrology, neurology, and palliative care, may all be called upon during or after an ECMO run. With the current trend to having ECMO patients more awake and active, the role of physiotherapists and ancillary staff is becoming even more important. Finally, it is essential to remember that most survivors of ECMO should have access to long-term follow-up related not only to their primary indication (e.g., neonatal, pulmonary, or cardiac) but also to additional services, including neuropsychology, developmental pediatrics, neurology, pulmonology, and surgical follow-up, such as vascular surgery and otolaryngology, which may be required to support some of the potential long-term morbidity. Although the number of patients annually referred to these individual services will

not be high, they will be complex patients, often with lifelong needs. A dedicated ECMO clinic that provides follow-up of only ECMO patients is provided in some centers and serves as an effective way of coordinating multidisciplinary care. This is generally well received by families and could be considered as an adjunct when developing an ECMO service.

Step 3–Implementing

Education and Training. Education and training are key determinants of the success and sustainability of an ECMO program. The level of education required will be, in part, determined by the existing expertise of the in-house ECMO team. However, one should not assume that simply because an individual has practiced ECMO in another institution that he/she will be well versed in this therapy or in the technologies that are being introduced locally. Different approaches are used to educate, disseminate, and maintain knowledge, skills, and competency of ECMO personnel and of the program itself. Opinions, shared philosophies, and minimal data exist to define the most efficient and cost-effective educational model. Some ECLS programs will use simulation as an educational tool, and some will use it as an evaluative tool; some for individual ECMO personnel whereas others for team performance training. Specific credentialing requirements that are shared across divisions help to ensure that all staff have similar knowledge of center-specific policies, procedures, equipment, and personnel.

Care models. The ECMO educational process is a challenge due, in part, to the multiple different craft groups and skill sets that an ECMO physician and specialist arise from. This diversity impacts their requirements for additional training in order to deliver high quality care. Furthermore, there is an expectation that all of these individuals will rapidly take on teaching responsibilities themselves as the team grows or undergoes the natural turnover of personnel over time. Although some institutions offer their own ECMO courses (29, 38), there is no mandatory regulatory certification for ECMO clinicians (physicians and specialists). As a result, most institutions have developed internal definitions of competency, depending on the scope of the program, and dialogue between ECMO centers can be used to develop templates for training in new centers. The current approach to ECMO training is the responsibility of the ECMO program director and coordinator. This includes not only development of core competencies but also monitoring compliance to the standards, with regular updates and documentation of the team members' clinical competency. Most centers have created a local training program that includes an institutional ECMO practice manual, didactic courses, and some form of "hands-on" training process. Large ELSO centers have shared their resources so that the wheel is not constantly being reinvented.

Training: current recommendations. ELSO has published some important recommendations, which include "Guidelines for Training and Continuing Education of ECMO Specialists" and "Guidelines for ECMO Centers," which are valuable resources for both current and future ECMO centers (7). Other training resources include the ELSO "Redbook" (1), ELSO ECMO Specialist Training Manual (6), and educational conferences hosted by established ECMO institutions and professional groups.

The ELSO training guidelines recommend an ECMO training course that runs for up to 1 week and includes 24–36 hours of didactic teaching and 8–16 hours of "hands-on" training, or so-called wet labs. The recommended didactic topics include physiology, indications, modes of support, criteria, anticoagulation, pharmacology, equipment, weaning, troubleshooting, and complications, as well as teaching on the ethics of ECMO, early and long-term outcomes, and end-of-life practices (e.g., palliative care, neurologic determination of death, and transition to organ support for donation).

Hands-on ECMO education can be carried out in a variety of settings, including a training room or wet lab, animal laboratories (though now rarely used), or a simulation facility. It should include a review of the equipment, components, functional checks of ECMO equipment, and basic and emergency procedures, with a primary focus on effective ECMO support and patient safety (1). High-fidelity simulation enhances learning through multiple factors, such as providing immediate feedback, allowing repetitive practice, increasing level of difficulty with attainment of skills, addressing multiple forms of learner strategies, and permitting clinical variation in learner responses (39). In a recent survey of ELSO ECMO centers that offer simulation, 71% use simulation to assess competency, 77% to conduct safety drills, and 82% to practice ECLS skills. The simulations traditionally performed included emergency drills (91%), technical skill development (77%), team dynamics including communication (67%), and routine bedside care (60%) (40). High-fidelity simulation has been shown to be an effective training tool in improving confidence and communication within the ECMO team (41, 42). Some essential behavioral skills include familiarity with equipment and the bedside environment, crisis planning, assumption of leadership roles, effective communication, distribution of workload, attention to details, utilization of available resources, request for help early in a crisis, and the maintenance of professional behavior (41, 42).

Assessment of competency. Competency is defined as the knowledge, skills, ability, and behaviors that a person must possess to perform tasks correctly and skillfully (43). ECMO competency should be assessed in theoretical and practical terms. In addition to a written test of theoretical knowledge, three skill sets should be considered when assessing competency, and these are somewhat aligned with the basic tenets of simulation. These are 1) cognitive (critical thinking), 2) technical, and 3) behavioral skill sets. The practical skill set can be assessed both in a training environment and by observation in a clinical setting. A training lab (wet lab or simulation setting) can be used to assess critical thinking skills that include decision making, prioritizing, the performance of day-to-day ECMO tasks, troubleshooting, and response to actual or potential events. Assessment of behavioral skills includes the

evaluation of communication with individuals and groups in a crisis situation. To confirm competency and readiness to care for ECMO patients, observation of actual patient situations in real life and stressful situations is required (44). It is therefore recommended that ECMO specialists in training work alongside experienced staff at the bedside for a predetermined time prior to caring for an ECMO patient alone. These "buddy" shifts must be anticipated by management as required personnel staffing-hours such that it may take several months to render educated new ECMO specialists competent to provide care independently and will typically require between 60 and 100 hours of patient care. In addition to ECMO specialists, physicians, surgeons, and other healthcare providers who are directly involved in the care of the ECMO patient should also be required to achieve competency in understanding the management of the disease on mechanical support, troubleshooting the circuit, and management of anticoagulation.

The First ECMO Patient. It is important that the timeline for introduction of ECMO is realistically set during the planning process, with a "go-live date" that neither presents additional risk due to lack of readiness nor imposes excessive cycles of virtual exposure which impose the risk of training fatigue and even complacency for those being trained.

There are no "rules" for how to approach the first ECMO patient, but a common sense approach would be predetermining the "ideal" patient well ahead of time, as the initial experience for any new high-risk therapy will significantly contribute to the program's success. The first patient will also be, in part, influenced by the spectrum of practice in a given institution. For example, an institution with cardiac surgical services may determine that their first ECMO patient should be an early postoperative patient with an open chest requiring central cannulation, but not in an emergency setting. Similarly, we would recommend that a new ECMO program does not start by attempting ECPR in their early adoption of ECMO. Although all practitioners will accept that ECMO survival in many patient groups is not much more than 50%, there is little doubt that a well-planned ECMO cannulation that does not occur in an emergent setting, and is followed by a smooth run, successful decannulation, and a good outcome, will provide a positive early experience for the program.

When defining the early scope of an ECMO program, exclusion criteria should be set and carefully considered, with particular respect to preexisting brain injury, additional neurologic events, and limited or no likelihood of a reasonable quality outcome for the patient. Often, seeking direct consultation from other more experienced centers or clinicians can be helpful in the early stages of a program. The ECMO community is very open to sharing advice and experiences across centers, and most ECMO medical directors will gladly provide advice directly.

Step 4–Sustaining the Program

Once implemented, an ECMO program must be sustainable. Sustainability relies on continued clinical demand and ideally a growth in the patient population, as well as demonstrable competency, and continuous monitoring and reporting of outcomes. It must also be fiscally sustainable. In addition, professional opportunities for clinical staff will help to retain and attract more individuals to join an ECMO team.

Maintaining Skills. Since ECMO is a high-intensity, low-volume therapy, ECMO centers will need to develop a process to ensure skills retention. This can be defined as a minimum number of pump hours annually as well as regular opportunities for didactic teaching and hands-on refresher courses and regular recertification. The ELSO guidelines recommend that these training sessions are available to all ECMO clinicians or at least every 6 months (1) with a recommendation for annual institutional recertification. There is clearly an opportunity for national, if not international, efforts to streamline ECMO training for specialists and physicians, with the ultimate goal of uniform certification in this highly specialized therapy.

The exposure of staff to ECMO will, in part, depend on the institutional setup. For example, a hospital that centralizes all ECMO to a single ICU will clearly maximize its staff's exposure and be the most resource-efficient compared to decentralized ECMO services. An alternative staffing model that brings the ECMO specialists to the patient in any of the ICU areas achieves a reasonable compromise, whereby a dedicated group of staff care for ECMO patients in more than one physical area. This approach combines the expertise of the non-ECMO clinicians within the parent ICU environment, with the ECMO specialists dedicated to the care of the extracorporeal circuit and all aspects of ECMO management.

All ECMO programs require approaches to maintain bedside competency and institutional systems proficiency for all involved healthcare providers. Specific scenarios to which ECMO specialists and other clinicians may have limited exposure include cannulation, weaning and decannulation, and unforeseen emergencies. Simulation allows for some skills and team performance scenarios to be practiced, but given the competing priorities in an intensive care environment, even adopting a "just in time" daily exercise program may not be sufficient to simulate all the competencies required for all care providers. In addition, the requirement to participate in wet labs and other training techniques as well as didactic teaching, as outlined in step 3, will assist in maintaining skills and knowledge.

The sustainability of an ECMO program is also intimately related to quality and efficiency and to the outcomes of the program. This will be discussed further in the next section.

Step 5–Evaluation

ECMO is a high-risk, infrequent, and complex therapy applied to the sickest patients, many of whom would likely die without it. Complications are very frequent and can be minor, life-threatening, or fatal. Some complications can be anticipated, others occur without warning. The ECMO team should be invested from the outset of the program in accurate and contemporaneous data collection, contributing to a quality cycle of constant evaluation and review, characterized by transparency and a mission for continuous improvement.

Data Collection. When designing a template for data collection, the ECMO leadership team should consider a preemptive submission to the institutional review board for the database as a quality improvement (or assessment) project. This will enable regular quality reviews, as well as the ability to prepare and submit retrospective data for publication. It is in general preferable to prepare a database with institutional research board approval from the outset rather than as a retrospective exercise.

ECMO programs require a robust mechanism for continuous collection of data, generally a primary responsibility of the ECMO coordinator and medical director. Some established ECMO centers may also have a data team, who are responsible for data entry and database management. Ensuring the quality of care delivered on ECMO should include a detailed record of patient demographics, indications, cannulation technique and direct complications (e.g., cerebral hemorrhage), mechanical failure events, additional organ failure, and patient outcome—which are the main components of the ELSO dataset. In addition, institutions should also collect accurate data regarding adherence to care guidelines, exposure to blood products (as a corollary to hemorrhage) and exposure to anticoagulation management, time to delivery of cointerventions (e.g., surfactant or left atrial decompression), and intrahospital transport (e.g., to radiology, the catheter laboratory, or the operating room). One difficulty in data reporting related to ECMO is that many definitions have been poorly standardized. New initiatives aimed at refining definitions globally will enhance data collection and sharing efforts.

Quality Improvement Initiatives

Reporting data. The ECMO leadership team of a new center should encourage a philosophy of collaboration and transparency with data, both locally and with the ECMO community at large. We recommend that all new ECMO centers submit their data to ELSO, as this will provide a useful minimum dataset, with measurable and reportable basic outcomes. Over time, this will provide a useful benchmarking template for an ECMO center. However, the activity of reporting has little impact on improvement unless it is combined with practice change directed at the source of the problem. The direct benefit for a program's quality improvement process to use the ELSO registry's reporting structure is to provide a common set of terms and vocabulary to review each case systematically. The ELSO registry itself allows for rare events (e.g., mechanical failure events) potentially to be evaluated across sites. The detail of data collected via the ELSO registry is limited and centers may choose to record more specific data as well. It is likely that the registry will undergo revision to incorporate more specific data in the near future, although this will require more work for coordinators to record and submit these new data fields until the ECMO technology allows for direct recordings and automated export of log files or data (dialed blood flow, temperature, triggered alarms) into central bedside monitoring systems.

Clinical outcome reviews. A new ECMO center should also schedule regular detailed clinical outcome meetings. This can be scheduled after "every ECMO run" in the first instance, and thereafter on an intermittent basis (e.g., monthly). The goal of these meetings should be to review critically the ECMO course of an individual patient, focusing on actual care delivered, with attention to objective data elements, such as anticoagulation or transfusion practice, outcomes, complications (however minor), and an opportunity to discuss "what worked and what did not and how to do better next time." Another very useful aspect of detailed reviews of individual cases relates to the opportunity for debriefing with the clinicians who were directly involved in the patient's care and to hear their perspectives on the case. Communication is an essential part of continuous quality improvement. It is very rare indeed, even in a well-established service, for an ECMO run to be free of an opportunity for improvement or refinement.

Quality improvement reviews. ECMO quality reviews should be held at least quarterly, to review activity and overall outcomes. These meetings should include medical ECMO leadership as well as the coordinator(s) and senior ECMO clinicians, including surgeons, transfusion physicians and, where appropriate, ECMO administrative leaders. The interprofessional forum also ensures that solutions proposed to improve care are more likely to be implemented, as they are either developed by the frontline input from the healthcare provider or with the input of the broad group responsible for the process. For example, this multidisciplinary forum may be used to review in detail and address issues related to new or recurring problems, such as cannulation site hemorrhage, circuit-related thrombus, end-of-life care, or team and family communication. A detailed review of documentation, together with firsthand reports from involved clinicians, will identify problems early and provide opportunities for practice review and improvement.

Outcomes. Patient outcomes can be considered at multiple levels. First, survival to decannulation or discharge from the ECMO center should be tracked. More useful in terms of defining overall quality of care for a given institution (and ideally across institutions) would be long-term outcomes and function, including discharge home, 6-and 12-month survival, as well as neurodevelopmental function, and monitoring of other long-term morbidities. Even in the absence of a formal follow-up clinic, it is important where possible for an ECMO program to maintain accurate follow-up information for the purposes of quality reviews, accurate knowledge of institutional outcomes, and potentially for research endeavors.

Strategic Planning Meetings. In addition to clinical outcome reviews, the ECMO leadership should meet on a regular basis to discuss contemporary outcomes and to use these data to address programmatic planning, with intermediate goals and endpoints, and to set future directions. Examples may be the consideration of advancing technologies, new approaches to cannulation, new indications for ECMO, and introduction of a service that requires new resources (e.g., ECPR or ECMO transport). Regular (quarterly or biannually) strategic planning meetings with the ECMO leadership team are useful to plan the annual training or budget requirement for the projected caseload. These meetings can be extended to include

key institutional stakeholders—for example, hospital financial leadership and blood bank representation—where appropriate, for input on infrastructure or system needs.

Financial Endpoints. In keeping with developing any new clinical service, another aspect of ongoing quality improvement is assessment of the financial impact of the program on the organization. The performance of the program based on the anticipated business plan should be assessed with other clinical operations. This review should be built in to ensure continuous opportunities to identify strengths and weaknesses within the program, and thus ensure its sustainability.

Step 6–Moving the Program Forward: Research and Innovation

New programs may not view research and innovation as a priority; however, all programs will encounter problems and solve them regularly with new ideas or with solutions that may not be reported in the literature. A new ECMO program should consider an infrastructure for research at the outset, while not necessarily embarking immediately on prospective studies. First, a comprehensive and inclusive database (approved by the institutional research board) should be integral to the development of a program, as this will undoubtedly facilitate future research. Maintaining ELSO membership and up-to-date reporting to this group should also be prioritized. Second, regular quality and clinical practice reviews (as previously outlined) will naturally give rise to questions from which research ideas and studies will develop. Third, participation in ELSO will enable longitudinal reviews and the opportunity to explore topics of interest and potentially to develop prospective collaborative research.

The field of ECMO naturally lends itself to collaborative clinical research, given the relatively small numbers in an institution. Basic and translational investigations can often be aligned with local research expertise, including, but not limited to, CPB-related organ preservation and restoration (15–45), resuscitation and neuroprotection (46–49), transfusion, anticoagulation, and thrombosis (50–52), and pharmacology (53–54), as well as technological advances—including circuit optimization, complications, miniaturization, or cannula development (55–60). Finally, research in the field of education—including simulation, crisis resource management, and debriefing—is becoming increasingly necessary in order to offer efficient, cost-effective education to ensure individual competency and team performance. The delicate balance between innovative practices and standard care is inevitable in the field of ECMO, and this is best addressed in a program that has been structured to allow excellence to be the driving spirit.

REFERENCES

1. Ogino MT, Chuo J, Short BL: ECMO administrative and training issues, and sustaining quality. *In*: ECMO: Extracorporeal Cardiopulmonary Support in Critical Care. Annich GM, Lynch W, MacLaren G, et al (Eds). Extracorporeal Life Support Organization, Ann Arbor, MI, 2012, pp 479–497
2. Kurusz M, Zwischenberger JB: Logistics of an ECMO programme. *Perfusion* 1991; 6:175–181
3. Sachweh JS, Tiete AR, Fuchs A, et al: Efficacy of extracorporeal membrane oxygenation in a congenital heart surgery program. *Clin Res Cardiol* 2007; 96:204–210
4. Valls i Soler A, Lopez Herrera MC, Lopez de Heredia y Goya J, et al: [Extracorporeal membrane oxygenation (ECMO). Is it really needed in Spain?]. *An Esp Pediatr* 1997; 46:261–265
5. Mullany DV, Bull TN, Hunt W, et al: Outcomes of the first 30 cases of an adult extracorporeal membrane oxygenation program: Strategies to manage the "learning curve" and implications for intensive care unit risk adjustment models. *Crit Care Resusc* 2012; 14:119–129
6. Extracorporeal Life Support Organization: ECMO Specialist Training Manual. Extracorporeal Life Support Organization, Ann Arbor, MI, ELSO, 2010
7. ELSO: Guidelines for ECMO Centers, Version 1.7, (2010), and ELSO Guidelines for the training and continuing education of ECMO Specialists, Version 1.5, (2012). Available at: http://www.elsonet.org/index.php/resources/guidelines.html. Accessed April 30, 2013
8. Allan CK, Thiagarajan RR, Beke D, et al: Simulation-based training delivered directly to the pediatric cardiac intensive care unit engenders preparedness, comfort, and decreased anxiety among multidisciplinary resuscitation teams. *J Thorac Cardiovasc Surg* 2010; 140:646–652
9. Combes A, Bacchetta M, Brodie D, et al: Extracorporeal membrane oxygenation for respiratory failure in adults. *Curr Opin Crit Care* 2012; 18:99–104
10. Turner DA, Williford WL, Peters MA, et al: Development of a collaborative program to provide extracorporeal membrane oxygenation for adults with refractory hypoxemia within the framework of a pandemic. *Pediatr Crit Care Med* 2011; 12:426–430
11. Park PK, Napolitano LM, Bartlett RH: Extracorporeal membrane oxygenation in adult acute respiratory distress syndrome. *Crit Care Clin* 2011; 27:627–646
12. Yeung JC, Wagnetz D, Cypel M, et al: Ex vivo adenoviral vector gene delivery results in decreased vector-associated inflammation pre- and post-lung transplantation in the pig. *Mol Ther* 2012; 20:1204–1211
13. Cypel M, Yeung JC, Hirayama S, et al: Technique for prolonged normothermic ex vivo lung perfusion. *J Heart Lung Transplant* 2008; 27:1319–1325
14. Cypel M, Rubacha M, Yeung J, et al: Normothermic ex vivo perfusion prevents lung injury compared to extended cold preservation for transplantation. *Am J Transplant* 2009; 9:2262–2269
15. Cypel M, Keshavjee S: The clinical potential of ex vivo lung perfusion. *Expert Rev Respir Med* 2012; 6:27–35
16. Humpl T, Furness S, Gruenwald C, et al: The Berlin Heart EXCOR Pediatrics–The Sickkids Experience 2004–2008. *Artif Organs* 2010; 34:1082–1086
17. Davis JS, Ryan ML, Perez EA, et al: ECMO hospital volume and survival in congenital diaphragmatic hernia repair. *J Surg Res* 2012; 178:791–796
18. Finks JF, Osborne NH, Birkmeyer JD: Trends in hospital volume and operative mortality for high-risk surgery. *N Engl J Med* 2011; 364:2128–2137
19. Grushka JR, Laberge JM, Puligandla P, et al; Canadian Pediatric Surgery Network: Effect of hospital case volume on outcome in congenital diaphragmatic hernia: The experience of the Canadian Pediatric Surgery Network. *J Pediatr Surg* 2009; 44:873–876
20. Salvin JW, Laussen PC, Thiagarajan RR: Extracorporeal membrane oxygenation for postcardiotomy mechanical cardiovascular support in children with congenital heart disease. *Paediatr Anaesth* 2008; 18:1157–1162
21. Skinner SC, Iocono JA, Ballard HO, et al: Improved survival in venovenous vs venoarterial extracorporeal membrane oxygenation for pediatric noncardiac sepsis patients: A study of the Extracorporeal Life Support Organization registry. *J Pediatr Surg* 2012; 47:63–67
22. Maclaren G, Butt W: Extracorporeal membrane oxygenation and sepsis. *Crit Care Resusc* 2007; 9:76–80
23. Lin YC, Ma JY, Yeh SJ, et al: Use of extracorporeal membrane oxygenation to rescue a newborn with early-onset group B streptococcal sepsis and cardiopulmonary failure. *J Formos Med Assoc* 2004; 103:67–70

24. Rais-Bahrami K, Short BL: Citrobacter sepsis and severe newborn respiratory failure supported with extracorporeal membrane oxygenation. *J Perinatol* 2000; 20:265–266
25. Stewart DL, Dela Cruz TV, Ziegler C, et al: The use of extracorporeal membrane oxygenation in patients with gram-negative or viral sepsis. *Perfusion* 1997; 12:3–8
26. Kumar A, Zarychanski R, Pinto R, et al; Canadian Critical Care Trials Group H1N1 Collaborative: Critically ill patients with 2009 influenza A(H1N1) infection in Canada. *JAMA* 2009; 302:1872–1879
27. White DB, Angus DC: Preparing for the sickest patients with 2009 influenza A(H1N1). *JAMA* 2009; 302:1905–1906
28. Prise en charge des formes graves du Syndrome de Détresse Respiratoire Aigüe liées au A(H1N1) en situation pandémique. Organisation du recours à l'assistance respiratoire extra-corporelle. Ministére des Affaires sociales et de la Santé, France. Available at: http://www.sante.gouv.fr/ecmo,956.html. Accessed April 30, 2013
29. Extracorporeal Life Organization: Extracorporeal life organization meeting listings. Available at: http://www.elsonet.org/index.php/meetings/elso.html. Accessed April 30, 2013
30. Fischer S, Simon AR, Welte T, et al: Bridge to lung transplantation with the novel pumpless interventional lung assist device NovaLung. *J Thorac Cardiovasc Surg* 2006; 131:719–723
31. Van Meurs K, Lally KP, Peek G, et al: ECLS administrative and training issues. *In:* ECMO Extracorporeal Cardiopulmonary Support in Critical Care. Nelson M (Ed). Ann Arbor, MI, ELSO, 2005, pp 235–252
32. Carli P. Prehospital cardiac arrest and ECMO: State of art. Arrêt cardiaque extrahospitalier et l'ECMO: Mise au point. *E-Mém l'Acad Natl Chir* 2010; 9:10–13
33. Moreno-Cabral RJ, Dembitsky WP, Adamson RM, et al: Percutaneous extracorporeal membrane oxygenation. *Adv Card Surg* 1994; 5:163–179
34. Reickert CA, Schreiner RJ, Bartlett RH, et al: Percutaneous access for venovenous extracorporeal life support in neonates. *J Pediatr Surg* 1998; 33:365–369
35. Shinn SH, Lee YT, Sung K, et al: Efficacy of emergent percutaneous cardiopulmonary support in cardiac or respiratory failure: Fight or flight? *Interact Cardiovasc Thorac Surg* 2009; 9:269–273
36. Sung K, Lee YT, Park PW, et al: Improved survival after cardiac arrest using emergent autopriming percutaneous cardiopulmonary support. *Ann Thorac Surg* 2006; 82:651–656
37. Walczak R, Lawson DS, Kaemmer D: Evaluation of a pre primed microporous hollow fiber membrane for rapid response ECMO. *Perfusion* 2005; 20:269–275
38. International Course on ECMO and short term circulatory/respiratory support, 2012. Available at: http://www.paris-ecmo.org/. Accessed April 30, 2013
39. Issenberg SB, McGaghie WC, Petrusa ER, et al: Features and uses of high-fidelity medical simulations that lead to effective learning: A BEME systematic review. *Med Teach* 2005; 27:10–28
40. Oldenburg G, Riley J, Ogino MT: Who are we? ELSO simulation survey results. ELSO Annual Meeting Pre-Conference. Seattle, WA, September 13, 2012
41. Anderson JM, Boyle KB, Murphy AA, et al: Simulating extracorporeal membrane oxygenation emergencies to improve human performance. Part I: Methodologic and technologic innovations. *Simul Healthc* 2006; 1:220–227
42. Anderson JM, Murphy AA, Boyle KB, et al: Simulating extracorporeal membrane oxygenation emergencies to improve human performance. Part II: Assessment of technical and behavioral skills. *Simul Healthc* 2006; 1:228–232
43. The Joint Commission: The joint commission e-dition: Accreditation, 2011. Available at: http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx. Accessed April 30, 2013
44. Miller GE: The assessment of clinical skills/competence/performance. *Acad Med* 1990; 65(9 Suppl):S63–S67
45. Cypel M, Yeung JC, Keshavjee S: Novel approaches to expanding the lung donor pool: Donation after cardiac death and ex vivo conditioning. *Clin Chest Med* 2011; 32:233–244
46. Joffe AR, Lequier L, Robertson CM: Pediatric outcomes after extracorporeal membrane oxygenation for cardiac disease and for cardiac arrest: A review. *ASAIO J* 2012; 58:297–310
47. Wu X, Drabek T, Tisherman SA, et al: Emergency preservation and resuscitation with profound hypothermia, oxygen, and glucose allows reliable neurological recovery after 3 h of cardiac arrest from rapid exsanguination in dogs. *J Cereb Blood Flow Metab* 2008; 28:302–311
48. Prodhan P, Fiser RT, Dyamenahalli U, et al: Outcomes after extracorporeal cardiopulmonary resuscitation (ECPR) following refractory pediatric cardiac arrest in the intensive care unit. *Resuscitation* 2009; 80:1124–1129
49. Raymond TT, Cunnyngham CB, Thompson MT, et al; American Heart Association National Registry of CPR Investigators: Outcomes among neonates, infants, and children after extracorporeal cardiopulmonary resuscitation for refractory inhospital pediatric cardiac arrest: A report from the National Registry of Cardiopulmonary Resuscitation. *Pediatr Crit Care Med* 2010; 11:362–371
50. Hanson SJ, Punzalan RC, Christensen MA, et al: Incidence and risk factors for venous thromboembolism in critically ill children with cardiac disease. *Pediatr Cardiol* 2012; 33:103–108
51. Agati S, Ciccarello G, Salvo D, et al: Use of a novel anticoagulation strategy during ECMO in a pediatric population: Single-center experience. *ASAIO J* 2006; 52:513–516
52. Ranucci M, Ballotta A, Kandil H, et al; Surgical and Clinical Outcome Research Group: Bivalirudin-based versus conventional heparin anticoagulation for postcardiotomy extracorporeal membrane oxygenation. *Crit Care* 2011; 15:R275
53. Wildschut ED, Ahsman MJ, Allegaert K, et al: Determinants of drug absorption in different ECMO circuits. *Intensive Care Med* 2010; 36:2109–2116
54. Wildschut ED, Ahsman MJ, Houmes RJ, et al: Pharmacotherapy in neonatal and pediatric extracorporeal membrane oxygenation (ECMO). *Curr Drug Metab* 2012; 13:767–777
55. Yokoyama N, Suzuki M, Hoshi H, et al: Feasibility of a TinyPump system for pediatric CPB, ECMO, and circulatory assistance: Hydrodynamic performances of the modified pump housing for implantable TinyPump. *ASAIO J* 2007; 53:742–746
56. Said MM, Rivera O, Mikesell GT, et al: Evaluation of the new generation dual-lumen catheter for neonatal ECMO. *Perfusion* 2013; 28:26–30
57. Spurlock DJ, Toomasian JM, Romano MA, et al: A simple technique to prevent limb ischemia during veno-arterial ECMO using the femoral artery: The posterior tibial approach. *Perfusion* 2012; 27:141–145
58. Horton S, Thuys C, Bennett M, et al: Experience with the Jostra Rotaflow and QuadroxD oxygenator for ECMO. *Perfusion* 2004; 19:17–23
59. Burnside J, Gomez D, Preston TJ, et al: In-vitro quantification of gaseous microemboli in two extracorporeal life support circuits. *J Extra Corpor Technol* 2011; 43:123–129
60. Meyer AD, Wiles AA, Rivera O, et al: Hemolytic and thrombocytopathic characteristics of extracorporeal membrane oxygenation systems at simulated flow rate for neonates. *Pediatr Crit Care Med* 2012; 13:e255–e261