

Neonatal Extracorporeal Membrane Oxygenation Devices, Techniques and Team Roles: 2011 Survey Results of the United States' Extracorporeal Life Support Organization Centers

Scott Lawson, MS, CCP; Cory Ellis, BS, CCP; Katie Butler, BSN, RN;
Craig McRobb, MS, CCP; Brian Mejak, BS, CCP

Department of Circulatory Support, Children's Hospital Colorado, Aurora, Colorado

Abstract: In early 2011, surveys of active Extracorporeal Life Support Organization (ELSO) centers within the United States were conducted by electronic mail regarding neonatal Extracorporeal Membrane Oxygenation (ECMO) equipment and professional staff. Seventy-four of 111 (67%) U.S. centers listed in the ELSO directory as neonatal centers responded to the survey. Of the responding centers, 53% routinely used roller pumps for neonatal ECMO, 15% reported using centrifugal pumps and 32% reported using a combination of both. Of the centers using centrifugal pumps, 51% reported that they do not use a compliance bladder in the circuit. The majority (95%) of roller pump users reported using a compliance bladder and 97% reported using Tygon® S-97-E tubing in the raceway of their ECMO circuits. Silicone membrane oxygenators were reportedly used by 25% of the respondents, 5% reported using micro-porous hollow fiber oxygenators (MPHF), 70% reported using polymethylpentene

(PMP) hollow fiber oxygenators and 5% reported using a combination of the different types. Some form of in-line blood monitoring was used by 88% of the responding centers and 63% of responding centers reported using a circuit surface coating. Anti-coagulation monitoring via the activated clotting time (ACT) was reported by 100% of the reporting centers. The use of extracorporeal cardiopulmonary resuscitation (ECPR) was reported by 53% of the responding centers with 82% of those centers using a crystalloid primed circuit to initiate ECPR. A cooling protocol was used by 77% of the centers which have an ECPR program. When these data are compared with surveys from 2002 and 2008 it shows that the use of silicone membrane oxygenators continues to decline, the use of centrifugal pumps continues to increase and ECMO personnel continues to be comprised of multidisciplinary groups of dedicated allied health care professionals. **Keywords:** ECMO, equipment, survey, devices. *JECT. 2011;43:236–244*

The use of extracorporeal membrane oxygenation (ECMO) for respiratory and/or cardiac failure continues to be the best support mechanism for a select group of critically ill patients. The first reported use of ECMO was described by Hill et al. in 1972 (1). The Extracorporeal Life Support Organization (ELSO) Registry reports an overall survival rate of 62% for all patients on ECMO. This survival rate of 62% represents 29,216 neonatal, 11,212 pediatric, and 4396 adult patients who have been treated with ECMO since 1979 (2). This survey was designed to ascertain both the current trends regarding devices routinely used in neonatal ECMO and a breakdown of current ECMO team roles. Several surveys have

been developed to ascertain both the current trends regarding devices routinely used in neonatal ECMO and a breakdown of the ECMO team roles (3–6). We began to notice change within the ECMO community's choice of equipment and its use of personnel with our first survey in 2002. This trend of change was again present in our 2008 survey of U.S. ECMO centers. Recent literature (7,8) has provided evidence of a continuation of this change, leading to this survey. The purpose of the current survey is to document any further shifts within the ECMO device paradigm and professional staffing practices since the 2008 survey and to compare these data with those from prior surveys on the same topic done in 2002 and 2008 by the authors. Comparison of these surveys will give the reader an understanding of the general trends, both past and present, that device use and personnel management are currently heading within the ECMO community. Extracorporeal cardiopulmonary resuscitation (ECPR) is a new section to this series of surveys. The practice of rapid initiation onto ECMO during cardiac arrest is currently

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Address correspondence to: Scott Lawson, MS, CCP, Department of Circulatory Support, Children's Hospital Colorado, 13123 East 16th Avenue, Box 100, Aurora, CO 80045. E-mail: Scott.Lawson@childrenscolorado.org
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being studied and the initial reports are encouraging for improved outcomes (9). The survey inquired as to which of the responding centers used ECPR, the main components of their circuit prime, if the patients undergoing ECPR were cooled globally, and if so, for how long cooling was used.

MATERIAL AND METHODS

Between January and March 2011, U.S. ECMO programs listed in the ELSO Directory ($n = 111$) were contacted by e-mail with a survey of current neonatal ECMO equipment use and ECMO team responsibilities. The survey was sent to the ECMO coordinator of each active U.S. neonatal ELSO program. Nonresponders, only, were selected for repeat survey mailings to increase the response rate. The institutional name of the responding center was recorded so that only one survey response per center was received and recorded into a Microsoft Excel database (Microsoft, Redmond, WA). Twenty-four questions were asked of the ECMO coordinators in fill-in-the-blank format.

RESULTS

Of the 111 U.S. ELSO centers that currently treat neonates, 74 centers responded to the survey indicating a 67% response rate.

Equipment

The majority of ELSO registered neonatal U.S. ECMO centers still use a roller pump for ECMO (85%). Of those centers, 97% use Tygon S-95-E tubing in the pump raceway (Saint-Gobain Performance Plastics, Akron, OH). Additionally, 95% of responding roller pump users reported using a venous compliance reservoir. The BB14 BetterBladder (Circulatory Technology Inc., Oyster Bay, NY) was used by 42% of the respondents, 29% reported using the Medtronic R14 reservoir (Medtronic, Inc., Minneapolis, MN), 13% reported using the Gish VRECMOB reservoir (formerly Gish Biomedical, Inc., no longer available), 11% reported using a homemade compliance reservoir, and 5% reported that they do not use a venous compliance reservoir in conjunction with a roller pump. Servoregulation was achieved with pressure measurement at 92% of the centers using a roller pump and 8% used mechanical servoregulation using a bladder box (Origen Biomedical Inc., Austin, TX).

A centrifugal pump was used as the arterial pump at 47% of the responding centers. The most commonly used centrifugal pump was the Maquet Rotaflow; 51% of the responding centers using centrifugal pump technology used the Rotaflow. The result of number and type of centrifugal pump used is reported in Figure 1. No venous compliance reservoir was used by 51% of the centrifugal pump users.

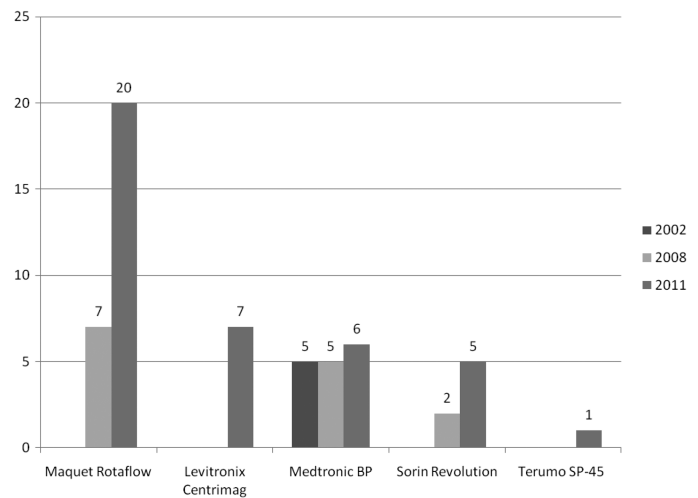


Figure 1. Number of the different centrifugal blood pumps reportedly used for extracorporeal membrane oxygenation in 2002, 2008, and 2011.

Of the remaining centers using centrifugal pumps and a compliance reservoir, 46% used the BB14 BetterBladder and 3% used a homemade device. Negative pressure monitoring on the venous line was used by 83% of the centrifugal pump users.

Many of the reporting centers (32%) used both a roller pump and a centrifugal pump for neonatal ECMO at the time of the survey.

The Maquet Pediatric Quadrox D polymethylpentene (PMP) oxygenator was routinely used by 55% of the responding centers for neonatal ECMO applications. The Medtronic 0800 silicone oxygenator was used by 25%, the Maquet Adult Quadrox D PMP device was used by 15%, the Medtronic Minimax microporous hollow fiber (MPHF) device was used by 4%, and the Terumo FX05 MPHF device was used by 1% of the responding centers.

Extracorporeal surface modification was used by 63% of the responding centers. The Medtronic Carmeda coating was used by 40% of the responding centers, 28% used the Maquet Bioline coating, the Sorin Group's Phosphorylcholine coating was reported by 10%, the Medtronic Trillium coating was reported by 8%, the Terumo X coating was reported by 6%, the Gish Biomedical GBS coating (no longer available) was reported by 6%, and the Maquet Safe-line coating was reported by 2% of the responding centers.

Monitoring

Inline blood parameter monitoring was reported by 88% of the responding centers.

The Terumo CDI 500 System was used by 63% of centers, use of the Spectrum Medical System M (Spectrum Medical, Inc., Charlotte, NC) device was reported by 20%, the Terumo CDI 101 System was used by 14%, Sorin Group's Cobe Sat/Hct monitor was used by 2% of the responding centers, and the Medtronic Biotrend monitor was used by 1%.

Anticoagulation monitoring through an activated clotting time (ACT) was reported by 100% of centers, 74% routinely monitor prothrombin time (PTT), 64% monitor partial thromboplastin time (PTT), 45% monitor anti-thrombin 3 (AT3) levels, and 40% reported routinely monitoring (heparin concentration (hep)). The fibrinogen level was routinely monitored at 8% of the responding centers, 7% monitored thromboelastograph (TEG), and 1% monitored D-dimer levels routinely.

The average low range ACT reported was 179 seconds and the average high range ACT was 208 seconds. The Hemochron Junior Signature Elite (International Technidyne, Edison, NJ) ACT device was used by 30% of the responding centers. The remaining devices used for ACT monitoring are listed in Figure 2.

Personnel

At 58% of the center's a team of certified clinical perfusionists (CCPs) are the personnel responsible to set up, prime, and initiate ECMO; they are also responsible for troubleshooting technical problems with the ECMO circuits. Registered nurses (RN) perform these duties at 26% of the centers, respiratory therapists (RTs) are responsible for these duties at 10%, and combinations of RNs and RTs fill this role at 12% of responding centers.

Traditionally, ECMO specialists are recruited from a wide variety of hospital departments. This continues to be the trend because a team comprised of RNs and RTs make up the team of ECMO specialists at 44% of the responding centers. A team of RNs alone made up 25% of responding centers, RTs alone made up 16%, and CCPs alone made up 10% of responding centers ECMO specialist teams. A combination of RNs, RTs, and CCPs made up 3% and a combination of CCPs and RTs made up the remaining 2%.

Extracorporeal Cardiopulmonary Resuscitation

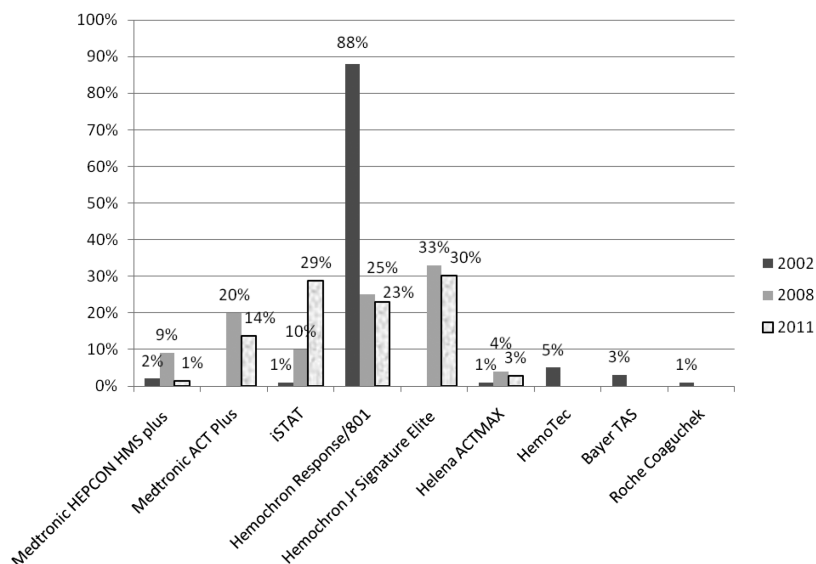
The use of ECPR was reported by 53% of the responding centers with 82% of those centers using a crystalloid primed circuit to initiate ECPR. A cooling protocol was used by 77% of the centers that have an ECPR program. Of those programs with a cooling protocol, 49% cool to 34°C, 28% cool to 35°C, and 23% remained at 36°C. The duration of cooling was 12–24 hours for 36% of centers and 24–72 hours for 45% of the responding centers. At 13% of the centers, this timeframe varied and 7% of the centers stayed cold for the entire ECMO run.

DISCUSSION

ECMO continues to be an extremely valuable support mechanism to a select group of critically ill patients worldwide. As of January 2011, the total number of ECMO runs reported to ELSO was 44,824 (2). Although the fundamental basis for ECMO support has remained unchanged, the equipment used to provide this support continues to evolve.

When examining the type of blood pump used for ECMO, the survey data shows that centrifugal pumps are rapidly gaining widespread acceptance. In 2002, only a small percentage of the responding centers reported routinely using centrifugal pumps; in 2008, that number grew significantly and in this most recent survey, nearly half of the responding centers report using centrifugal blood pumps for ECMO (Figure 1). It is also noteworthy that currently 32% of the responding centers routinely use both a roller pump and a centrifugal pump for neonatal ECMO compared with 23% in 2008. Many of the responses to this query indicate that centers are currently in a state of change toward centrifugal pumps. As these centers transition to

Figure 2. Percentage of the different types of ACT monitoring devices reportedly used for extracorporeal membrane oxygenation in 2002, 2008, and 2011. ACT, activated clotting time.



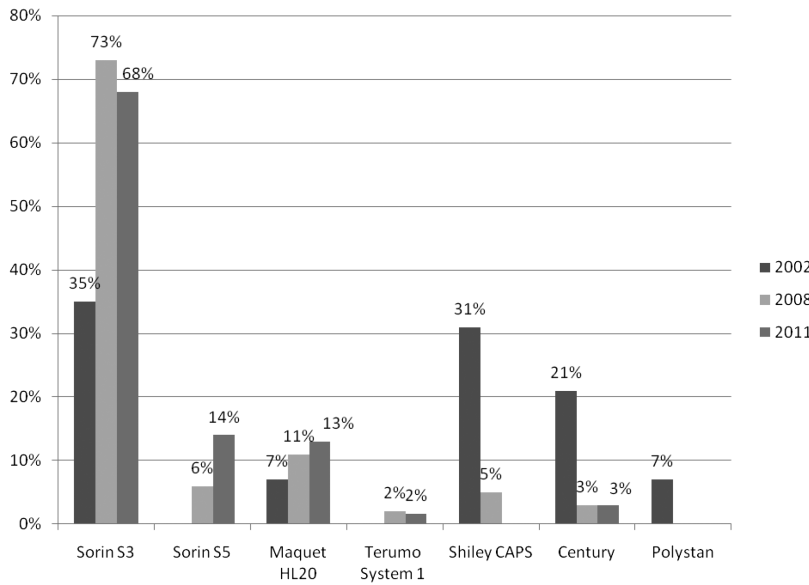


Figure 3. Percentage of the different roller blood pumps reportedly used for extracorporeal membrane oxygenation in 2002, 2008, and 2011.

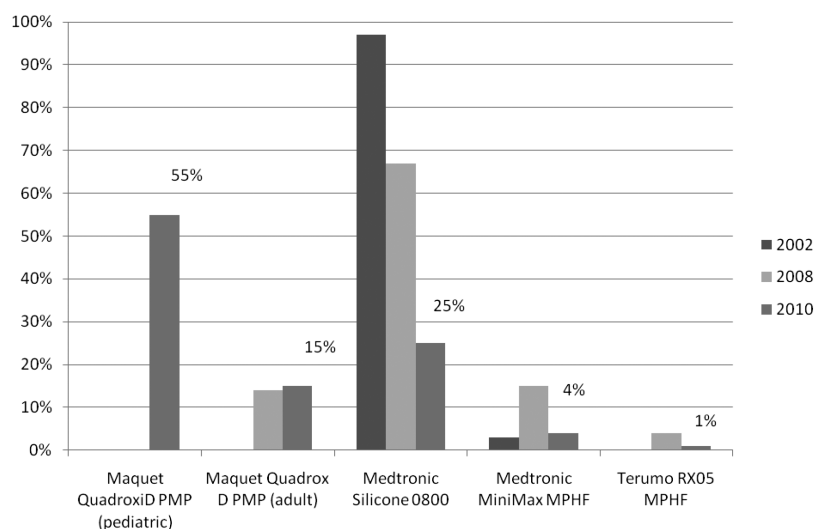
their new pump systems, they still have roller pumps in use until hospital budgets allow for complete changeover.

Roller pumps still make up the majority of ECMO pumps used worldwide according to this most recent survey with 85% of the responding centers reporting roller pump use. The distribution of roller pump manufacturers is similar to that of the 2008 survey except for a slight increase in Sorin S5 use and a corresponding decrease in Sorin S3 use (Figure 3).

Oxygenator technology is another area of ECMO equipment that has changed significantly over the past few years. Surveys by others have reported higher rates of use of hollow fiber-type oxygenators and higher rates of use of centrifugal pumps than surveys from our group. It is likely that these differences in reported rates are related to the respondent groups and to the patient populations treated by respondents. The surveys by Gundst in 2004 (10) and Groom in 2005 (11) were of perfusionists at cardiac surgery programs in the United States. Respondents likely were reporting use of ECMO for postcardiotomy support. Our current survey and prior surveys from 1990 (4) and 2002 (6) were directed to ELSO Registry participants and likely encompass a more broad use of ECMO than the more specific use (postcardiotomy failure) addressed in their surveys. At the time of the survey done in 2008, PMP fiber technology was just becoming available in the United States in an adult size without extracorporeal surface modification as an option. During the relatively short period of time that this new fiber technology has become readily available in the United States (approved for 6 hours of continuous use by the U.S. Food and Drug Administration [FDA]), there has been a very significant shift toward its use because the current survey reports that 70% of the responding centers use PMP technology. The results for

current neonatal ECMO oxygenator use are summarized in Figure 4. Some of the advantages of PMP fiber technology include: the surfaces of the fibers can be modified using both heparin and nonheparin surface modification techniques, they do not leak plasma leading to consistent premature device failure, the ease and quickness of oxygenator priming, and improved flow characteristics with very low transmembrane pressure drops and minimal insensible water loss (12,13). Khoshbin et al. showed that PMP oxygenators decreased the amount of inflammation post-ECMO initiation as compared with silicone devices (14). The march of progress can be relatively slow as indicated by 25% of the respondents still using silicone membrane oxygenators. This result could be attributable to the comfort some have with old technology and the knowledge that with new technology, the inevitable learning curve events also occur. It could also be the result of the lack of U.S. FDA approval of PMP oxygenators for use longer than 6 hours. The 2008 survey showed a slight increase in the use of MPHf devices that is likely the result of a number of centers looking for the advantages of quick priming, surface modification options, and improved flow dynamics over silicone devices. However, MPHf devices leak plasma across the hollow fibers over time as a result of phospholipid concentration in the blood, which can result in the device failing to transfer oxygen (15). Because PMP devices have the same advantages as MPHf devices without the problem of premature device failure from protein leakage, it is no surprise that the use of MPHf devices has fallen out of favor. The survey from 2008 showed the first signs of a shift in the ECMO equipment paradigm from roller pumps and silicone membrane oxygenators toward centrifugal pumps and hollow fiber oxygenator technology, the most recent survey data confirm that this shift is proceeding.

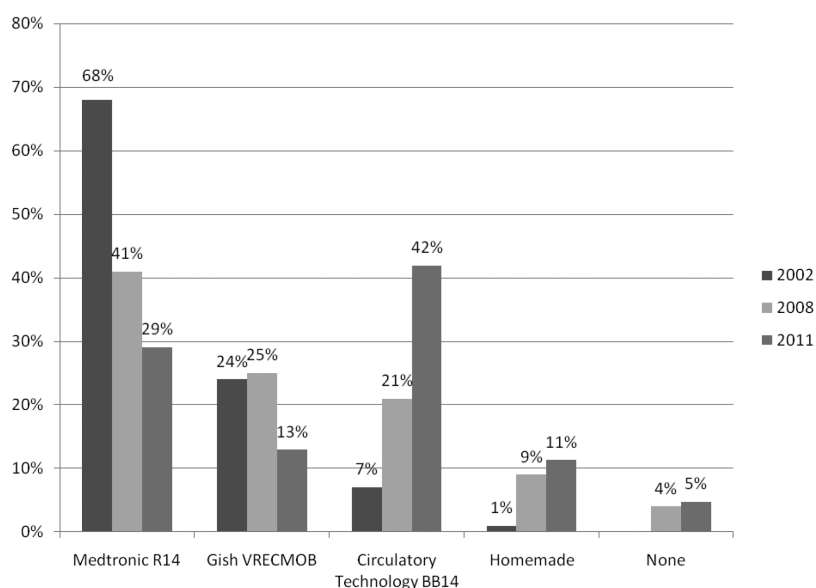
Figure 4. Percentage of the different oxygenators reportedly used for extracorporeal membrane oxygenation in 2002, 2008, and 2011.



Some ECMO clinicians are advocating a very simple ECMO circuit with minimal access and very short line lengths (16). The widespread acceptance of the newer centrifugal pump technology and PMP oxygenator technology is making it feasible to design this type of extracorporeal circuitry with safety in mind. Safety is improved as a result of reduced access sites and hence reduced incidence of human error at these access sites. Reduced line lengths ensure smaller prime volumes and surface areas decreasing the blood to a foreign surface interface and may lead to bed-mounted ECMO systems, which would make ECMO transport safer. Elimination of the ECMO bridge, or the use of a stopcock bridge, would eliminate the transient volume and pressure shifts to ECMO patients' cerebral circulation (17–19).

The use of a venous compliance reservoir was reported by 95% of the roller head users and by 49% of the centrifugal pump users. It is noteworthy that 5% of the roller head users did not use a bladder and that 51% of the centrifugal pump users likewise refrained. The lack of a venous compliance reservoir could be very dangerous to the right atrium of patients placed on an ECMO system that uses a roller pump for ECMO flow. The absence of this reservoir within a centrifugal pump system is more understandable because this system is believed to be more forgiving when preload is lacking. The distribution of venous compliance reservoirs for roller head users is shown in Figure 5. For centrifugal pump users, 46% used the Circulatory Technology BB14 and 3% used a homemade version of a bladder.

Figure 5. Percentage of the different venous compliance bladders used for extracorporeal membrane oxygenation (roller head pumps only) in 2002, 2008, and 2011.



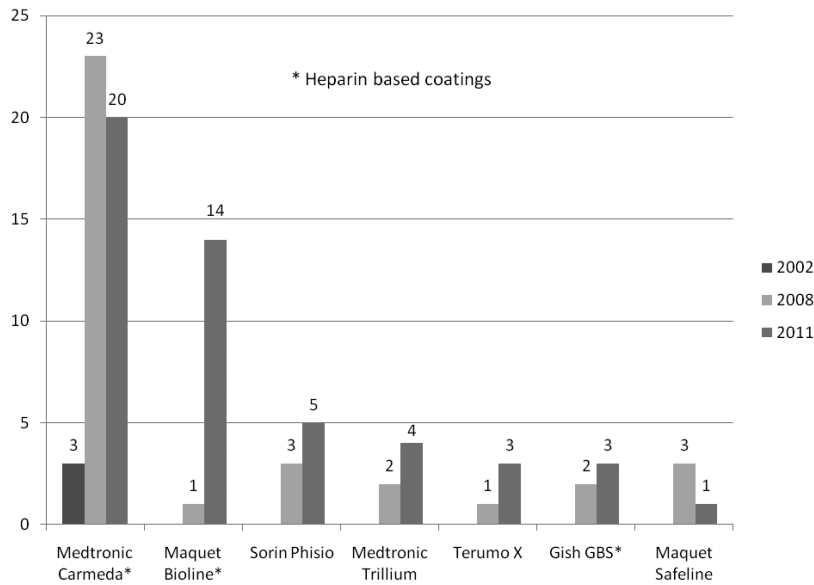


Figure 6. Number of different surface coatings used for extracorporeal membrane oxygenation in 2002, 2008, and 2011.

An extracorporeal surface modification, or coating, was used by 63% of the responding centers. This is compared with 44% in 2008 and a mere 8% in 2002. There is a general lack of data to support the use of a circuit coating in an ECMO setting. Burkhart et al. reported that the use of a Medtronic Carmeda coating, a heparin surface coating, eliminated the release of plasticizers from products used in extracorporeal circulation (20). Despite the general lack of outcome data regarding circuit coatings, the percentage of centers using them continues to increase. This is likely the result of a perceived advantage of surface modification with a decreasing cost difference between coated and uncoated circuits. There is also the theory that with a bleeding cardiac patient placed on ECMO for acute

cardiac distress, the managing clinician feels it is safe to minimize or withhold systemic heparin administration for a short amount of time when using a coated ECMO circuit. This strategy has not been studied widely; however, the practice continues. The number of centers using each type of coating is seen in Figure 6.

The use of inline, continuous blood parameter analysis was reported by 88% of the survey's responding centers. These data are slightly higher than the 2008 survey in which 64% of centers used these types of devices and significantly higher than the 5% recorded in 2002. The Terumo CDI 501 device continues to be the most commonly used monitor of this type; however, the Spectrum Medical M3 device has made significant gains. It will be

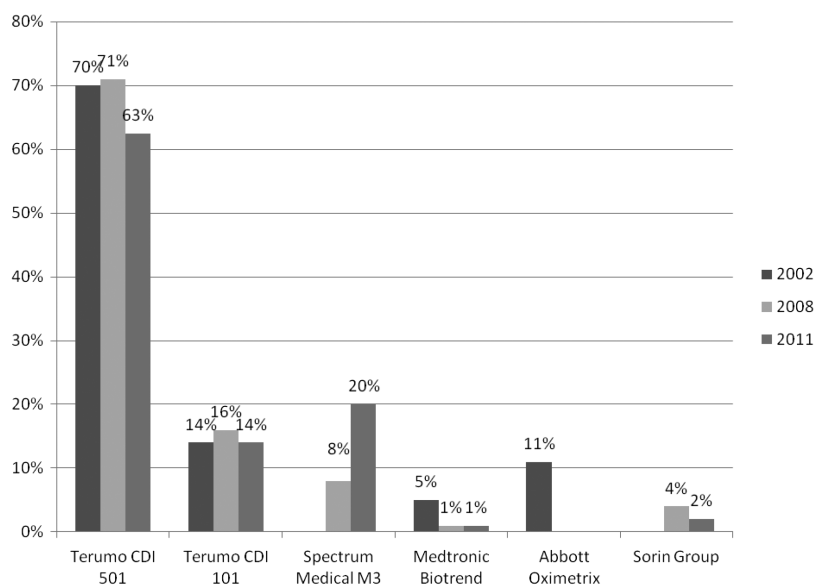


Figure 7. Percentage of the different in-line blood parameter monitors used for extracorporeal membrane oxygenation in 2002, 2008, and 2011.

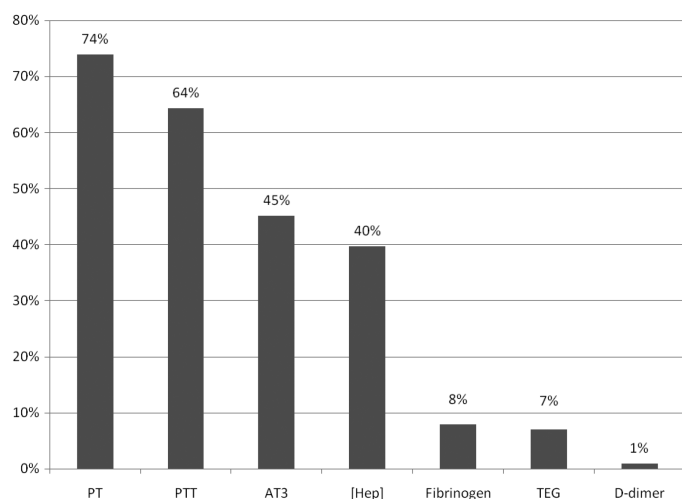


Figure 8. Percentage of the different anticoagulation monitoring tests, other than the ACT, used for extracorporeal membrane oxygenation in 2002, 2008, and 2011. PT, prothrombin time; PTT, partial thromboplastin time; AT3, antithrombin 3; [Hep], heparin concentration; TEG, thromboelastograph.

of interest to observe the future of these types of monitoring devices as ECMO professionals try to simplify and minimize ECMO circuits. The distribution of inline blood parameter analyzer use is seen in Figure 7.

Anticoagulation monitoring using the ACT continues to be universally accepted. The average ACT low range derived from the respondents was 179 seconds and the average high range was 208 seconds. A distribution chart of other types of anticoagulation monitoring (PT, PTT, heparin concentration, AT3, fibrinogen, TEG, and D-dimer levels) is seen in Figure 8. These assays were not queried in previous surveys, but the authors believe that the use of heparin concentration and AT3 level monitoring is

increasing and the collection of these data is seen as useful for prospective surveys. ECMO professionals are beginning to understand that the ACT test in isolation is of limited value in understanding an ECMO patient's overall level of anticoagulation.

The demographics of a team of ECMO specialists continue to evolve (Figure 9). RNs continue to dominate the structure of most centers' team of ECMO specialists and it appears that perfusionists acting as an ECMO specialist has reached a plateau. A multidisciplinary group of RNs and RTs continues to be the most common makeup of this team because this type of specialist group has seen a steady gain in popularity since the survey in 2002. There has been a dramatic increase in the percentage of perfusionists who set up, prime, troubleshoot, and round on patients on ECMO since 2002 and even from 2008 until the present (Figure 10). This sharp rise in perfusionist involvement in ECMO may be the result of educational outreach by the American Society of Extracorporeal Technology's (AmSECT) Pediatric Perfusion Committee (PPC). The AmSECT PPC has been involved with promoting perfusion involvement in ECMO programs for quite a few years by encouraging and educating pediatric CCPs that ECMO involvement does not have to entail sitting at the bedside 24 hours a day. More ECMO programs may have found that CCP services would be better used by setting up, priming, and troubleshooting the ECMO circuit as well as rounding on patients on ECMO (21).

ECPR is another new section to this series of surveys. The practice of rapid initiation of ECMO support during cardiac arrest is currently being studied and the initial reports are positive (9). The responses to this section of the survey (Figure 11) showed that a majority of centers used some form of ECPR. Most of these centers used a

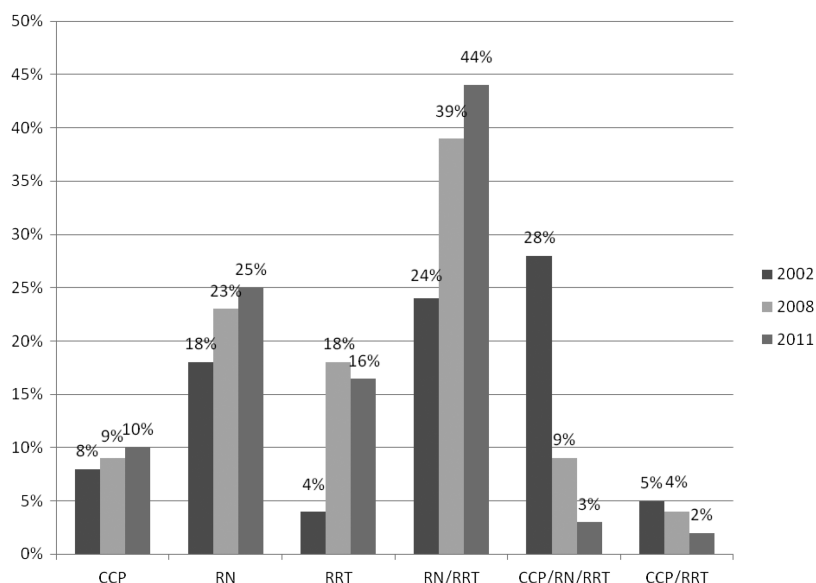


Figure 9. Percentage of allied health professionals who act as extracorporeal membrane oxygenation specialists reported from 2002, 2008, and 2011. CCP, certified clinical perfusionist; RN, registered nurse; RRT, registered respiratory therapist.

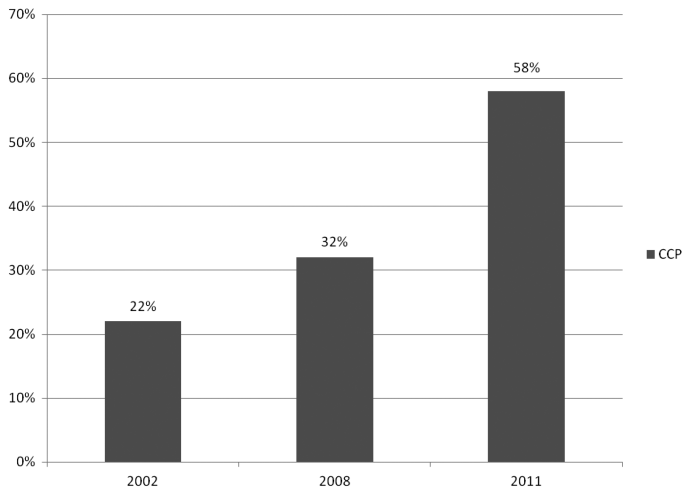


Figure 10. Percent of CCPs reportedly involved in extracorporeal membrane oxygenation in 2002, 2008, and 2011. CCP, certified clinical perfusionist.

crystalloid prime to initiate ECPR. When a patient has cardiac arrest, the time it takes to initiate ECMO support is critical and this is the reason many centers use a crystalloid prime rather than wait to receive uncrossmatched, O-negative emergency release packed red blood cells. Many of these centers who use crystalloid prime stated that if time allowed, they would go ahead and add blood to the ECMO circuit.

In conclusion, since 2002, the shift away from silicone oxygenator use continues and from 2008, there has been a significant increase in the use of PMP devices. This can be attributed to the ease of access to these devices previously difficult to obtain in the United States. There may be a clear advantage to PMP oxygenators over silicone devices and the majority of U.S. centers have accepted this as fact.

There continues to be movement away from roller head blood pumps toward centrifugal pump technology. In 2002, only five responding centers routinely used centrifugal pumps for neonatal ECMO applications, whereas 39 centers report routine use in 2011. This represents an eight-fold increase in usage over a 9-year period. The use of circuit surface modifications has likewise grown in an unprecedented fashion. In 2002, three neonatal centers routinely used a surface coating; however, from this survey, 50 centers reported using a surface coating. This represents a 16-fold increase in routine use of circuit coatings despite a lack of strong scientific evidence to support that this technology has an outcome benefit in the ECMO population. Perfusionists are more involved with ECMO programs than ever before. In 2011, there were nearly twice as many perfusionists involved in ECMO than in 2008 and nearly three times as many as from 2002. For CCPs as a group, this is a very gratifying statistic because it has been stated that the employment of CCPs within an ECMO program makes that program better able to care for patients on ECMO (3).

Survey methodology can be corrupted by errors as a result of incomplete sampling or as a result of misinterpretation of survey questions by the respondents. To reduce these types of error, repeated attempts to elicit responses from ELSO centers was attempted to increase the sampling pool. Also, follow-up communication was used when responses did not address the query in a logical fashion. This survey provides information on ECMO practices from ELSO Registry participants. Like with all surveys, the possibility of sampling bias exists. This survey represents the practice pattern of ELSO Registry participants, because each of the registry participants was provided with equal opportunity to respond and overall response rate and program broad spectrum of program demographics

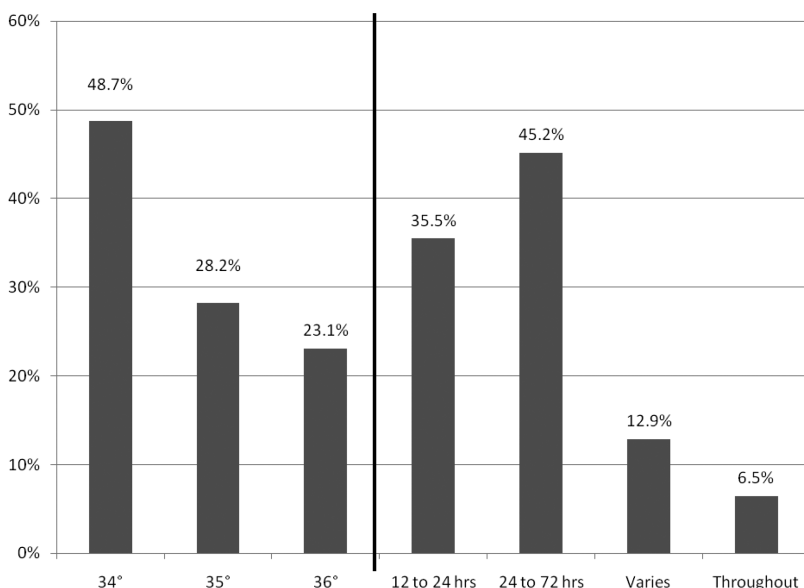


Figure 11. Temperature control and duration of temperature manipulation reported for extracorporeal membrane oxygenation in 2011. ECPR, extracorporeal cardiopulmonary resuscitation. 34° = 34°C; 35° = 35°C; 36° = 36°C. Varies, no specific time frame established; Throughout, a designated temperature is used during the entire ECMO run.

suggest that these results represent the current practice of ELSO registry participants.

This survey describes trends in current ECMO device use and should not be used to set criteria for practice.

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