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North American Neonatal Extracorporeal Membrane Oxygenation (ECMO) Devices: 2002 Survey Results

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Abstract: In mid 2002, surveys of active extracorporeal membrane oxygenation (ECMO) centers in the United States and Canada were conducted via E-mail regarding neonatal equipment and personnel. Seventy-four out of 99 (75%) North American ECMO centers listed in the Extracorporeal Life Support Organization (ELSO) directory responded to the survey. Of the responding centers, 95% use roller pumps, and the remaining 5% use centrifugal pumps. Silicone membrane oxygenators were used by 97% of the respondents, while 3% used hollow fiber oxygenators. Of the silicone membrane oxygenator users, 82% used the Medtronic ECMOtherm heat exchanger, 15% used a Gish heat exchanger, and 3% used the Dideco D720 heat exchanger. Sixty-one percent of the responding centers used some form of in-line blood gas monitoring. Five percent of the centers used a bubble trap in the arterial line, and 12% used an arterial line filter. A bladder was used by 92% of the centers, and 29% used a mechanical bladder box for servo regulation, the remaining 71% used pressure servo regulation. An air bubble detector was used by 65% of the responding centers, although 81% had the device available. Heparin coating was used by 5% of the centers on all their neonatal ECMO patients. The average low range ACT was 183 seconds, and the average high range ACT was 216 seconds. At 49% of the responding centers, perfusionists were involved with the ECMO program, registered nurses were involved at 84% of the centers, and respiratory therapists were involved at 61% of the centers, perfusion assistants were involved at one center (1%), and biomedical engineers were involved at one of the centers. When compared to a 1990 survey, a shift away from using bladder boxes and toward using air bubble detectors is apparent. But other than those two shifts, ECMO is done in much the same manner as it was done 12 years ago. **Keywords:** neonatal, extracorporeal membrane oxygenation, devices, survey, equipment. *JECT. 2004;36:16–21*

Extracorporeal membrane oxygenation (ECMO) is modified cardiopulmonary bypass (CPB) or pulmonary support to treat severe cardiopulmonary failure. A mechanical blood pump circulates a patient's blood volume through an artificial lung to support a failing respiratory or cardiac system. The first successful use of ECMO was reported by Hill et al. in 1972 (1). Since that time ECMO has become a widely accepted and valued therapy for neonatal, pediatric, and adult patients in acute cardiac or respiratory distress. The Extracorporeal Life Support Organization (ELSO) Registry reports an overall survival rate of 67%, which includes 19,102 neonatal, 4868 pediatric, and 1231 adult patients having undergone ECMO since 1979 (2). This survey was designed to assess the current status of neonatal ECMO devices and personnel. Although technology has improved the safety of ECMO systems, the general circuitry has not changed significantly since the early days of ECMO.

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MATERIALS AND METHODS

Between May and July 2002, all North American ECMO programs listed in the ELSO directory were contacted via electronic mail with a survey of neonatal ECMO equipment usage and personnel. The survey was sent to the ECMO coordinator of each active North American neonatal program. Twenty-nine questions were asked of the ECMO coordinators in fill-in-the-blank format (Appendix 1). One survey response per center was recorded into a Microsoft Excel database (Microsoft Inc., Red-

mond, WA). After the initial questionnaire was sent to the different programs, a period of 2 weeks was allowed to elapse before a follow-up questionnaire was sent to the nonresponders. A total of four mailings were sent in this manner. Of the 99 North American ELSO programs, 74 institutions responded, indicating a 75% response rate.

RESULTS

Equipment

The frequency of the responses using a roller pump was 95%, of those centers, 100% used Tygon® S-65-HL tubing (Saint-Gobain Performance Plastics Corp., Akron, OH) in the pump raceway. Five percent of the responding centers used centrifugal pumps for neonatal ECMO, and all of these centers reported using the Medtronic BP-40 centrifugal pump (Medtronic Inc., Minneapolis, MN). Figure 1 shows the range of ECMO consoles used by the responding centers. The Medtronic 0800 silicone membrane was reportedly used by 97% of the centers. Of the silicone membrane users, 81% used the Medtronic ECMOtherm heat exchanger. The remainder of the heat exchanger data are shown in Figure 2. The Medtronic Minimax hollow fiber oxygenator was used by 3% of centers and usually in conjunction with a BP-40 centrifugal pump. Bubble traps in the arterial line were used by 5% of responding centers. These four centers all used the Terumo Cardiovascular Systems device (Terumo Cardiovascular Systems, Tokyo, Japan). An arterial line filter (ALF) was used by 12% of responding ELSO centers. The breakdown of these data is shown in Figure 3. A bladder reservoir was used by 92% of responding centers. Figure 4 shows that the Medtronic R-14 ECMO bladder was reportedly being used in most of the responding centers. Bladder Box venous reservoir servo regulation was reported by 28% of all respondents.

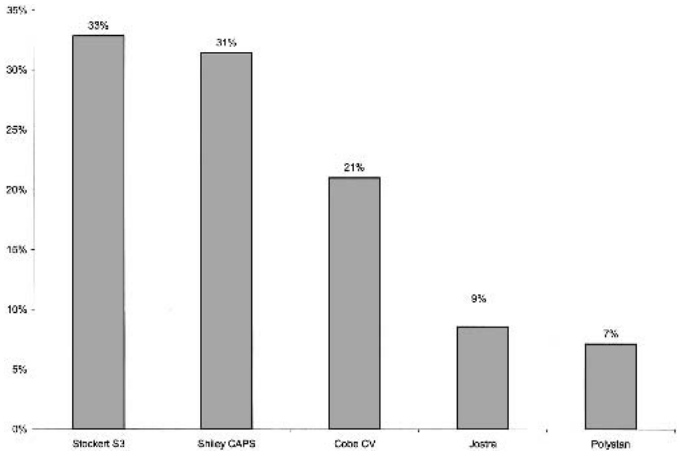

Figure 1. Percentage of responding centers using each type of roller pump console for neonatal ECMO applications. CAPS—Computer Assisted Perfusion System.

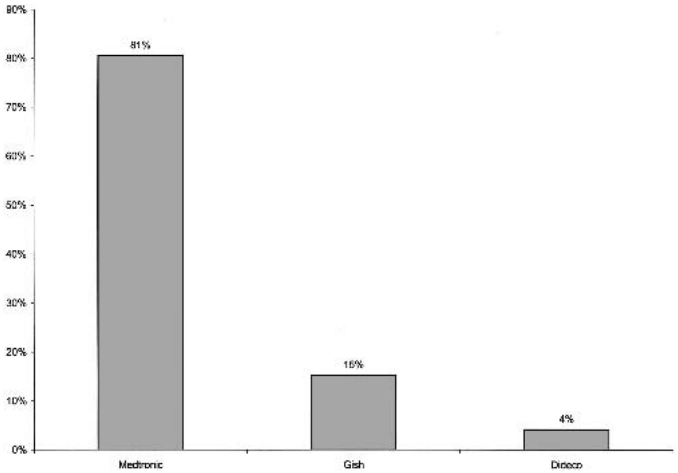

Figure 2. Percentage of responding centers using each brand of heat exchanger for neonatal ECMO applications.

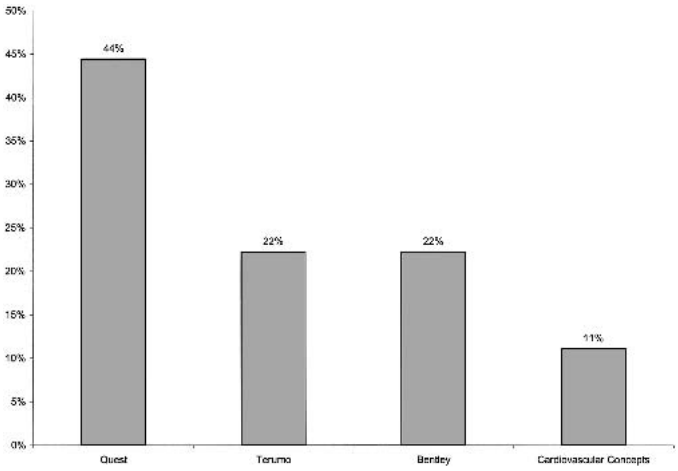

Figure 3. Percentage of responding centers using each brand of arterial line filter for neonatal ECMO applications. A total of 12% of the responding centers reported using arterial line filtration for neonatal ECMO.

Pressure servo regulation was reported by 71%. Of those centers using a Bladder Box, 81% used a Seabrook device (Seabrook Medical Systems, Inc., Cincinnati, OH), 14% used a "home- made" device, and 5% used a OriGen device (OriGen Biomedical, Austin, TX). An air bubble detector was reportedly used by 65% of the centers. A servo controlled bubble detector was used by 55% of the responding centers, while 10% used a bubble detector with an audible alarm. An illustration of bubble detectors represented by responding centers is shown in Figure 5. A surface coating was used on ECMO circuits at 8% of the responding centers, and all of these used Carmeda® BioActive Surface by Medtronic.

Monitoring

All of the responding centers monitored activated clotting times (ACTs). An overwhelming majority used an

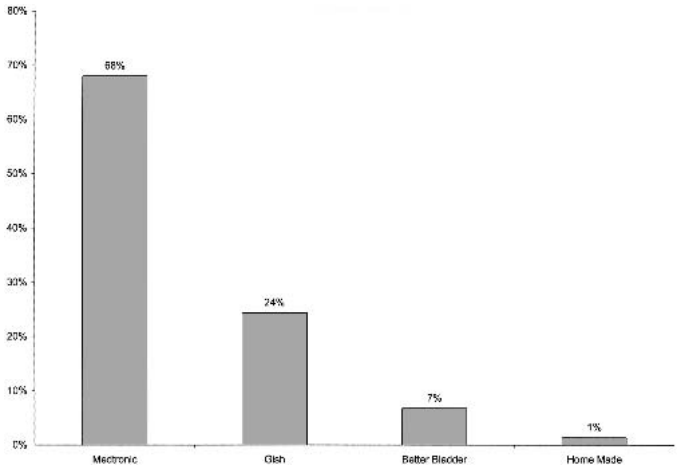

Figure 4. Percentage of responding centers using each type of bladder reservoir for neonatal ECMO applications. A total of 92% of the responding centers used a bladder reservoir for ECMO.

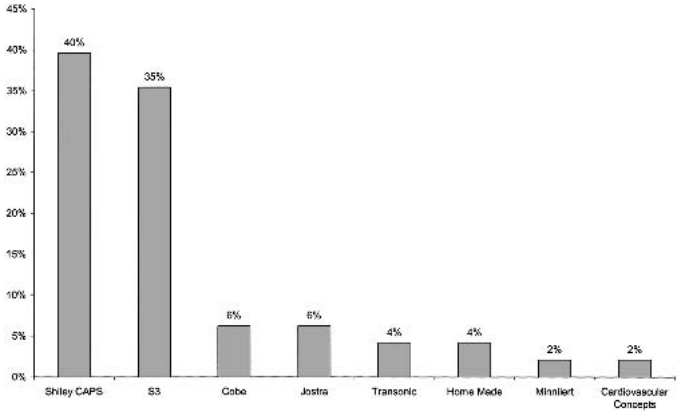

Figure 5. Percentage of responding centers using each type of air bubble detector for neonatal ECMO applications. A total of 65% of the responding centers reported using air bubble detectors.

Hemochron® device (International Technidyne, Edison, NJ). The remaining devices used for anticoagulation monitoring are shown in Figure 6. The average low range ACT was 183 seconds, and the average high range ACT was 216 seconds (Table 1). Forty percent of responding centers do not use inline blood gas monitoring. Of the centers using inline technology, the Terumo CDI 500/100 system was used most often (70%). The remaining centers using inline technology used venous side blood oxygen saturation monitoring only (Figure 7).

Personnel

ECMO Specialists often come from a variety of departments to form a team. A team of registered nurses (RNs), registered respiratory therapists (RRTs), and certified clinical perfusionists (CCPs) made up 27%, and a team of RNs and RRTs make up 24% of the responding centers' ECMO specialists. A complete list of ECMO specialists is shown in Table 2. At 22% of the responding centers, perfusionists were responsible for ECMO circuitry setup, priming, initiation, and troubleshooting. In addition, at 27% of the ELSO centers, perfusionists were listed among the ECMO specialists. Overall, perfusionists were involved in the ECMO program, in some capacity, at 49% of the responding ELSO centers.

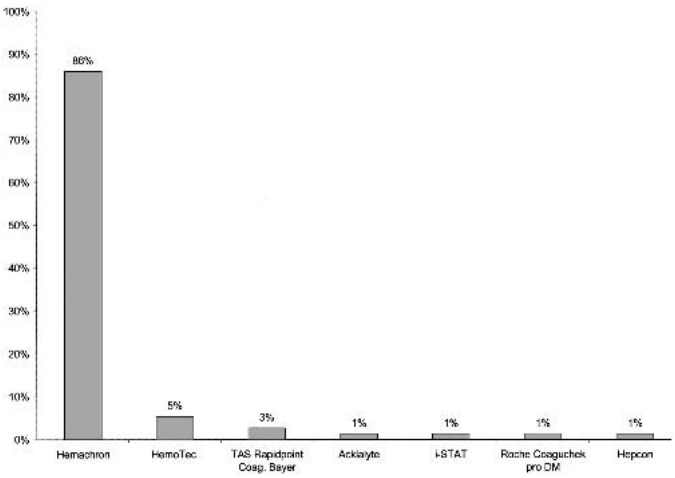

Figure 6. Percentage of responding centers using each brand of anticoagulation monitoring for neonatal ECMO applications.

Table 1. Activated clotting time data.

ACT Values	Low Range	High Range
Average	183	216
Standard Deviation	20	22
Minimum	120	150
Maximum	230	260

Average ACT range, low and high value along with one standard deviation, minimum and maximum reported values.

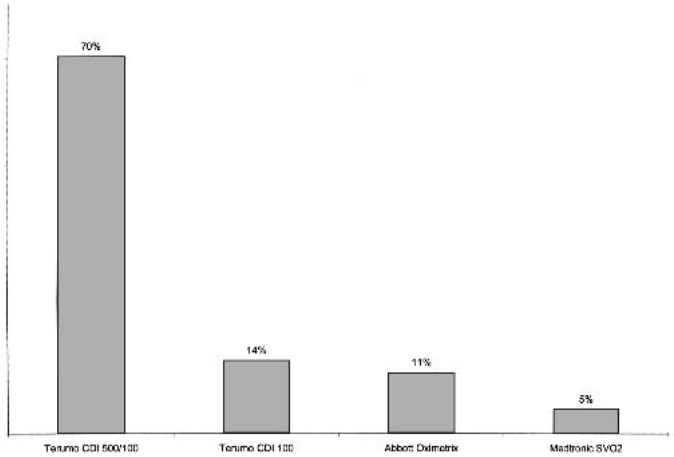

Figure 7. Percentage of responding centers using each type of inline monitoring system for neonatal ECMO applications. A total of 60% of responding centers reported using in-line blood gas monitoring.

Table 2. ECMO specialists.

CCP, RN, & RRT	27%
RN & RRT	24%
RN	18%
CCP & RN	12%
CCP	7%
CCP & RRT	5%
RRT	4%
CCP & perfusion assistants	1%
CCP, RN, RRT, & biomed. eng.	1%

Percentage of responding centers' ECMO specialist team members by Allied Health specialty.
CCP - certified clinical perfusionist; RN - registered nurse; RRT - registered respiratory technologist; biomed. eng. - biomedical engineer.

DISCUSSION

ECMO is a widely used and valuable asset in many pediatric centers (3). ELSO has reported that, to date, over 26,000 patients have been placed on ECMO with a 67% survival rate (2). This survey was designed to assess the current state of ECMO equipment and personnel. The response rate of 75% for this survey indicates, to the authors, that ELSO is well organized and that communication with the ECMO community is easily accomplished using ELSO's Directory. In an earlier report by Allison et al., 90% of the ELSO centers responded to a similar survey regarding ECMO equipment and personnel (4). At the time of that survey, there were 52 ECMO centers listed in the ELSO directory. At the time of this survey, 99 centers were listed in the ELSO directory, and the authors believe that a 75% response adequately reflects the state of ECMO equipment usage.

Most ELSO centers in North America use roller pumps to generate arterial flow (95%) for ECMO systems. This survey shows that roller pumps are still the standard and concurs with the report from 1990 reporting 96% usage (4). The Stockert S3, Shiley CAPS, and Cobe CV roller pump consoles account for most of the systems in use at the time of this survey. Several of the coordinators stated that they were in the process of changing pump consoles to newer systems. However, their systems at the time of the survey are reflected in the data.

Centrifugal pumps have been reported to cause hemolysis during long-term support (5,6). A report by McDonald, et al. suggests that the Medtronic BioMedicus centrifugal pump itself is responsible for hemolysis and that simply changing out the pump alleviates the problem for a brief period (6). If one uses a centrifugal pump for ECMO applications, the use of servo regulation to prevent high negative inlet pressures is warranted (7). There is a new generation of centrifugal pumps available currently, which should be evaluated for use in the ECMO setting.

The use of silicone membrane oxygenators also remains the standard for ECMO, although there is a slight increase in hollow fiber oxygenator usage. This small shift toward the use of hollow fiber oxygenators is, likely, because of its ability to be primed quickly and used as a rapid-deployment life-support device.

The Medtronic ECMOtherm heat exchanger was the most reportedly used heat exchanger by a large margin. A report by Darling et al. showed that this heat exchanger worked well but that other commercially available devices had superior air trapping capabilities (8). The authors believe that the Medtronic device is adequate but that its domination of the market is because of its convenience. Medtronic makes a full line of ECMO products and provides the only silicone membrane oxygenator available to the ECMO community.

Arterial line filters (12%) and bubble traps (5%) are rarely used for ECMO. The use of these devices at low heparin levels can be risky and, judging from the survey response, few centers believe they are advantageous.

The use of a venous bladder reservoir is widely reported in North America (92%). The traditional bladder is still the standard used at most centers. However, recently a new bladder has become available for ECMO use that is radically different, and its vertical design has been reported to have superior flow characteristics (9). This bladder allows the user to raise the level of the bladder up off the floor and decrease tubing lengths. The Better-Bladder™ (Circulatory Technology Inc., Oyster Bay, NY) is beginning to appear in ELSO centers and is currently being used at 7% of responding centers.

The use of a bladder box to servo regulate pump flow is reported by 28% of respondents. This is a shift from a previous report from 1990, where 87% of ELSO centers were cited as using bladder box servo regulation (4). This shift toward using pressure servo regulation may have been attributable to the appearance of newer pumps that offer pressure monitoring. In the early days of ECMO, smaller consoles with pressure-transducing capabilities were unavailable; hence, the advent of bladder boxes. Pressure servo regulation has the advantage of offering not only negative pressure regulation on the bladder but also positive pressure regulation to stop the pump in the case of an inadvertent pump clamp application.

Another major shift from the 1990 report by Allison et al. is that the use of bubble detectors has increased from 17% to 65% (4). This represents an increase of 48% from the Allison paper. This dramatic increase in the use of bubble detectors over the last 12 years may be because of the greater availability of such devices. It is interesting to note that 81% of the responding centers own pumps that can be configured with a bubble detector, but chose not to use this option.

The use of surface coatings on ECMO circuitry is not widely used. Only 8% of responding centers used surface coatings routinely. Several centers reported using coatings

in such special circumstances as post-cardiotomy patients. Although there is evidence showing advantages using coated circuits during CPB (10), there are no data indicating that the use of a surface coating offsets its cost in the ECMO patient.

Universally, ACTs were used to monitor ECMO patient anticoagulation status. A report in 1996 by Graves et al. showed that most ECMO centers at that time using an ACT range of 180–220 (11). This survey shows similar ACT ranges are still the standard. Newer coagulation monitoring devices are continually being released to the market, and some are being used at a few ELSO centers. ISTAT (ISTAT Corp., East Windsor, NJ) and Actalyte (Helena Laboratories, Beaumont, TX) are two of the newer devices mentioned by responding centers.

The use of in-line blood gas analyzers was common. The Terumo CDI devices dominate the ECMO market. The CDI 500 offers a potassium value along with blood gas parameters, is easy to use, and has been reported to be a reliable device (12). A minority of centers monitor venous saturation only, much the same way as was done 12 years ago.

The demographics of ECMO specialists have changed over the past 12 years. In 1990, perfusionists were cited as comprising 14% of the total ECMO specialist population (4). In 1992, perfusionists were listed as 2% of the total number of specialists (13). Currently, perfusionists monitor long-term ECMO at 27% of the ELSO centers responding. In addition, perfusionists are involved with ECMO at another 22% of institutions where they set up, prime, troubleshoot, and consult on ECMO cases. This increased involvement of perfusionists with ECMO is a positive shift. Allison et al., in 1990, stated: "Our personal experience favors the use of perfusionist expertise in every ECMO program" (4). At that time, perfusionists were involved in ECMO training and were available for consultation at 30% of ELSO centers. One reason for increased participation of perfusionists is that the number of North American ELSO centers has grown from 52 in 1990 to 99 at the time of this paper. This increase in programs offering ECMO has given perfusionists an opportunity to become involved in ECMO.

The future of ECMO circuitry and equipment may drastically differ from the data in this survey. A new type of hollow fiber oxygenator, currently in use in Europe, has been developed for long-term applications (14). The Medos Hilite® 7000 LT (Medos Medizintechnik AG, Stolberg, Germany) is an example of this new, closed fiber technology. The fiber is nonporous, constructed of polymethylpentene, preventing the problem of plasma leakage. This product is not yet available in the United States. This new technology may soon allow for a much more compact and portable ECMO system.

In conclusion, few changes have been considered for neonatal ECMO equipment over the past 12 years. More centers use pressure servo regulation than mechanical, bladder box, or servo regulation. More centers are using servo-regulated bubble detectors. However, the ECMO circuit is essentially the same as it was a decade ago. New, improved centrifugal pumps are now available, which must be evaluated in the ECMO setting. If these pumps are shown to be acceptable for prolonged use, ECMO circuitry could be reduced, and bed-mounted ECMO systems could become a reality. This study shows that perfusionists are more involved with ECMO than ever previously reported. This may be because of the recent increase in off-pump cardiac procedures. However, whatever the reason, perfusionists are now more involved with ECMO, and it should be the perfusion community that leads the way for improvements to ECMO circuitry.

APPENDIX 1

Neonatal ECMO Survey

Dear Sir,

I would like to take few moments of your time to ask a few questions. I am interested in what neonatal ECMO equipment you are using at your institution. So, please take a few minuets to answer the following questions:

(Please refer to your typical neonatal equipment only!)

1. Do you use a roller pump?

If so, what brand?

Do you use Super Tygon S-65-HL tubing in your raceway?

2. Do you use a centrifugal pump?

If so, what brand?

Do you monitor venous line negative pressures?

3. Do you use a silicone membrane?
4. What heat exchanger do you use?
5. Do you use a hollow fiber member?

If so, what brand?

6. Do you use in-line blood gas monitoring?

If so, what brand?

7. Do you use a bubble trap?

If so, what brand?

8. Do you use an arterial line filter?

If so, what brand?

9. Do you use a bladder?

If so, what brand?

If not, how do you servo regulate?

10. Do you use a bladder box?

If so, what brand?

11. Do you use pressure servo regulation?

If so, how?

12. Do you use an air bubble detector?

If so, what brand?

13. Does your ECMO circuit have a surface coating?

If so, what kind/brand?
14. What device do you use to monitor ACTs?
What ACT range do you normally use?
15. Who are your ECMO Specialists?
RNs:
RRTs:
Perfusionists:
Perfusion assistants:
Other:
Thank you very much for participating in this survey!
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