

## Original Articles

# Survey of the Routine Practice Limits for Physiologic and Technical Parameters Managed by Clinical Perfusionists during Adult Cardiopulmonary Bypass

Bruce Searles, MS, CCP, LP;\* Edward M. Darling, MS, CCP, LP;\*  
Jeffrey B. Riley, MHPE, CCP-Emeritus, LP;\* Jason R. Wiles, PhD†‡

\*Department of Cardiovascular Perfusion, SUNY Upstate Medical University, Syracuse, New York; and †Department of Biology, and ‡Department of College Science Teaching, Syracuse University, Syracuse, New York

---

**Abstract:** Cardiopulmonary bypass (CPB) is a highly technical clinical discipline with a recognized variability in practice. Professional standards and guidelines documents help direct clinical practice and reduce variability, but these guidelines are necessarily vague and fall short of providing specific objective recommendations of clinical practice metrics. If clinical practice metrics were known, they would be informative when writing departmental policy manuals, structuring quality improvement initiatives, describing product R&D specifications, and designing educational assessment rubrics. Therefore, to address this gap, we conducted a national survey of clinical practice with the purpose of producing a benchmark of the typical variability of specific technical parameters that are commonly managed during adult CPB procedures. A pool of expert clinical perfusionists collaborated to compile a data set of normal ranges for 41 individual physiologic and technical parameters (pressures, flows, saturation, times, solutions, and temperatures) that are commonly managed during adult CPB procedures. Results were collected using an online survey application. Respondent demographics and

measures of central tendency with descriptive quartile statistics and confidence intervals for each parameter are presented. Of the 335 people who participated in the survey, 315 met the inclusion criteria. The geographic demographics of the respondents were representative of the American Board of Cardiovascular Perfusion's distribution of certified clinical perfusionists. Of the 41 parameters investigated, there were 13 hemodynamic parameters, 13 normal flow rates and technical circuit parameters, 10 blood gasses and hematocrit parameters, and five parameters of patient temperatures. The data presented here are informative and provide a consensus-based objective assessment of the standard practice for adult CPB as reported by practicing clinical perfusionists. Based on these survey data, we have identified the typical clinical limits for the 41 parameters that are managed during adult CPB. This information may be incorporated into guiding documents to support the work of clinicians, researchers, and educators. **Keywords:** CPB, clinical parameters, simulators, survey, technical ranges. *J Extra Corpor Technol. 2020;52:165–72*

---

The first drafting of professional standards in the field of clinical perfusion was developed in the late 1960s by the American Society of Extracorporeal Technology (AmSECT) (1). Since this seminal work, many professional organizations worldwide have published documents intended to standardize the practice of the clinical perfusionists in their

community (2–5). These documents are rigorously vetted by expert authors and validated by the vote of organizational committees and often the organization's general membership. The goal of these documents is “to provide perfusionists with a framework to guide safe and effective extracorporeal support care to their patients. The AmSECT recommends that clinical teams use their document as a guide for developing institution-specific protocols for patients receiving extracorporeal support” (4). Although professional standards documents are influential, they lack a degree of specificity that is also needed by clinicians who are developing institutional-specific protocols. For example, AmSECT's standards state that clinicians are required to monitor physiologic blood

---

Received for publication February 10, 2020; accepted July 16, 2020.  
Address correspondence to: Bruce Searles, MS, CCP, LP, SUNY Upstate Medical University, Department of Cardiovascular Perfusion, 750 E. Adams St., Syracuse, NY 13210. E-mail: searlesb@upstate.edu  
The senior author has stated that the authors have reported no material, financial, or other relationship with any healthcare-related business or other entity whose products or services are discussed in this paper.

pressures and temperatures and technical extracorporeal circuit pressures, flows, and temperatures, as well as blood gas parameters, hemoglobin levels, and gas flow rates. The standards further require that the clinician manage these parameters within limits that are determined to be “acceptable” and “appropriate.” Therefore, it would be advantageous to develop a complementary document that would support the standards documents. This document would report routine practice limits for the guidance of clinicians, educators, and researchers when determining the actual range of “acceptable and appropriate” values for each of these parameters. Unfortunately, there is no such reference, and clinicians must apply a variety of resources to this task. Most commonly, authors of clinical practice guidelines rely on their individual training and experience to set these limits, and although this method is not necessarily inappropriate, it is biased and poorly validated. Textbooks may provide an external and referenceable metric, but texts are often heavily biased to the experience of each chapter’s author (6,7). Although the medical literature may provide diverse evidence of specific practice parameters, there are often conflicting reports derived from experimental protocols that may not be generalizable to standard practice, and the recommended parameters may be novel and years ahead of widespread clinical practice. One method of determining what values are acceptable and appropriate would be to collect a large sample of data from a diverse group of clinical practices. Ideally, these data would be electronically sampled without error directly from the electronic perfusion record logging equipment during clinical procedures. Logically then, the data from electronic medical records may be the most precise.

Large multi-institutional registries should be evaluated when possible. There are at least four well-known registries in the field of clinical perfusion: 1) the Northern New England Cardiovascular Disease Study Group (8), 2) SpecialtyCare Operative Procedural Registry™ (SpecialtyCare, Brentwood, TN) (9), 3) Australian & New Zealand Collaborative Perfusion Registry (10), and PERForm, which is managed by the Michigan Society of Thoracic and Cardiovascular Surgeons and endorsed by the AmSECT (11). The limitations of these databases include geographical bias (8,10,11), small number of participating institutions (8,10,11), and proprietary access (8–11). In addition, some or all of the perfusion data are manually entered, not electronically captured, and many technical perfusion parameters identified in the standards are not collected. Based on these limitations and to address this reference gap, we conducted a national survey of expert perfusionists and compiled a referenceable resource based on a large population sample which establishes the contemporary standard practice with regard to the management of 41 parameters which are managed by perfusionists during adult cardiopulmonary bypass (CPB) procedures. In particular, this investigation seeks to provide supporting evidence which may aid clinicians when determining the limits that are acceptable

and appropriate with regard to parameters identified in sections 7-Monitoring, 10-Blood flow, and 11-Blood pressure of the AmSECT Standards and Guidelines for Perfusion Practice (4).

## MATERIALS AND METHODS

Following review by our campus Institutional Review Board, this study was determined to be exempt. The survey was conducted between August and October of 2015. The survey contained three core sections: 1) demographics, 2) physiologic parameters, and 3) technical CPB circuit parameters. The questions were formatted on a web-based commercial survey site<sup>1</sup>. Survey participation was voluntary and anonymous. The target population included clinically active perfusionists with experience in managing adult CPB procedures. An invitation for participation was posted to the two most widely circulated email lists: PerfList and Perfmail. The invitation was posted two times: 4 weeks apart and closed after 12 weeks. The inclusion criteria for data compiled in the final parameter results were as follows: 1) respondents had completed their perfusion training before the survey 2) respondents’ clinical experience included adult procedures, and 3) respondents were clinically active the year before the survey.

### Data Analysis

Nonparametric and categorical data are presented as percentages (%) of the total number of respondents meeting the inclusion criteria. Interval data were subject to statistical analysis with SPSS version 13.0 (www.spss.com). The Kolmogorov–Smirnov test for normality was performed for each parameter. When respondent parameter values were normally distributed, the 95% confidence intervals (CIs) were estimated for the mean. When the parameter values were not normally distributed, CIs were estimated for the median. The data tables report the mean, median, mode, SD of the mean,  $Q_1$ ,  $Q_3$ , and interquartile range (IQR) as well as the low and high limits of the 95% CIs.

## RESULTS

### Demographics

There were 335 total respondents. Of this, 315 met the inclusion criteria and were included in the final data analysis. Survey respondent demographic data are shown in Table 1. Respondents had a median of 23 (IQR = 17) years of experience as a clinical perfusionist. The median number of adult CPB procedures performed by the respondents in 2014 was 112 (IQR = 67) cases. The collective case volume reported by the survey respondents was more

<sup>1</sup>www.surveymonkey.com, San Mateo, CA.

**Table 1.** Respondent demographic data.

Clinical Position	%
Chief perfusionist/manager	40
Staff perfusionist, full-time	56
Staff perfusionist, part-time	0
Full-time perfusion education faculty	2
Locum tenens	1
Retires	1
Other	0
Gender	%
Female	26
Male	74
Employment venue	%
Hospital-based/academic	31
Hospital-based	36
Contract group	29
Self-employed	4
Clinical practice	%
Adult CPB	83
Adult and pediatric CPB	17
Roller pump	35
Centrifugal pump	65

than 38,535 cases in 2014. The median size of the respondent's perfusion team was 5 (IQR = 5) members, and the median annual case load for the respondents' programs was 500 (IQR = 623) cases. Respondents reported centrifugal arterial pump usage at 65% and roller pump usage at 35%. The geographic regions represented by the respondents were diverse and are displayed in Table 2 for comparison to the 2014 worldwide distribution of the American Board of Cardiovascular Perfusion (ABCP) certified clinical perfusionists<sup>2</sup> (CCP).

#### Patient Hemodynamic Pressure Data (Table 3)

There were 13 hemodynamic parameters surveyed. Between 110 and 169 respondents submitted data regarding the high and low pressure limits for the arterial, venous, and pulmonary vascular systems before, during, and after CPB. None of the respondent hemodynamic parameter results were normally distributed. There are minimal differences between the high and low limits for the 95% CIs.

#### Flow Rates and Technical Circuit Data (Table 4)

Thirteen parameters of normal flow rates and technical circuit data (pressures, temperatures, and delivery intervals) were surveyed. Between 10 and 151 respondents submitted data regarding the flow rates for arterial blood and cardioplegia, pressure limits for the extracorporeal circuits arterial line and the cardioplegia delivery system, and the temperature and dosing intervals for cardioplegic solutions during CPB. The responses regarding the cardioplegia initiation dose were bimodal and have been separated into two parameters representing cold and warm initiation of cardioplegic arrest. The data

**Table 2.** Geographical location of survey respondents compared with CCP distribution.

Geographic Location of Respondents	Survey Respondents (n = 315), %	2014 CCP Population (n = 3,996), %
Northeast United States	19	19.3
Southeast United States	27	26
Midwest United States	25	24.9
West United States	13	14.3
Southwest United States	7	10.6
Outside of the United States	10	3.8

sample for dosing intervals of non-Buckberg (for this survey, "non-Buckberg" refers to cardioplegic solutions that are delivered at blood:crystalloid ratios other than 4:1) cardioplegic solutions was normally distributed, and the CIs are reported for the mean of the sample. None of the parameter results were normally distributed. There are minimal differences between the high and low limits for the 95% CIs.

#### Saturations, Blood Gasses, pH, and Hematocrit Data (Table 5)

Ten parameters of normal blood gasses and hematocrit were surveyed. Between 69 and 134 respondents submitted data regarding the high and low limits of blood gas, pH, and hematocrit values before, during, and after CPB. None of the other parameter results in this table were normally distributed. There are minimal differences between the high and low limits for the 95% CIs.

#### Patient Temperature Targets and Gradient Data (Table 6)

Five parameters of patient temperature targets and gradients were surveyed. Between 120 and 131 respondents submitted data regarding the target core temperature (for normal and deep hypothermic circulatory arrest cases), cooling/rewarming gradients, and circuit arterial blood temperature during CPB. None of the data samples were normally distributed. There are minimal differences between the high and low limits for the 95% CIs.

#### Types of Cardioplegic Solutions Used During Adult CPB (Table 7)

Respondents (n = 162) identified the types of cardioplegic solutions that they typically use during adult CPB. High and low potassium solutions delivered at a ratio of four parts blood to one part crystalloid is the most common formulation.

## DISCUSSION

These unique data provide insights about the limits of parameters that are managed during the standard practice of CPB. The strength of these data is that they are more representative of clinicians' routine practice metrics than

<sup>2</sup>ABCP Inc., 2014 Booklet of Information, www.abcp.org.

**Table 3.** Normal range of patient hemodynamic pressures during adult CPB.

Parameter	n	Mean	SD	$Q_1$	Median	$Q_3$	IQR	Mode	Low 95 CI	High 95 CI
Patient systolic arterial blood pressure (mmHg)										
Before bypass (low limit)	167	84	12	80	80	90	10	80	80	88
Before bypass (high limit)	167	137	21	120	135	150	30	120	130	140
After bypass (low limit)	167	83	13	75	80	90	15	80	80	80
After bypass (high limit)	167	121	15	110	120	130	20	120	120	120
Patient diastolic arterial blood pressure (mmHg)										
Before bypass (low limit)	161	48	10	40	50	54	14	40	45	50
Before bypass (high limit)	161	83	13	80	85	90	10	90	80	90
After bypass (low limit)	161	49	10	40	50	55	15	50	49	50
After bypass (high limit)	161	78	12	70	80	85	15	80	80	80
Mean arterial blood pressure (mmHg)										
During CPB (low limit)	169	54	7	50	55	60	10	50	50	55
During CPB (high limit)	169	82	9	75	80	90	15	80	80	80
Central venous blood pressure (mmHg)										
Before bypass	160	11	4	8	10	12	4	10	10	12
During bypass	157	2	2	0	2	3	3	0	1	2
After bypass	161	12	4	10	12	15	5	10	10	12
Patient systolic pulmonary artery blood pressure (mmHg)										
Before bypass (low limit)	122	23	9	20	20	25	5	20	20	25
Before bypass (high limit)	122	44	14	35	45	50	15	35	40	45
After bypass (low limit)	122	23	9	20	20	25	5	20	20	25
After bypass (high limit)	122	42	12	35	40	50	15	40	40	45
Patient diastolic pulmonary artery blood pressure (mmHg)										
Before bypass (low limit)	115	11	3	8	10	12	4	10	10	10
Before bypass (high limit)	116	25	12	20	25	30	10	25	20	25
After bypass (low limit)	117	12	9	10	10	15	5	10	10	12
After bypass (high limit)	117	26	12	20	25	30	10	20	20	25
During CPB (low limit)	111	7	12	0	10	10	10	0	0	5
During CPB (high limit)	110	14	16	5	10	18	13	10	10	12

Descriptive statistics for survey pressure-related parameters. n is the number of respondents, mean is the average of responses, SD is one SD,  $Q_1$  is the 25th percentile, median is the 50th percentile,  $Q_3$  is the 75th percentile, and Mode is the most frequent response. Except for n, all parameters are in mmHg. The parameter responses did not fit a normal distribution. Low and high 95 CIs are the limits for the 95% CI for the median.

would be a similar data set extracted from an electronic registry because it summarizes the contributions of hundreds of clinicians, and each clinician's input was weighted equally. Electronic registries are often biased by a few anchor institutions which contribute a large number of cases. Furthermore, whereas clinical practice guidelines are vitally important documents which identify how clinicians should practice, our data set reflects how clinicians believe that they actually do practice. These results have implications on the clinical care and research of real patients, and the development and use of virtual patients.

### Implications for the Real Clinical Patient: A Reference of Standard Practice for Clinical and Research Protocols

These data support and augment professional standards for clinical practice that are promulgated within the field. We have identified the practice limits of many of the technical and physiologic parameters that are specifically identified in the standards. In particular, when compared with the Standards and Guidelines for Perfusion Practice (4) that are endorsed by the AmSECT, American Academy of Cardiovascular Perfusion, and the International Consortium of Evidence-Based Perfusion, this data set

provides the detail that is necessary to meet the standards and guidelines identified in 7-Monitoring, 10-Blood flow, and 11-Blood pressure (12). When compiled into a narrative representing the median (M) or the first and third quartile ( $Q_1$ - $Q_3$ ) limits reported for uncomplicated adult CPB cases, the parameter results may be summarized as follows.

Before CPB, the patient's ABP (M sys/M dia, mmHg) is between 80/50 and 135/85, central venous pressure (CVP) ( $Q_1$ - $Q_3$ , mmHg) is between 8 and 12, and pulmonary artery pressure (PAP) (M sys/M dia, mmHg) is between 20/10 and 45/25. On initiation of CPB, blood flow is maintained between ( $Q_1$ - $Q_3$ , L/min/M<sup>2</sup>) 2.2 and 2.4, which generally yields an arterial line pressure (M, mmHg) between 123 and 250, and mean arterial blood pressure between (M, mmHg) 55 and 80, and CVP between ( $Q_1$ - $Q_3$ , mmHg) 0 and 3. Patients are cooled at a gradient of ( $Q_1$ - $Q_3$ , °C) 5-10 with an arterial line temperature (M, °C) of 32-37 to achieve a patient's core temperature of ( $Q_1$ - $Q_3$ , °C) 32-34. During CPB, the typical blood gas parameters are maintained between PaO<sub>2</sub> (M, mmHg) of 150 and 300, PCO<sub>2</sub> (M, mmHg) 35 and 46, pH ( $Q_1$ - $Q_3$ ) 7.38 and 7.40, and hematocrit (HCT) ( $Q_1$ - $Q_3$ , %) 24 and 28. Sweep gas flow rates (M) are typically 50-80% of the arterial blood flow and sodium bicarbonate would be

**Table 4.** Normal range of flow rates and technical circuit data during adult CPB.

Parameter	n	Mean	SD	$Q_1$	Median	$Q_3$	IQR	Mode	Low 95 CI	High 95 CI
CPB cardiac index (L/min/M <sup>2</sup> )										
Normothermic cardiac index on CPB	141	2.34	.35	2.20	2.40	2.40	.20	2.40	2.20	2.40
Heart–lung machine circuit arterial line pressure (mmHg)										
Low limit	143	125	44	99	123	150	51	150	120	140
High limit	143	235	77	200	250	300	100	300	250	250
Cardioplegic solution delivery line pressures (mmHg)										
Antegrade (low limit)	145	165	53	140	180	200	70	150	150	180
Antegrade (high limit)	145	246	51	200	250	280	70	250	240	250
Retrograde (low limit)	145	85	48	40	85	120	80	50	70	100
Retrograde (high limit)	145	141	74	73	140	200	138	100	120	150
Ostial (low limit)	145	105	42	80	100	125	43	100	100	100
Ostial (high limit)	145	162	57	120	150	200	80	150	150	150
Coronary sinus pressure: retrograde delivery (mmHg)										
Low limit	151	30	21	20	25	30	10	25	25	30
High limit	151	51	31	40	45	50	10	45	45	50
Cardioplegic solution pump flow rate (mL/min)										
Antegrade (low limit)	143	214	71	168	200	250	75	200	200	220
Antegrade (high limit)	143	359	98	300	350	400	100	300	320	350
Retrograde (low limit)	143	123	49	100	120	150	50	100	100	125
Retrograde (high limit)	143	236	79	200	235	263	80	200	220	250
Ostial (low limit)	143	80	40	50	80	100	50	50	75	80
Ostial (high limit)	143	150	60	100	140	180	70	150	125	150
Cardioplegic solution temperatures (°C)										
Initiation dose cold	138	6.4	3.3	4.0	5.0	8.0	4.0	4.0	5.0	6.0
Initiation dose warm†	16	35.7	.9	35.0	36.0	36.0	3.0	35.0	35.0	36.0
Maintenance dose (intermittent doses)	129	6.6	4.1	4.0	5.0	8.0	4.0	4.0	5.0	6.0
Hot shot (before clamp removal)	129	35.0	1.8	35.0	36.0	37.0	2.0	37.0	35.0	36.0
Cardioplegia dosing interval (minutes)										
Non-Buckberg solutions*	10	56*	21	41	53	68	33	45	41	71
Buckberg solutions	146	17	4	15	20	20	5	20	15	20

Descriptive statistics for survey flow rate– and technical circuit–related parameters are listed. n is the number of respondents, mean is the average of responses, SD is one SD,  $Q_1$  is the 25th percentile, median is the 50th percentile,  $Q_3$  is the 75th percentile, and mode is the most frequent response. Low and high 95 CIs are the limits for the 95% CI for the median except for the normally distributed parameter where the CIs are for the mean. About 15% of respondents report to not use a hot shot. About 22% of respondents report to vent the aortic root during antegrade cardioplegic solution delivery. About 95% of respondents report to vent the aortic root during retrograde cardioplegic solution delivery.

\*Only one parameter fit a normal distribution.

†About 12% of respondents report the use of warm initiation dose of 35–37°C.

administered to treat base excess ( $Q_1$ – $Q_3$ , mEq/L) between –2 and –4. Although no particular cardioplegic solution formulation is clearly dominant, myocardial protection is nearly universally produced with a solution that uses potassium as the arrest agent. Cardioplegic arrest is generally initiated, with cold ( $Q_1$ – $Q_3$ , °C) 4–8 high K (>15 mEq/L) solution (87% respondents) and cold ( $Q_1$ – $Q_3$ , °C) 4–8 low K (<15 mEq/L) solution (73% respondents) being delivered ( $Q_1$ – $Q_3$ ) every 15–20 minutes. Antegrade cardioplegia (M) is delivered at a flow of 200–350 mL/min and at a cardioplegic circuit pressure (M) of 180–250 mmHg, whereas retrograde cardioplegic solution is delivered at a flow (M) of 120–235 mL/min at a coronary sinus pressure (M) of 25–45 mmHg and a cardioplegic circuit pressure (M) of 85–140 mmHg. When direct ostial perfusion is provided, it is delivered at (M) 80–140 mL/min and (M) 100–150 mmHg. Patients are rewarmed with a gradient of ( $Q_1$ – $Q_3$ , °C) of 7–10. A hot shot dose of cardioplegic solution is generally delivered at ( $Q_1$ – $Q_3$ , °C) 35–37 to prepare the heart for x-clamp removal. At the conclusion of CPB, the patient's ABP (M sys/M dia, mmHg)

is between 80/50 and 120/80, CVP ( $Q_1$ – $Q_3$ , mmHg) is between 10 and 15, and PAP (M sys/M dia, mmHg) is between 20/10 and 40/25.

In addition to supporting the development of institutional practice protocols, these data may be used to inform research protocols by further clarifying and standardizing the methods of conducting CPB. These limits may be helpful for differentiating between control and treatment groups and may be a helpful reference for article authors who have classically penned a heretofore un-referenceable sentence in their methods section; "... CPB was conducted in the standard fashion."

#### Implications for the Virtual Patient: Validating Models for Education, Research, and Product Development

Several virtual patient simulator models have been developed for commercial distribution within the extracorporeal perfusion field (13–15). In addition, many educational centers have developed their own proprietary models (16), most of which are not described in the literature. The

**Table 5.** Normal limits of blood gas, saturations, and hematocrit during adult CPB.

Parameter	N	Mean	SD	$Q_1$	Median	$Q_3$	IQR	Mode	Low 95 CI	High 95 CI
Continuous monitoring mixed venous saturation (%)										
Low limit	133	63	6	60	65	65	5	65	60	65
High limit	132	86	6	80	85	90	10	85	85	85
Cerebral NIRS regional saturations (%)										
Low limit	69	50	11	43	50	60	17	50	45	50
High limit	69	82	9	75	80	90	15	80	80	85
PaO <sub>2</sub> values: what are the normal limits (mmHg)?										
Low limit	129	157	52	122	150	185	63	150	150	150
High limit	128	320	94	250	300	350	100	300	300	320
PaCO <sub>2</sub> values: what is the normal limits (mmHg)?										
Low limit	129	36	8	35	35	36	1	35	35	35
High limit	129	50	23	45	46	50	5	45	45	48
Sweep gas: gas-to-blood flow ratio normothermic CPB (%)										
Low limit	113	53	21	40	50	60	20	50	50	50
High limit	113	88	27	75	80	100	25	100	75	100
Normal HCT: what is the patient's normal HCT (%)?										
Before bypass	131	35	3	33	35	36	3	35	34	35
During bypass	131	26	3	24	25	28	4	25	25	26
After bypass	131	29	3	26	29	30	4	30	28	30
Bicarbonate administration: what is the base excess (mEq/L) to give bicarbonate?										
Base excess (negative mEq/L)	129	-3.5	1.5	-4.0	-3.0	-2.0	2.0	-4.0	-3.7	-3.2
Normal pH: what is the patient's normal pH?										
Normal pH during CPB	134	7.39	.04	7.38	7.40	7.40	.02	7.40	7.38	7.40

Descriptive statistics for survey blood gas-, hematocrit-, and pH-related parameters. n is the number of respondents, mean is the average of responses, SD is one SD,  $Q_1$  is the 25th percentile, median is the 50th percentile,  $Q_3$  is the 75th quartile, and mode is the most frequent response. The parameter responses did not fit a normal distribution. Low and high 95 CIs are the limits for the 95% CI for the median. Log pH values were converted to linear hydrogen ion activity values to perform the statistical analysis. About 98% of respondents report continuous monitoring of mixed venous saturation during CPB. About 46% of respondents report continuously monitoring cerebral regional saturations.

potential value of these systems is without question as the adoption and application of medical simulation techniques and technologies are currently at the leading edge of healthcare education. As these models gain a greater application in the educational process and are applied to high-stakes decisions, it is critical to validate their performance (17,18) and identify the limits within which these devices can be expected to produce an experience and data stream that is representative of a real patient. With a validated

simulation platform and a detailed description of a specific clinical skill set (19), an educational program is well prepared to develop objective assessment rubrics and design a curriculum which effectively teaches and measures skill.

Virtual patients are also being applied to the research and development of medical devices. A recent publication Faris et al. (20) describes the FDA's position on the collection of data for its 510K clearance program and states that...

**Table 6.** Patient temperature targets and gradients during adult CPB.

Parameter	N	Mean	SD	$Q_1$	Median	$Q_3$	IQR	Mode	Low 95 CI	High 95 CI
Normal patient cooling: normal "core" temperature after cooling										
Core temperature target (°C)	130	33.1	2.0	32.0	34.0	34.0	2.0	34.0	33.0	34.0
Cooling gradient: normal temperature gradient followed during cooling										
Cooling gradient (°C)	120	8.1	4.4	5.0	10.0	10.0	5.0	10.0	8.0	10.0
Arterial blood temperature: normal limits of circuit arterial blood temperature										
Low limit of normal range	131	31.4	4.1	28.0	32.0	34.0	6.0	32.0	32.0	32.0
High limit of normal range	131	36.8	1.6	37.0	37.0	38.0	1.0	37.0	37.0	37.0
Warming gradient: gradient followed during warming										
Warming temperature gradient (°C)	125	8.0	2.7	7.5	8.0	10.0	3.0	10.0	8.0	10.0
Deep hypothermia circulatory arrest										
Actual "core" temperature as you initiate circulatory arrest (°C)	125	20.3	3.6	18.0	20.0	22.0	4.0	18.0	18.0	20.0

Descriptive statistics for survey temperature-related parameters. n is the number of respondents, mean is the average of responses, SD is one SD,  $Q_1$  is the 25th percentile, median is the 50th percentile,  $Q_3$  is the 75th percentile, and mode is the most frequent response. The parameter responses did not fit a normal distribution. Low and high 95 CIs are the limits for the 95% CI for the median.

**Table 7.** Types of cardioplegic solutions.

Type of Cardioplegic Solutions	n	%
“High K” (potassium concentration delivered at >15 mEq/L)	141	87
“Low K” (potassium concentration delivered at <15 mEq/L)	119	73
4:1 (Blood:cardioplegia)	100	62
del Nido solution	52	32
Other (MPS, microplegia, 1:16, etc.)	45	28
8:1 (blood:cardioplegia)	25	15
Crystalloid cardioplegia (no blood at delivery)	20	12
Custodial HTK solution	18	11
Buckberg solution	17	10
Bretschneider solution	2	1
University of Wisconsin solution	1	1
Celsior	0	0

Distribution of types of cardioplegic solutions used by respondents. Percentages are based on 162 responses.

*“If it can be shown that these virtual patients are similar, in a precisely defined way, to real patients, future trials may be able to rely partially on virtual patient information, thus lessening the burden of enrolling additional real patients.”*

We posit that the parameter results presented here identify many of the physiological and technical limits for parameters that a virtual patient must reliably reproduce to be recognized as valid surrogate for a real patient as they would present before during and after CPB.

## LIMITATIONS

### Survey Fatigue

Our survey instrument had many questions, and the completion rate for the survey was only 41%. Although the 141 individuals who answered every question spent an average of 21 minutes to complete the survey, the average time spent for all 335 people who started the survey was only 9 minutes. Consequently, the number of respondents is variable for each question. To account for this variable response rate, the 95% CI was calculated for each individual parameter and is included in the results tables.

### Level of Evidence

The data reported here are a retrospective aggregate of the memories of experienced clinicians (American College of Cardiology/American Heart Association [ACC/AHA] level of evidence C-EO) (21). There are several levels of evidence that rank higher than expert opinion; unfortunately, no such data set was available at the time of the study. Previous authors have demonstrated that data collected automatically, into an electronic medical record, may differ from what the clinician may report from their memory (22). Unfortunately, no

large-scale database of such data exists for these data points, and the creation of such a database would have been prohibitively complicated, as illustrated by the fact that none of the organizations that dedicate considerable resources to the collection of perfusion data collect these sets of data at a higher level of evidence, if they collect these points at all.

### Weighting of Individual Respondent Data

Each respondent’s datum was weighted equally in the parameter results, despite the number of years of experience or the number of clinical procedures the respondent used as the basis of their memory.

### Individual Respondents May Have Participated In The Survey Multiple Times

Participation in the survey was open to the public, and survey data were collected anonymously. It is possible that a single individual could have completed the survey multiple times.

## SUMMARY

We report here the limits of 41 physiologic and technical parameters that are managed by clinical perfusionists during adult CPB procedures. These parameter results represent the first attempt at producing an authoritative resource that may be referenced to support the development of clinical practice guidelines, research protocols, educational rubrics, and medical device R&D. This information, when partnered with professional clinical practice standards and guideline documents, can be used to substantiate and temper institutional practice protocols. We propose that these normal limits meet the “acceptable” and “appropriate” threshold called for in professional standards.

When incorporated into an educational curriculum’s assessment rubrics, this information will facilitate both standardization and diversity. With this information faculty from disparate regions and backgrounds can prepare entry-level clinicians to practice within the clinical parameter limits that are representative of the field diversity of practice and not weighted to the instructor’s personal opinion or experience base. Furthermore, researchers and engineers may reference these data when designing experimental protocols that are intended to replicate clinical practice parameters for the purpose of scientific exploration or product R&D and validation of clinical technologies and patient simulators.

## ACKNOWLEDGMENT

This project was supported by a service contractor agreement with Datascope Corporation, Wayne, NJ.

## REFERENCES

1. Kurusz M. Standards of practice in perfusion. *Perfusion*. 1994;9:211–5.
2. The Society of Clinical Perfusion Scientists of Great Britain and Ireland. Recommendations for Standards of Monitoring During Cardiopulmonary Bypass. 2016. Available at: <http://www.scps.org.uk>. Cited January 10, 2020.
3. Caneo LF, Matte G, Groom R, et al. The Brazilian Society for Cardiovascular Surgery (SBCCV) and Brazilian Society for Extracorporeal Circulation (SBCEC) standards and guidelines for perfusion practice. *Braz J Cardiovasc Surg*. 2019;34:239–60.
4. American Society of ExtraCorporeal Technology. Standards and Guidelines For Perfusion Practice. 2017. Available at: <http://www.amsect.org/d/do/1370>. Cited April 22, 2019.
5. Kunst G, Milojevic M, Boer C, et al. 2019 EACTS/EACTA/EBCP guidelines on cardiopulmonary bypass in adult cardiac surgery. *Br J Anaesth*. 2019;123:713–57.
6. Ronald B, Brodie JE. *The Manual of Clinical Perfusion*, 2nd ed. Lich BV, Brown DM, eds. Augusta, GA: Glendale Medical Corporation; 2004.
7. Mongero LB, Beck JR, eds. *On Bypass: Advanced Perfusion Techniques*. Totowa, NJ: Humana; 2008.
8. Likosky DS. Lessons learned from the northern New England Cardiovascular Disease Study Group. *Prog Pediatr Cardiol*. 2012;33:53–6.
9. Mongero L, Stammers A, Tesdahl E, et al. The effect of ultrafiltration on end-cardiopulmonary bypass hematocrit during cardiac surgery. *Perfusion*. 2018;33:367–74.
10. Newland RF, Baker RA, Barratt CA. Integration of electronic perfusion data for perfusion registries. *J Extra Corpor Technol*. 2018;50:102–12.
11. Paugh TA, Dickinson TA, Theurer PF, et al. Validation of a perfusion registry: Methodological approach and initial findings. *J Extra Corpor Technol*. 2012;44:104–15.
12. AmSECT. AmSECT Perfusion Practice Standards and Guidelines. 2017. Available at: <http://www.amsect.org/cm/ld/ld=1617>. Cited March 19, 2019.
13. Lansdowne W, Machin D, Grant DJ. Development of the Orpheus perfusion simulator for use in high-fidelity extracorporeal membrane oxygenation simulation. *J Extra Corpor Technol*. 2012;44:250–5.
14. Raasch DD, Austin JJ, Tallman RR. Self-priming hemodynamic reservoir and inline flow meter for a cardiopulmonary bypass simulation. *J Extra Corpor Technol*. 2010;42:145–9.
15. Ninomiya S, Tokumine A, Yasuda T, et al. Development of an educational simulator system, ECCSIM-Lite, for the acquisition of basic perfusion techniques and evaluation. *J Artif Organs*. 2007;10:201–5.
16. Chan R, Sun CT. Construction of the real patient simulator system. *Perfusion*. 2012;27:187–92.
17. Katarzyna S, Danuta Z, Małgorzata D, et al. Basic guidelines for high-fidelity medical simulation. *J Educ Health Sport*. 2018;8:384–90.
18. Katarzyna S, Danuta Z. Initiatives for the quality of medical simulation in the training of nurses. *J Educ Health Sport*. 2019;9:90–5.
19. Searles B, Darling E, Riley J, et al. Fundamental clinical skills of adult cardiopulmonary bypass: Results of the 2017 national survey. *Perfusion*. 2019;34:290–6.
20. Faris O, Shuren J. An FDA viewpoint on unique considerations for medical-device clinical trials. *N Engl J Med*. 2017;376:1350–7.
21. Halperin JL, Levine GN, Al-Khatib SM, et al. Further evolution of the ACC/AHA clinical practice guideline recommendation classification system: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. *Circulation*. 2016;133:1426–8.
22. Paugh TA, Dickinson TA, Theurer PF, et al. Michigan society of thoracic and cardiovascular surgeons perfusion measures and outcomes (PERForm) registry. Validation of a perfusion registry: Methodological approach and initial findings. *J Extra Corpor Technol*. 2012;44:104–15.