Technique

A Fax-Back Oxygenator-Perfusionist Clinical Performance Data Collection and Statistical Analysis Method

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ABSTRACT

A method to collect clinical oxygenator performance data daily is described. At the end of a bypass procedure, the perfusionist fills in a fax-back form designed to automatically input patient-oxygenator performance data into a computer spreadsheet.

Multiple blood gases, FiO_2, gas and blood flow data, venous oxygenator blood inlet conditions (hemoglobin, O_2 saturation, hematocrit and temperature), time on bypass and device manufacturer information are collected at the end of each cardiopulmonary bypass procedure at multiple institutions. A large sample database is created that allows multi-parametric analyses in regard to clinical practice, device performance, manufacturing consistency and patient requirements.

The database and analyses facilitate institutional, manufacturer, and clinician benchmarking. Monthly reports to the clinicians give valuable feedback to improve oxygenator use and patient blood gas control. Reports to the device manufacturer provide information used to evaluate the clinical consequences of small changes in the manufacturing process.

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INTRODUCTION

It is useful to the perfusionist and the oxygenator manufacturer to collect information regarding clinical management of oxygenator performance. Clinicians are interested in their ability to control blood gases as well as to predict oxygenator management parameters such as FiO_2 and gas to blood flow ratio in specific patient scenarios. Oxygenator manufacturers are interested in the clinical situations in which their devices are being employed. Both the manufacturer and the clinician are interested in the consistency of both the oxygenators' and perfusionists' performance.

It is useful to the clinical team to benchmark its performance to control the oxygenator to obtain desired clinical results. The manufacturer is interested in benchmarking the performance of its device to other devices. Furthermore, the manufacturer is interested in clinical performance differences that may result from subtle changes in the manufacturing process. A method to collect multi-institutional oxygenator management and performance data is presented.

METHODS

A method to collect oxygenator clinical performance data from several institutions is described. A fax-back form (Figure 1) to collect clinical data was generated by the authors using a computer software package[a] designed to author and read forms.

The clinician enters the oxygenator data onto the fax-back form at the completion of the clinical procedure. The form is faxed by the clinician to a central location where the information is transcribed into a database[b] by the computer receiving the fax. The data is organized according to date, oxygenator type, and clinical site, and is stored as each blood gas measurement representing a record.

Several calculated parameters are derived for each record. The blood gases are temperature corrected to the venous blood temperature recorded by the clinician to obtain actual blood values. PvO_2 is estimated from SvO_2 (1). Oxygen transfer rate, gas to blood flow ratio, and the ventilating gas pO_2 (from the product of atmospheric pressure and FiO_2) are estimated from the clinical data for each data record (2).

The oxygenator information is output to a spreadsheet[c], which is passed to a computer statistics package[d] for analysis. Group descriptive statistics are generated for each institution and oxygenator type. For example, Table 1 represents the descriptive statistics for Institution One employing Oxygenator Three.

Similar descriptive statistic tables including minimum and maximum parameter values are created for each participating institution and oxygenator type.

Reports may be generated for each oxygenator or clinical site. A run-time chart by month for blood gases, FiO_2, and gas to blood flow ratio is generated for each institution and type of oxygenator. For example, Figure 2 presents the PaCO2 control chart for Institution Two employing Oxygenator Two.

Each institution contributing data is given its institution's run charts. Another chart analyzing process control is available.

a Fax-back, Cardiff Software, San Marcos, CA
b Access 97, Microsoft Corporation, Redmond, WA
c Excel 97, Microsoft Corporation, Redmond, WA
d Minitab Statistical Software, Release 11, State College, PA

Table 1: Parameters collected by the fax-back form and passed to the statistics package for Institution One for the month of February 1998

Variable	N	N*	Mean	Median	Tr Mean	StDev	SE Mean
Age (yr)	97	0	68.07	69.00	68.33	10.78	1.09
BSA (m^2)	97	0	1.8825	1.9000	1.8724	0.2424	0.0246
Oxy_Man	97	0	3.0000	3.0000	3.0000	0.0000	0.0000
atm_pres (mmHg)	97	0	760.00	760.00	760.00	0.00	0.00
Min_Prim (min)	91	6	72.01	76.00	71.58	31.46	3.30
Bld_Q (L/min)	97	0	4.1124	4.2000	4.1092	0.7387	0.0750
Gas_Q (L/min)	97	0	2.600	2.300	2.316	2.681	0.272
GB_Ratio	97	0	0.6475	0.5806	0.5694	0.7654	0.0777
FiO2 (%)	97	0	66.680	65.000	66.816	9.365	0.951
VentO2 (mmHg)	97	0	506.77	494.00	507.80	71.17	7.23
PaO2_T (mmHg)	97	0	292.84	291.67	290.82	59.64	6.06
SaO2 (%)	97	0	99.521	99.574	99.535	0.202	0.021
PaCO2_NT (mmHg)	97	0	39.113	39.000	39.126	3.805	0.386
SvO2 (%)	88	9	76.886	76.500	76.800	5.947	0.634
Ven_Temp (°C)	97	0	32.994	32.800	33.001	2.994	0.304
Hct (%)	97	0	21.691	22.000	21.713	3.140	0.319
O2_Trans (ml/min)	88	9	125.29	121.40	123.60	39.40	4.20
Min_CPB (min)	97	0	40.66	34.00	37.70	29.91	3.04

'Oxy_Man' = oxygenator manufacturer code; "Min_Prim" = minutes the oxygenator was primed before CPB; "GB_Ratio" = gas to blood blood ratio calculation; "VentO2" = oxygenator ventilating gas pO2 – the product of FiO2 and Patm; "PaO2_T" = temperature corrected PaO2; "PaCO2_NT" = non-temperature corrected PaCO2; "O2_Trans" = estimated oxygen transfer rate including dissolved oxygen; and "Min_CPB" = minutes on CPB that the blood gases were measured and the control parameters recorded.

Figure 1: Fax-back form employed to collect oxygenator and patient data immediately post-CPB. Instructions for use and definition of variables are published on the back of the form.

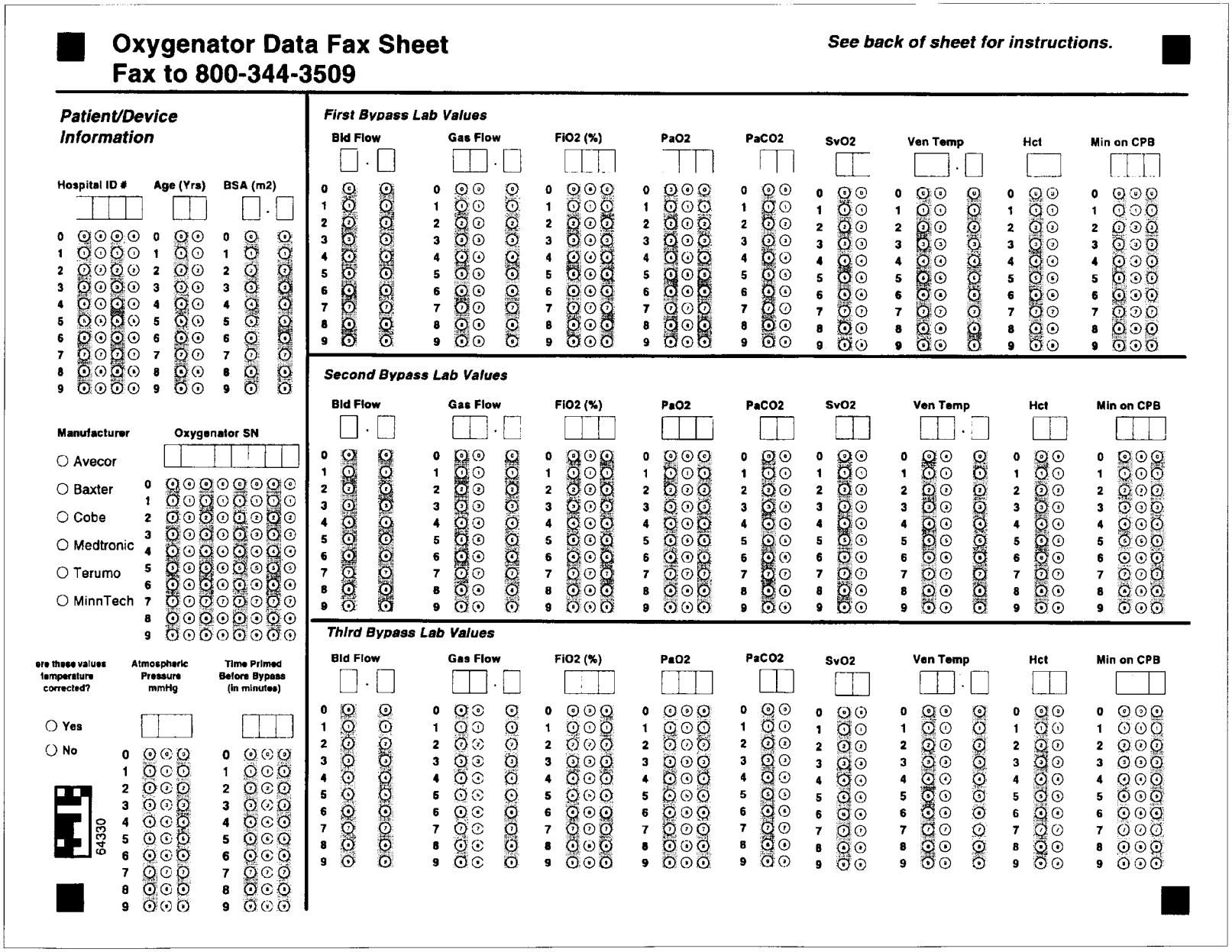


Figure 2: Run chart for non-temperature corrected $PaCO_2$ for Institution Two employing Oxygenator Two. The goal for the perfusion team is to keep the PaCO2_NT within 40 ± 3 mmHg. For all the $PaCO_2$ values for February, there are numerous examples where the process goal was not accomplished.

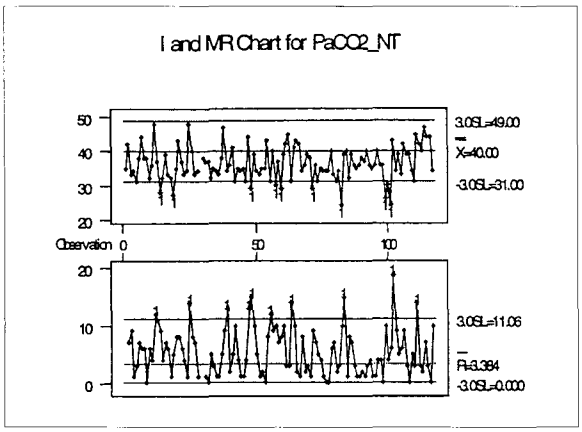


Figure 3: Process control results for Institution Three employing Oxygenator Two illustrates success for the perfusion team in keeping the PaO_2 within 100 to 300 mmHg. The desired limits may be altered by institution analysis before analysis.

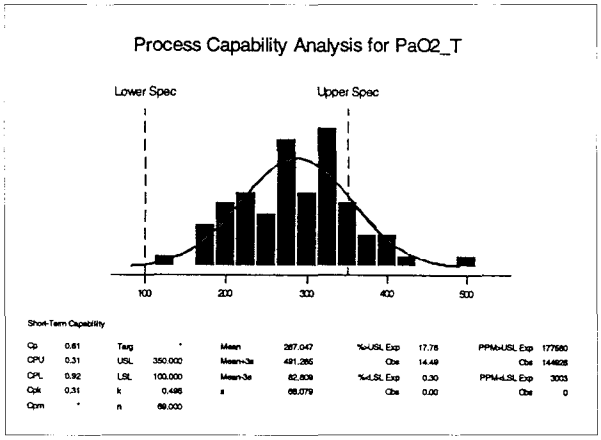
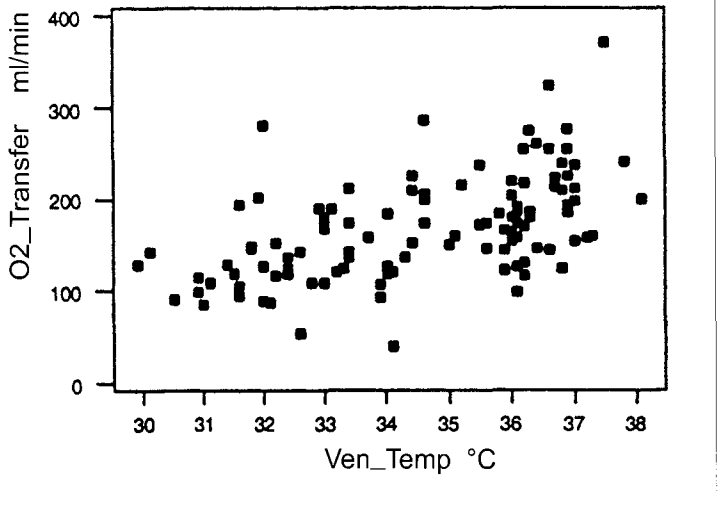


Figure 4: Oxygen transfer rate varies greatly with venous blood temperature at Institution Two employing Oxygenator Two in February



The run chart for PaO_2 is also available.

The same process capability analysis can be performed for the different oxygenator manufacturer types for comparison to help evaluate the possible difference and be able to control PaO_2. Of course, control of PaO_2 is multivariant during cardiopulmonary bypass (CPB), especially with the varying oxygen transfer requirements from patient to patient and institution to institution interfering with comparisons of oxygenator performance and control ability. For example, Figure 4 illustrates the variance in oxygen transfer versus venous blood temperature at Institution Two employing Oxygenator Two in February.

Table 2 presents the analysis of variance comparing oxygen transfer rates between institutions. Table 3 presents the analysis of variance comparing oxygen transfer rates between two oxygenator types in February.

The underlying causes for different oxygen transfer rates between oxygenators and institutions is discovered by comparing patient BSA and age, as well as the resulting SvO_2 and blood flows realized during CPB. Table 4 illustrates the difference in patient age between institutions that will affect the observed different oxygen transfer rates.

The same analysis of variance may be performed between oxygenators to compare patient age, BSA, blood flow, and SvO2 to facilitate device comparison, and understand the performance and control ability of oxygenator blood gas management.

To compare oxygenator performance, multiple linear regression for the dependent variables, temperature corrected PaO_2 and gas to blood flow ratio may be performed for each oxygenator and institution (3). Table 5 illustrates the predictive ability of the required oxygenator ventilating gas pO_2 (FiO_2 x P_{atm}) to achieve a desired actual blood PaO_2 given blood flow, temperature, and SvO_2. The same statistical method may be used to analyze the effect of minutes the oxygenator is primed before CPB and the effect of elapsed CPB time on required FiO_2.

The same linear regression models may be employed to create an equation to predict the gas to blood flow ratio required to obtain a desired $PaCO_2$ employing hematocrit, SvO_2, blood flow and temperature.

Table 2: One-way analysis of variance

Analysis of Variance for O2_Trans

Source	DF	SS	MS	F	P
Hosp_cod	2	133962	66981	26.56	0.000
Error	267	673379	2522		
Total	269	807341			

Level	N	Mean	StDev	Individual 95% CIs For Mean Based on Pooled StDev
1	88	125.29	39.40	(-*-)
2	113	167.28	55.79	(-*-)
3	69	179.06	52.83	(—*-)

Pooled StDev = 50.22

125 150 175 200

Tukey's Pairwise Comparisons

Family error rate = 0.0500
Individual error rate = 0.0198

Critical value = 3.31

Intervals for (column level mean) - (row level mean)

	1	2
2	-58.7 -25.3	
3	-72.7 -34.9	-29.7 6.2

Patients at Institution One exhibited significantly lower ($p < 0.05$) oxygen transfer rates during CPB than Institutions Two and Three which were not significantly different from each other.

Table 3: One-way analysis of variance

Analysis of Variance for O2_Trans

Source	DF	SS	MS	F	P
Oxy_man	1	124167	124167	48.71	0.000
Error	268	683174	2549		
Total	269	807341			

Level	N	Mean	StDev	Individual 95% CIs For Mean Based on Pooled StDev
2	179	171.90	55.22	(-*--)
3	91	126.53	39.49	(----*---)

Pooled StDev = 50.49

120 140 160 180

Tukey's Pairwise Comparisons

Family error rate = 0.0500
Individual error rate = 0.0500

Critical value = 2.78

Intervals for (column level mean) - (row level mean)

	2
3	32.57 58.16

Oxygenator Two was challenged by significantly greater ($p < 0.001$) oxygenator transfer rates in the February data set.

DISCUSSION

A method to track oxygenator and perfusion team ability to manage oxygenator performance was demonstrated in this communication. Individual clinician information was not collected, but clinical team information was collected. The addition of one more field (perfusionist identification number) to the fax-back form could facilitate monitoring individual clinician performance. In addition, other variables such as arterial line pressure or any other parameter that may be hypothesized to affect oxygenator control parameters or perfusionist ability to manage oxygenators may be studied by this method.

Oxygenator devices may be compared. and perfusion teams can learn easily the variables they manage that most affect their ability to control CPB blood gases. In addition to learning their own practice limits, clinicians may benchmark their ability to keep PaO_2 and $PaCO_2$ within desired limits to other institutions employing the same or different oxygenator device. Differences in clinical performance between oxygenator manufacturing lots are easily measured by these methods, since the oxygenator serial number is also collected.

Other clinical tasks such as patient cooling and warming may be analyzed and benchmarked in a similar manner employing a similar fax-back form and statistical reporting method to that presented here. Perfusion team patient and oxygenator management processes during CPB are modeled well by the process capability analysis presented here. The perfusion team may employ the information provided by this method to improve their process quality.

These methods take perfusion team capability monitoring to a new multi-institution level and create the platform for clinician and device performance benchmarking.

REFERENCES

1 Severinghaus JW. Simple equations for human blood O2 dissociation computations. J Appl Physiol 34:599, 1979

2 Riley JB, Heinemann SO, Cavanaugh DS. Technique to give relevance to calculated oxygen transfer during cardiopulmonary bypass. J Extra-Corpor Technol 15(2):35, 1983

Table 4: One-way analysis of variance

Analysis of Variance for Age

Source	DF	SS	MS	F	P
Hosp_cod	2	1014	507	4.92	0.008
Error	280	28850	103		
Total	282	29864			

Level	N	Mean	StDev	Individual 95% CIs For Mean Based on Pooled StDev
1	97	68.07	10.78	(-----*----)
2	117	66.41	9.07	(----*----)
3	69	63.09	10.95	(-----*-----)

Pooled StDev = 10.15

63.0 66.0 69.0

Tukey's Pairwise Comparisons

Family error rate = 0.0500
Individual error rate = 0.0198

Critical value = 3.31

Intervals for (column level mean) - (row level mean)

	1	2
2	-1.60 4.92	
3	1.24 8.73	-0.28 6.93

Institution One treated significantly younger patients ($p < 0.05$) in February compared with Institutions Two and Three, which did not have different age patients.

Table 5: Regression analysis

Regression Analysis

The regression equation is:

VentO2 = -198 + 0.530 PaO2_T + 35.7 Bld_Q + 14.2 Ven_Temp - 1.54 SvO2 + 3.49 Hct

179 cases used, 4 cases contain missing values

Predictor	Coef	StDev	T	P
Constant	-198.25	91.66	-2.16	0.032
PaO2_T	0.52955	0.04883	10.84	0.000
Bld_Q	35.677	6.508	5.48	0.000
Ven_Temp	14.176	2.074	6.84	0.000
SvO2	-1.5446	0.5104	-3.03	0.003
Hct	3.493	1.115	3.13	0.002

S = 47.96 R-Sq = 61.5% R-Sq(adj) = 60.3%

Analysis of Variance

Source	DF	SS	MS	F	P
Regression	5	634383	126877	55.17	0.000
Error	173	397859	2300		
Total	178	1032242			

Source	DF	Seq SS
PaO2_T	1	172634
Bld_Q	1	160994
Ven_Temp	1	255510
SvO2	1	22669
Hct	1	22576

The multiple linear regression equation to predict the required ventilating gas pO_2 to achieve a given PaO_2 is significant ($p < 0.001$), and the contribution of the CPB parameters SvO_2, blood flow, temperature and hematocrit are significant ($p < 0.003$).

3. Riley JB, Jallad MS, Winn BA, Hurdle MB: Recommended ventilation technique for the microporous hollow fiber membrane blood oxygenator. Proc Amer Acad Cardiovasc Perf 1984. 5: 101-105